IOWA

Harold M. Daily, Belle Plaine.
Dean C. Van Horn, Hampton.
Marvin E. Nelson, Roland.
John L. Sloan, Waucoma.

KANSAS

Ferdinand A. Boling, Clyde.
Francis P. McGaughey, McCracken.
Lorn R. Lahey, Sr., McCune.

KENTUCKY

Freda L. Gooch, Kings Mountain.
Pauline P. Terry, Upton.

MAINE

Erroll E. Grant, Abbot Village.
George A. Haines, Easton.

MARYLAND

Erma M. Pickens, Fork.
Charles R. Taylor, Riderwood.

MASSACHUSETTS

Samuel A. Vinniti, Seekonk.

MICHIGAN

Rex E. Lewis, Cement City.
Marie P. Alexander, East Saugatuck.
David O'Donnohue, Jr., Harbert.
Dallas R. Ries, Sand Creek.
Wendell R. Gerring, South Boardman.
Leonard W. Kennedy, Topinabee.

MISSOURI

Joseph H. Kiley, Baring.
Elmo C. Martin, Jackson.
J. Denzel Koontz, Larussell.
Albert J. Prior, Wright City.

MONTANA

William T. Surmi, Jr., Sandcoulee.

NEW YORK

Welland L. Hitchcock, Bainbridge.

NEBRASKA

James C. Bryant, Ashland.

NORTH CAROLINA

Ophelia S. Wilson, Columbus.
William C. White, Cooleemee.
James B. Teal, Hoffman.
Nell H. Cox, Linwood.
Julia E. Mangum, Pinebluff.
Cecil S. Hargett, Richlands.
Louise L. Taylor, Seaboard.
Randolph G. O'Neal, Jr., Wanchese.
Eugene Reed, Whittier.
Coy M. Maye, Wingate.

NORTH DAKOTA

Lorraine I. Gilbertson, Dunn Center.

OHIO

James E. Myers, Bethel.
Malcolm M. Maynard, Chardon.
Richard L. Zehringer, Fort Recovery.
Sue A. Carman, Harveysburg.
Joseph Presznick, Lodi.
David A. Jasper, New Burlington.
Harold G. White, West Milton.

OKLAHOMA

Arnold E. Krause, Corn.
Max Anderson, Snyder.

PENNSYLVANIA

Michael A. Eannace, Burgettstown.
A. Aaron Boyce, Columbia Cross Roads.
Robert J. Bandel, Eightyfour.
Mable A. Simpson, Enon Valley.
Daniel G. Phillips, Dunns Station.
Leonard R. Santore, Greensboro.
Willard K. Allison, Jr., Hickory.
Roger V. Courtwright, Wind Ridge.

SOUTH CAROLINA

Joel C. Butler, Dillon.
Linwood A. Robinson, Summerton.
Joe E. Murphree, Walhalla.

TENNESSEE

Virginia F. Spurlin, Riceville.
Mrs. Cecil M. Knott, St. Andrews.

TEXAS

Laura A. Williams, Glen Flora.
Jack E. Easton, Lovelady.
C. Max Ohr, Ranger.
George W. Finch, San Benito.
Wallace A. Kristensen, Timpson.

UTAH

Clare S. Larson, Eureka.

VERMONT

Wilmer E. Bowen, Derby.
Arlene E. Lavigne, Hinesburg.

VIRGINIA

Billie B. Rose, Carrsville.
Fred W. Dougherty, Gate City.
Robert A. Lacy, Wytheville.

WASHINGTON

Melburn E. Mason, Battle Ground.
Earl H. Luiten, Ritzville.
Kenneth D. Crofoot, Riverside.
Lester O. Johanson, Warden.

WEST VIRGINIA

James E. Gore, Ranson.

WISCONSIN

Gordon E. Mead, Dalton.
Richard P. Nelson, Jim Falls.
Beatrice J. Houtz, Somers.
Marold A. Johnson, Somerset.

CIVIL AERONAUTICS BOARD

Alan S. Boyd, of Florida, to be a member of the Civil Aeronautics Board for the term of 6 years expiring December 31, 1968.

HOUSE OF REPRESENTATIVES

THURSDAY, SEPTEMBER 27, 1962

The House met at 12 o'clock noon.

The Chaplain, Rev. Bernard Braskamp, D.D., offered the following prayer:

Amos 5: 24: *Let judgment run down as waters, and righteousness as a mighty stream.*

Almighty God, grant that in the midst of the turmoil and trouble of these days we may be inspired with the triumphant and all-transfiguring faith that truth and righteousness will ultimately be victorious.

No matter how dark and desperate the present crises in world affairs may become, help us to see beyond the shadows and take our refuge in Thee.

Show us how we may detect and defeat the subtle attacks that are being made by the adversary to shatter our faith and to fill us with mingled feelings of terror and despair.

May our President, our Speaker, our Congress, and all our citizens courageously and heroically meet the demands of our time with a faithful and firm reliance upon the Lord our God from whose thoughts and love we are never absent.

Hear us in Christ's name. Amen.

THE JOURNAL

The Journal of the proceedings of yesterday was read and approved.

MESSAGE FROM THE PRESIDENT

A message in writing from the President of the United States was communicated to the House by Mr. Ratchford, one of his secretaries, who also informed the House that on the following dates the President approved and signed bills of the House of the following titles:

On September 25, 1962:

H.R. 298. An act to provide for the recovery from tortiously liable third persons of the cost of hospital and medical care and treatment furnished by the United States;

H.R. 2125. An act for the relief of Soon Tai Lim;

H.R. 5393. An act to amend the Bankruptcy Act, as amended;

H.R. 6413. An act to extend to fishermen the same treatment accorded farmers in relation to estimated income tax;

H.R. 9280. An act to amend section 2 of the act of July 31, 1947 (61 Stat. 681), and for other purposes;

H.R. 9578. An act for the relief of Annie Yasuko Bower;

H.R. 9728. An act to amend the Cooperative Forest Management Act;

H.R. 9914. An act for the relief of San-Man Inn of Manning, Inc.;

H.R. 9954. An act to amend the act of June 6, 1924, chapter 270 (43 Stat. 463), relating to the National Capital Park and Planning Commission, as amended by the National Capital Planning Act of 1952 (66 Stat. 781; 40 U.S.C. 71);

H.R. 10062. An act to extend the application of certain laws to American Samoa;

H.R. 10160. An act for the relief of Mrs. A. R. Lendian;

H.R. 12459. An act to provide for the relief of certain enlisted members of the Coast Guard;

H.R. 12689. An act to repeal section 557 and to amend section 559 of the act entitled "An act to establish a code of law for the District of Columbia," approved March 3, 1901; and

H.R. 12870. An act making appropriations for military construction for the Department of Defense for the fiscal year ending June 30, 1963, and for other purposes.

On September 26, 1962:

H.R. 11974. An act to authorize appropriations for the Atomic Energy Commission in accordance with section 261 of the Atomic Energy Act of 1954, as amended, and for other purposes.

MESSAGE FROM THE SENATE

A message from the Senate by Mr. McGown, one of its clerks, announced that the Senate had passed without amendment a concurrent resolution of the House of the following title:

H. Con. Res. 474. Concurrent resolution extending the greetings and felicitations of the Congress to the Bethel Home Demonstration Club of Bethel Community, Sumter County, S.C.

The message also announced that the Senate had passed, with amendments in which the concurrence of the House is requested, a bill of the House of the following title:

H.R. 8952. An act to amend the Internal Revenue Code of 1954 with respect to the conditions under which the special constructive sale price rule is to apply for purposes of certain manufacturers excise taxes.

The message also announced that the Senate had passed bills and joint resolutions of the following titles, in which the concurrence of the House is requested:

S. 151. An act for the incorporation of the Merchant Marine and Maritime Service Veterans Association;

S. 2873. An act for the relief of Claude S. Reeder and Reeder Motor Co., Inc.;

S. 3698. An act to incorporate the McCarran Foundation, and for other purposes;

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

S.J. Res. 208. Joint resolution to establish a Commission to develop and execute plans for the celebration of the 150th anniversary of the Battle of Lake Erie, and for other purposes; and

S.J. Res. 213. Joint resolution to provide for the actual participation of the United States in the West Virginia Centennial celebration.

The message also announced that the Senate agrees to the amendments of the House to a bill of the Senate of the following title:

S. 455. An act to provide for public hearings on air pollution problems of more than local significance under, and extend the duration of, the Federal air pollution control law, and for other purposes.

REPORT ON PROJECTS AND PROGRESS OF THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION—MESSAGE FROM THE PRESIDENT OF THE UNITED STATES (H. DOC. NO. 588)

The SPEAKER laid before the House the following message from the President of the United States, which was read, and, together with the accompanying papers, referred to the Committee on Science and Astronautics and ordered to be printed with illustrations:

To the Congress of the United States:

Pursuant to the provisions of the National Aeronautics and Space Act of 1958, as amended, I transmit herewith a report on the projects and progress of the National Aeronautics and Space Administration for the period of July 1, 1961, through December 31, 1961. This is the sixth of these reports since the passage of the legislation establishing that agency.

This report reveals evidence of the constructive impact of the decision, made earlier in the year and supported strongly by the Congress, to accelerate our space efforts. The accomplishments summarized and detailed in this document constitute an important part of the national program, in which the National Aeronautics and Space Administration, as well as other Government agencies, cooperate.

JOHN F. KENNEDY.

THE WHITE HOUSE, *September 27, 1962.*

COMMITTEE ON PUBLIC WORKS

Mr. EDMONDSON. Mr. Speaker, I ask unanimous consent that the Public Works Committee may have until midnight tomorrow night to file a report on the omnibus rivers and harbors bill.

The SPEAKER. Is there objection to the request of the gentleman from Oklahoma?

There was no objection.

DRUG AMENDMENTS OF 1962

Mr. SISK. Mr. Speaker, by direction of the Committee on Rules I call up House Resolution 808 and ask for its immediate consideration.

The Clerk read the resolution, as follows:

Resolved, That upon the adoption of this resolution it shall be in order to move that the House resolve itself into the Committee of the Whole House on the State of the Union for the consideration of the bill (H.R. 11581) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the Act; and to amend related laws. After general debate, which shall be confined to the bill and shall continue not to exceed three hours, to be equally divided and controlled by the chairman and ranking minority member of the Committee on Interstate and Foreign Commerce, the bill shall be read for amendment under the five-minute rule. It shall be in order to consider the substitute amendment recommended by the Committee on Interstate and Foreign Commerce now in the bill, and such substitute for the purpose of amendment shall be considered under the five-minute rule as an original bill. At the conclusion of such consideration the Committee shall rise and report the bill to the House with such amendments as may have been adopted, and any Member may demand a separate vote in the House on any of the amendments adopted in the Committee of the Whole to the bill or committee substitute. The previous question shall be considered as ordered on the bill and amendments thereto to final passage without intervening motion except one motion to recommit, with or without instructions.

That after the passage of H.R. 11581, the Committee on Interstate and Foreign Commerce shall be discharged from the further consideration of the bill, S. 1552; that it shall then be in order in the House to move to strike out all after the enacting clause of said Senate bill and insert in lieu thereof the provisions contained in H.R. 11581 as passed.

CALL OF THE HOUSE

Mr. GROSS. Mr. Speaker, I make the point of order that a quorum is not present.

The SPEAKER. Evidently a quorum is not present.

Mr. ALBERT. Mr. Speaker, I move a call of the House.

A call of the House was ordered.

The Clerk called the roll, and the following Members failed to answer to their names:

[Roll No. 253]

Alexander	Dominick	Moss
Ashley	Dooley	Moulder
Aspinall	Elliott	O'Brien, Ill.
Bailey	Flynt	Pilcher
Barry	Frazier	Pirnie
Bass, N.H.	Garland	Powell
Belcher	Goodling	Reifel
Bell	Green, Oreg.	Riehlman
Berry	Griffiths	Robison
Blitch	Halleck	Rogers, Tex.
Bolling	Hansen	Santangelo
Bolton	Harrison, Va.	Saund
Bonner	Harvey, Ind.	Scranton
Breeding	Herlong	Seely-Brown
Brewster	Hiestand	Shelley
Bromwell	Hoffman, Mich.	Shipley
Broomfield	Johnson, Wis.	Short
Cahill	Jones, Ala.	Siler
Celler	Kearns	Smith, Miss.
Chiperfield	Kee	Spence
Clancy	King, N.Y.	Steed
Coad	Loser	Taber
Conte	McDonough	Thompson, N.J.
Curtis, Mass.	McIntire	Vanik
Curtis, Mo.	McSween	Van Pelt
Davis, James C.	McVey	Vinson
Davis, Tenn.	Macdonald	Weis
Derwinski	Michel	Wright
Diggs	Moorehead, Ohio	Yates

The SPEAKER. On this rollcall, 344 Members have answered to their names, a quorum.

By unanimous consent, further proceedings under the call were dispensed with.

DRUG AMENDMENTS OF 1962

The SPEAKER. The gentleman from California is recognized for 1 hour.

Mr. SISK. Mr. Speaker, I yield 30 minutes to the gentleman from California [Mr. SMITH] and, pending that, yield myself such time as I may consume.

The SPEAKER. The gentleman is recognized.

Mr. SISK. Mr. Speaker, House Resolution 808 provides for the consideration of H.R. 11581, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws. The resolution provides an open rule with 3 hours of general debate.

The principal purpose of H.R. 11581 is to protect better the public health by imposing additional requirements and improving procedures in connection with controls of manufacture of drugs to assure that manufacturing methods are in conformity with current good manufacturing practice. It would require that new drugs be shown to be effective as well as safe and would require the keeping of records and furnishing of reports in connection with safety and effectiveness of new drugs and antibiotics.

It would outline procedures to be followed in the testing of investigational drugs, including patients' consent, and agency procedures to be followed in approving new drugs. Also, it would provide summary suspension of new drugs where there is an imminent hazard to public health and withdrawal of new drugs when their safety or effectiveness is no longer assured.

The bill would require certification of all antibiotics for man, factory inspection of establishments manufacturing as simplification of drug nomenclature. to make available adequate information concerning safety and effectiveness of drugs advertised to physicians, as well as simplification of drug nomenclature.

Mr. Speaker, I urge the adoption of House Resolution 808.

Mr. SMITH of California. Mr. Speaker, I yield myself such time as I may use.

Mr. Speaker, as stated by the gentleman from California [Mr. SISK], House Resolution 808 provides for an open rule for the consideration of the bill H.R. 11581 and 3 hours debate. In addition it provides the opportunity to substitute whatever language is agreed to in H.R. 11581 into the already passed Senate bill, S. 1552, in an effort to save some time, and get to conference more quickly in that way.

As stated by the gentleman from California, the purpose of this legislation is set forth on pages 1 and 2 of the report.

There are 11 different reasons mentioned therein as to why this bill should be supported, 11 reasons in support of the legislation. I would recommend that you read those 11 different statements. Then after you have read them I would suggest that you try to figure out if anybody on the floor of the House knows what this bill actually contains.

The committee held hearings on this bill earlier in the year. There were two bills, as a matter of fact—H.R. 11581 and H.R. 11582—the cosmetic bill.

Mr. Speaker, when hearings were held, I believe the Secretary was present for a short period of time, and another witness was present. The hearings broke up and they let the matter go for some period of time inasmuch as it was a very controversial subject, and there are extremists on both sides and a number of questions involved.

Mr. Speaker, I doubt very much that we would have this bill here today for consideration if it were not for the thalidomide episode. However, by the same token, this is not an antithalidomide bill. In any event, the President did write to Senator EASTLAND and requested that some action be taken and suggested that he preferred parts of the House bill more than he did the Senate bill.

Mr. Speaker, the Senate then passed S. 1552. Hearings were held, I believe, last week by the Committee on Interstate and Foreign Commerce of the House on this particular bill. The report came out on Monday of this week. The matter was heard before the Committee on Rules on Tuesday, and here it is today, Thursday, when we have this bill before the House for consideration, with little history upon which to proceed and with little, if any, chance to submit the final bill and report to the various manufacturers of these drugs and other interested people in our districts, to find out whether or not they are for or against this particular measure.

Mr. Speaker, it seems to me we might have done better had we sent the bill out of the Rules Committee in sufficient time so that the public would know that we intended to hear the subject and then upon the return of the 88th Congress they could at that time go into this subject and study it and have a few more hearings on it in an effort to resolve some of these things about which we are now uncertain.

Mr. Speaker, as an example, take title II of this particular bill: I assume that the manufacturers and developers of drugs are using their own money and expense and experts to develop various types of drugs and then attempt to patent these drugs, because they have to protect their patent rights, their proprietary rights and know-how. With reference to their efforts along this line they have used to develop certain drugs, as I understand it, in title II there is a provision which states that this information is confidential. But, by the same token, another sentence in title II says that it is not confidential insofar as Senate and House committees are concerned, which means that a committee of either body could demand all of the proprietary data and information of any manufacturer or firm which has developed various items, and order or ask them to come to the committee.

As you well know, that is the same as putting it in the newspapers, or putting it out over the radio, because everyone will then have that particular information.

Mr. Speaker, the testimony before the Rules Committee indicated that the Interstate and Foreign Commerce Committee thinks it is a pretty good bill. There will be opposition and there will be support for the bill. But actually what is going to happen, in my opinion, will be that we will pass H.R. 11581 here today when few of us, if any, have had an opportunity to study this very serious and important subject. Then it will go to conference and it will be up to the members of the staff of the conference and the conferees to write a bill and bring it back here in the closing days of the session, and then we will be asked to approve the conference report.

Mr. Speaker, I have no doubt that this may go along the same lines upon which we have proceeded heretofore in other instances where there will be material in this conference report which will not be in either of the bills.

Mr. Speaker, inquiry has been made in connection with this particular matter as to why the Federal Government has gone so far in connection with this bill to interfere with private enterprise. The answer given to us is that the U.S. Government has a responsibility to protect the lives and the health of individuals and that is the reason why they have gone so far.

Mr. Speaker, another question is this: We have all heard of H.R. 3. We remember the Steve Nelson case and the efforts made by the distinguished gentleman from Virignia [Mr. SMITH], chairman of the Rules Committee to correct this preemption doctrine in line with the Supreme Court decision holding that the Federal law preempts the State law. However, there is no language in this bill which says anything to the effect that this particular measure will not preempt all State food and drug laws. Many States are doing a great deal along this line. In fact, there was an article which appeared in the paper today as to what California is doing in connection with testing drugs.

Mr. Speaker, it seems to me that if we are going to pass this law, someone ought to offer an amendment to make certain that the passage of this bill, which gives all of this additional power to the Department of Health, Education, and Welfare and the Food and Drug Administration, will not preempt any State laws.

Mr. Speaker, the gentleman from California [Mr. YOUNGER] was just showing me a number of telegrams which have been received from various organizations, including the Stanford Hospital and others throughout the country, which includes UCLA Medical School, objecting to the so-called Friedel amendment which is contained in this particular measure.

Therefore, Mr. Speaker, I am sorry that we are going to have to take up this very important subject today because all of us on the floor of the House want to do that which is absolutely right and to make certain that our drug laws are correct and that we take care of the lives of our people, and that we do it in a safe, sane manner. In my opinion we are acting too quickly in considering this measure today.

However, we have it here today and I hope we can make a reasonably good bill out of it so that we can say to our constituents and the public that we have done as good a job as possible under the circumstances.

Mr. Speaker, I know of no objection to the rule; and I reserve the balance of my time.

Mr. SISK. Mr. Speaker, I yield 5 minutes to the gentleman from Texas [Mr. CASEY.]

Mr. CASEY. Mr. Speaker, yesterday we passed a resolution expressing our strong concern over the situation in Cuba. On the dock at the port of Houston for the last 48 hours there has been unfolding a drama and a lesson which I think the State Department could well observe and could well follow. The people are tired of talk and no action. There is a boat riding at the dock at the port of Houston called the *Drzic*. It is a Yugoslavian-flag ship. It just unloaded Russian cargo in Cuba and came to Houston to pick up a load of flour under the Public Law 480 program. They are lending aid to our avowed enemy, Castro, and then they come over here expecting you, the taxpayers, to help pay their freight, to help this flagship operate in carrying flour to another country, the United Arab Republic.

The patriotic Maritime Union workers have put up a picket line around that ship; the patriotic longshoremen of Texas will not cross that picket line. Patriotic citizens have joined with them in this picket. The Masters, Mates, & Pilots Union say they will not hook a tug to that ship if it loads with this flour.

We expressed the sentiment that we want every bit of pressure put on Castro that we can. Here is one way we can do it, to tell these flagships, if you are going to carry our free gifts to other countries, you are going to have to quit carrying cargo to Cuba. If you want to carry cargo to Cuba, go ahead and carry it, but you go back empty. You are not to be carrying our cargo.

I have been waiting for the Department of Agriculture to draft a policy statement now for over 24 hours. They have not come up with it yet, a statement covering this condition. But they are going to say that the United Arab Republic is paying their freight cost for this shipment. But indirectly we are paying because you know and I know that that flour is not going to cost them one cent. All we get is, what one of my favorite colleagues, the gentleman from North Carolina, HERBERT BONNER, calls "Chickasola" currency that we cannot spend; it is worthless. So we are paying for it. We are depriving our own seamen of their jobs by allowing our bounty, our gift, ot be hauled on foreign-flag ships. We are kicking our own foreign policy in the teeth on the one hand and also kicking our own economy in the pants on the other.

It is a double-barreled slap at the taxpayers and the patriotic citizens of this country.

I brought this to the attention of President Eisenhower as early as July 1960. I have been calling it to the attention of the State Department, the executive branch, frequently since that date, and many of you have joined me. The gentleman from Florida [Mr. ROGERS] introduced a bill to stop all shipments to Cuba from the United States, and I and others joined with him and introduced similar bills. We passed the bill in the House. Later the President put this into effect by Executive order, before the Senate action.

If we are going to talk tough, let us act tough. Let us not wait for the man on the street to show us what to do. They are sick and tired of their officials not following their words with action.

Mr. ROGERS of Florida. Mr. Speaker, will the gentleman yield?

Mr. CASEY. I yield.

Mr. ROGERS of Florida. I thank the gentleman. Certainly his efforts in trying to do something about this situation are to be commended. He has been a real leader in the fight. I point out now as I did yesterday that this can be stopped by administrative action right now under the Export Control Act. There is authority now for the President to stop the shipment of any export on any ship coming into an American port. The administration can now consider this and do it. I am sure the gentleman has been working on the problem, and I hope by constant insistence for action we can get this done and done quickly.

Mr. CASEY. I thank the gentleman for his contribution. His contributions in this regard are well known and appreciated. He has been a tireless worker in the fight against Castro.

If we want to save the lives of some American boys, if we do not want to spill their blood on the sands of Cuba, let us bring to bear the pressures we can bring peaceably by stopping this economic aid. Castro can be overthrown only by three ways: First, by internal revolution, second, by invasion by Cuban exiles, and third, by American boys on the beaches.

I urge your support in trying to get something done now.

Mr. SMITH of California. Mr. Speaker, I yield 3 minutes to the gentleman from Florida [Mr. CRAMER].

Mr. CRAMER. Mr. Speaker, I ask unanimous consent to speak out of order.

The SPEAKER. Is there objection to the request of the gentleman from Florida?

There was no objection.

Mr. CRAMER. Mr. Speaker, I listened with a great deal of interest to the remarks of the gentleman from Texas [Mr. CASEY] and I am in sympathy with his attitude toward the problem. There was written into the mutual security appropriation bill an amendment to cover the problem to withhold aid to any country that trades with Cuba, the problem being to get the administration or the executive branch of the Government to carry out what is the clearly expressed will of the House.

Yesterday the House had an opportunity on the motion to recommit to strengthen the Cuban resolution, to put some teeth and backbone into it, to refuse to rubberstamp the buildup in Cuba that has already been accomplished, to refuse to give a stamp of approval to it as a pattern for Communist infiltration in this hemisphere into other countries by declaring that the present arms buildup in Cuba is a violation of the Monroe Doctrine. I think it was most interesting to note the lack of support from the other side of the aisle.

It is one thing to talk about getting tough on Cuba, it is another thing actually to get tough with them. I am sure the Members of this House are just as concerned as I am, and I believe I speak for all Members of the House when I say that when this administration permits the Soviet Union to establish a "fishing port"—quote, unquote—we know what they are fishing for, the defeat of freedom. To let the Communists establish a "fishing port," the histories of which in other places have proven they soon become submarine ports permitted to be established in this hemisphere in Cuba without even so much as a protest from the Government of the United States of America.

What else are we going to let them do? It is inconceivable to me under these circumstances that at the very time the House is considering a resolution with regard to getting tough on Cuba, at the very same time the Russians are setting up a "fishing port" in Cuba—when are we going to start doing something about it? The passing of resolutions and apparently even the passing of amendments to the Mutual Security Act are not having that effect on the Executive so far as taking action is concerned.

I ask the Members of the House this question: Is the administration going to take effective action before, or are they going to wait until it happens that Cuba joins the Warsaw Mutual Defense Pact? This is the first step of it—this fishing port. Are we going to wait until Cuba joins the Warsaw Pact nations and enters into a common defense compact with the Reds? I hope the administration will heed the action of the House yesterday even thought not as forceful as I would have liked, and the clearly expressed action of the House previously in the mutual security bill and do something about Cuba to get rid of Castro and communism in this hemisphere.

The SPEAKER. The time of the gentleman has expired.

Mr. SMITH of California. Mr. Speaker, I yield 3 minutes to the gentleman from Michigan [Mr. MEADER].

Mr. MEADER. Mr. Speaker, I take this time to raise a question and direct it to the chairman of the Committee on Interstate and Foreign Commerce, if I may.

I might say by way of introduction, I am a member of the antitrust subcommittee of the House Committee on the Judiciary which for many weeks sat in hearings on the so-called Celler-Kefauver drug bill.

First I want to congratulate the Committee on Interstate and Foreign Commerce on having taken action in this field related solely to amendments to the Food, Drug, and Cosmetic Act so that we do not have before us some of the very controversial provisions of the Celler-Kefauver bill, such as compulsory drug patent licensing.

I would like to ask the gentleman if he heard the remarks of the gentleman from California [Mr. SMITH] with reference to the effect of the passage of this bill upon existing State laws in the field of regulation of foods and drugs? Was any thought given in the Committee on Interstate and Foreign Commerce that by the passage of this bill and by giving additional authority to the Food and Drug Administration, we may be striking down existing State laws and interfering with existing State machinery in this field because of the preemption doctrine of the Nelson case.

Mr. HARRIS. Mr. Speaker, will the gentleman yield?

Mr. MEADER. I yield to the gentleman.

Mr. HARRIS. I can say to the gentleman that there is nothing in this bill that in any way preempts the authority and prerogatives of the States with reference to this program.

Mr. MEADER. It was not the intention of the committee, then, in the adoption of this phraseology in any way to interfere with the operation of existing State laws in this field?

Mr. HARRIS. No, I do not think there is anything here that would do that or that would even imply that it would do that.

Mr. MEADER. I may say to the gentleman in passing additional Federal criminal laws, the Committee on the Judiciary has been careful to insert in each one of them a little H.R. 3 declaring our intention that when we make something a crime, that is, a Federal crime which has not been a Federal crime before, that we do not intend to interfere with any existing State laws in the same field. Does the gentleman not think that language of that kind would be appropriate here to avoid any possibility of a result which I fear?

Mr. HARRIS. I would say to the gentleman, I have had no opportunity to consider any amendment along the line that the gentleman had mentioned. As I said before, I do not think it is necessary. There is nothing in this bill that in any way takes anything away, any rights and prerogatives of the States. We stayed strictly with the Federal prerogatives in connection with this important problem.

Mr. MEADER. I thank the gentleman.

The SPEAKER. The time of the gentleman has expired.

Mr. SISK. Mr. Speaker, I yield 2 minutes to the gentleman from Oklahoma, the distinguished majority leader [Mr. ALBERT].

Mr. ALBERT. Mr. Speaker, I ask unanimous consent to speak out of order.

The SPEAKER. Is there objection to the request of the gentleman from Oklahoma?

There was no objection.

Mr. ALBERT. Mr. Speaker, the statement made by the gentleman from Florida that the motion to recommit the

Cuban resolution would have strengthened it is a political self-serving declaration and cannot be justified upon the basis of the language either in the resolution itself or the language in the motion to recommit.

Mr. Speaker, the truth of the matter is, that a plain reading of the language in the resolution clearly indicates that this country is determined to prevent Communist aggression in this hemisphere whether such aggression is in violation of the Monroe Doctrine or otherwise.

The language of the motion to recommit, language which incidentally was changed and weakened before it was offered, limited action to so-called violations of the Monroe Doctrine.

Mr. Speaker, the Cuban resolution passed this House by a vote of 384 to 7. The gentleman from Florida voted for it. I think the time has come to stop playing politics with this issue. Partisan arguments which divide our people should not be made in connection with the problems which relate to our security in this hemisphere.

Mr. SISK. Mr. Speaker, I move the previous question on the resolution.

The previous question was ordered.

The resolution was agreed to.

A motion to reconsider was laid on the table.

AUTHORIZING PRINTING OF DOCUMENT

Mr. HAYS. Mr. Speaker, by direction of the Committee on House Administration I offer a privileged resolution (H. Res. 795) and ask for its immediate consideration.

The Clerk read the resolution, as follows:

Resolved, That the document entitled "Free Trade, Tariff Legislation, and Common Markets for the Western Hemisphere: A Collection of Excerpts and Selected References Prepared by the Legislative Reference Service of the Library of Congress", be printed as a House document; and that there be printed eleven thousand additional copies for the use of the House of Representatives.

Mr. SCHENCK. Mr. Speaker, reserving the right to object, I ask my colleague from Ohio whether the resolutions he is now presenting are now for printing.

Mr. HAYS. I am sorry I did not have the chance to consult the gentleman from Ohio, but this opportunity presented itself suddenly and I wanted to take advantage of it.

Mr. SCHENCK. All were approved by the subcommittee and the full committee?

Mr. HAYS. Absolutely, unanimously.

The SPEAKER. Is there objection to the request of the gentleman from Ohio?

There was no objection.

The resolution was agreed to.

A motion to reconsider was laid on the table.

PRINTING OF WALL MAP OF THE UNITED STATES

Mr. HAYS. Mr. Speaker, by direction of the Committee on House Administration I call up House Concurrent Resolution 574, and ask for its immediate consideration.

The Clerk read the resolution, as follows:

Resolved by the House of Representatives (the Senate concurring), That there be compiled and printed fifty-eight thousand eight hundred copies of a wall map of the United States prepared for the Bureau of Land Management, Department of the Interior, by the Geological Survey, Department of the Interior, showing the extent of public surveys, national parks, national forests, Indian reservations, national wildlife refuges, and reclamation projects, size six and a half feet by four and a half feet, of which fifteen thousand copies shall be for the use of the Senate; and forty-three thousand eight hundred copies shall be for the use of the House of Representatives.

Mr. GROSS. Mr. Speaker, reserving the right to object, there are no employees in any of these, as there was in one resolution a year or 2 ago, no additional employees?

Mr. HAYS. No employees, just printing.

The SPEAKER. Is there objection to the present consideration of the resolution?

There was no objection.

The resolution was agreed to.

A motion to reconsider was laid on the table.

PRINTING OF ADDITIONAL COPIES OF HEARINGS

Mr. HAYS. Mr. Speaker, by direction of the Committee on House Administration I call up House Concurrent Resolution 513 and ask for its immediate consideration.

The Clerk read the resolution, as follows:

Resolved by the House of Representatives (the Senate concurring), That there be printed for the use of the Committee on Appropriations, House of Representatives, ten thousand additional copies of the hearings entitled "Education for All Children—What We Can Learn From England".

Mr. CANNON. Mr. Speaker, will the gentleman yield?

Mr. HAYS. Mr. Speaker, I yield to the gentleman from Missouri.

Mr. CANNON. Mr. Speaker, the Committee on Appropriations has had an unprecedented demand for this document. We have exhausted all copies the committee is authorized to print and an unfilled backlog of more than 12,000 requests.

The resolution, which was introduced some days ago, provides for 10,000. That would not be sufficient to fill the requests already on file.

I will say, Mr. Speaker, that these requests come from school men, from teachers, from parent-teacher associations, and they come from every State in the Union.

It is merely a professional discussion in which the school men of the Nation are deeply interested, and most of these requests are from superintendents of schools, college faculties, or from those interested in national defense.

Russia is every year turning out more skilled engineers and scientists than all American colleges and universities combined.

Would the gentleman from Ohio consider increasing the number from 10,000 to 20,000?

Mr. KYL. Mr. Speaker, reserving the right to object.

Mr. HAYS. Mr. Speaker, actually I thought I yielded to the gentleman from Missouri.

The SPEAKER. Unanimous consent is required for this resolution to be considered because it has not been formally reported by the committee. The gentleman is operating under a unanimous-consent request for the consideration of the resolution.

Mr. KYL. Mr. Speaker, will the gentleman yield?

Mr. CANNON. I yield to the gentleman from Iowa.

Mr. KYL. May I ask the distinguished chairman of the Committee on Appropriations this question: Is it possible that the printed material could carry a statement from the committee indicating that this is the report of a personal view of an individual who is not an educator rather than an approved document of the Appropriations Committee? I ask this question because many people have said, is this being suggested by the Congress of the United States? Among other things that are being suggested is, Are we establishing a system of national standards for education? There is also some criticism by the British people that the summary of their educational system is not accurate. If the appraisal is not accurate, would it be possible to include some disclaimer on the part of Congress indicating this is not a recommendation by the Committee on Appropriations of the Congress?

Mr. CANNON. Mr. Speaker, in response to the suggestion, which I think is well taken, all hearings are merely the personal opinion of the witnesses who appeared before the committee. They do not necessarily reflect the opinion of the committee. The committee has not issued any report or any recommendation on the matter. It is an expression of the opinion of Admiral Rickover alone. The committee has not formally considered it and has issued no report on the subject.

Mr. HAYS. Mr. Speaker, I withdraw the unanimous-consent request and by direction of the Committee on House Administration I send to the desk a privileged report and ask for its immediate consideration.

The Clerk read as follows:

Resolved by the House of Representatives (the Senate concurring), That there be printed for the use of the Committee on Appropriations, House of Representatives, ten thousand additional copies of the hearings entitled "Education for all Children—What We Can Learn From England."

Mr. HAYS. Mr. Speaker, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. HAYS: On page 1, strike "ten thousand" and substitute in lieu thereof "twenty thousand."

The amendment was agreed to.

The House concurrent resolution, as amended, was agreed to.

A motion to reconsider was laid on the table.

PRINTING OF ADDITIONAL COPIES OF HEARINGS OF JOINT ECONOMIC COMMITTEE

Mr. HAYS. Mr. Speaker, by direction of the Committee on House Administration, I send to the desk a privileged report and ask for the immediate consideration thereof.

The Clerk read the Senate concurrent resolution (S. Con. Res. 90), as follows:

Resolved by the Senate (the House of Representatives concurring), That there be printed for the use of the Joint Economic Committee five thousand additional copies of its hearings of the Eighty-seventh Congress, second session, entitled "State of the Economy and Policies for Full Employment".

The SPEAKER. The question is on the Senate concurrent resolution.

The Senate concurrent resolution was agreed to.

A motion to reconsider was laid on the table.

AUTHORIZING PRINTING OF ADDITIONAL COPIES OF HEARINGS ON DEPARTMENT OF AGRICULTURE HANDLING OF POOLED COTTON ALLOTMENTS OF BILLIE SOL ESTES

Mr. HAYS. Mr. Speaker, by direction of the Committee on House Administration I call up Senate Concurrent Resolution 91 and ask for its immediate consideration.

The Clerk read the resolution, as follows:

Resolved by the Senate (the House of Representatives concurring), That there be printed for the use of the Committee on Government Operations two thousand additional copies of all parts of the hearing held by its Permanent Investigating Subcommittee during the current session on Department of Agriculture handling of pooled cotton allotments of Billie Sol Estes.

The Senate concurrent resolution was agreed to.

A motion to reconsider was laid on the table.

DRUG AMENDMENTS OF 1962

Mr. HARRIS. Mr. Speaker, I move that the House resolve itself into the Committee of the Whole House on the State of the Union for the consideration of the bill (H.R. 11581) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws.

The SPEAKER. The question is on the motion offered by the gentleman from Arkansas.

The motion was agreed to.

Accordingly, the House resolved itself into the Committee of the Whole House on the State of the Union for the consideration of the bill (H.R. 11581), with Mr. FLOOD in the chair.

The Clerk read the title of the bill.

By unanimous consent, the first reading of the bill was dispensed with.

The CHAIRMAN. Under the rule, the gentleman from Arkansas [Mr. HARRIS] will be recognized for 1½ hours, and the gentleman from Michigan [Mr. BENNETT] will be recognized for 1½ hours.

The Chair recognizes the chairman, the gentleman from Arkansas [Mr. HARRIS].

Mr. HARRIS. Mr. Chairman, I yield myself 30 minutes.

Mr. Chairman, I think by now most everyone here knows that the drug bill we are considering today is one of the most important measures to come before the Congress during this session. This bill, H.R. 11581, and a companion bill, H.R. 11582, was introduced by me on May 3, 1962, at the request of the Secretary of Health, Education, and Welfare.

Mr. Chairman, H.R. 11581, as amended by the committee, deals principally with drugs and factory inspection. The other bill requested by the Secretary, H.R. 11582, deals principally with cosmetics and therapeutic devices. Together these bills sought to provide the legislative program to give effect to a part of the President's message on consumer protection, that portion of it which dealt with strengthening the regulatory authority of the Food and Drug Administration with respect to food, drugs, cosmetics, and devices.

Mr. Chairman, the Committee on Interstate and Foreign Commerce initiated hearings on these two bills June 19. In view of what the gentleman from California [Mr. SMITH], a member of the Committee on Rules, said a few moments ago, I hope all of the members of the committee will listen as I discuss this matter.

Mr. Chairman, we conducted hearings for several days. Many witnesses were heard. The former Secretary of the Department of Health, Education, and Welfare, our former colleague here in the House, the Honorable Abe Ribicoff, was the leadoff witness and was on the witness stand all day. Commissioner Larrick, whom many of the members of the committee know, was present with the Secretary, and also testified. Members of Congress testified.

We heard industry witnesses. And then in view of the fact that the committee's attention was directed to other important bills to be considered in this Congress, we suspended the drug hearings in order to consider these other matters.

Then on August 20 we returned to the drug hearings and continued with them all that week, including some late night sessions. So the committee worked very hard during the course of the hearings in an effort to develop a full and complete record on this important subject. I would not want the Members of this House to get the impression, which might have been left by our colleague from California, that thorough consideration was not given to this program.

In addition to that the committee met for several days in executive session in marking up the bill.

Mr. Chairman, I want to say here that the members of this great committee are to be complimented on their dedicated efforts to doing a good job not only with this important proposal but with almost everything we bring to this House for your consideration.

The members of this committee sat long hours during the day, morning, and afternoon and at night. When the bill was finally reported it was about 7 o'clock in the evening. Therefore, I feel that thorough consideration has been given to it and I say to you that in my judgment the members of the committee are quite familiar with what is in this bill.

At this point I would like to suggest that you get a copy of the committee report which is available. It would not take very long to read the major part of the report and see the basic problems that were dealt with. As a matter of fact, the first seven pages in this report summarize the entire bill and you can get a good idea of what we have dealt with and what is included in the bill. Then if you will take just a little more time and read further, there is a section-by-section analysis of the bill. You can turn to any section and very quickly read what is included in any part of the bill.

Then we had pending before the committee the Senate-passed bill, S. 1552. We had the benefit of the long and tedious consideration that was given to it by the other body. Let me say that I have some knowledge of the consideration that was given to it by the committee in the other body.

It was after lengthy hearings and much study and consideration by members of the committee and the staff and after consultations with the Government agencies involved and consultations with the industry that we reported the bill. Therefore we gave thorough consideration all across the board to the provisions of the bill which is of such great importance to the health of the American people.

Then we had the staff prepare a comparative print for the committee's benefit and consideration. In this comparative print we have the original bill, H.R. 11581, and S. 1552. The committee decided that we would limit our consideration to the drug portion in the bill H.R. 11581. We decided we would not tackle the problems in H.R. 11582, which dealt with cosmetics and therapeutic devices.

We had the committee staff take the original bill dealing with drugs and the bill as passed by the Senate, S. 1552, and prepare for us a comparative print, with a brief explanation of both the House bill and the Senate bill. It is one of the best jobs I have seen done on an important bill. It is highly technical and complicated, but I wanted it done for the information of the committee. If anyone wants a copy of it I think we can get sufficient copies to make them available to you. It is a comprehensive print with information as to what we are dealing with in this bill. In the back of the comparative print we show what the present law is and how the law would be changed, in other words, the Ramseyer rule, by the House bill as introduced and the bill that was passed by the Senate.

So I would say to the gentleman who said that we do not know what is in

this bill that at least the members of the committee, 33 of them, are throughly familiar with the provisions of this bill, and we can make available momentarily any information any Member wants if he cares to inquire about it. So I think it has had thorough analysis and study and consideration.

The purpose of the reported bill, Mr. Chairman, is to provide consumers with better and safer drugs. This is achieved by imposing additional requirements and improving procedures in connection with, one, controls of manufacture of drugs to assure that manufacturing methods are in conformity with current good manufacturing practice. You may raise some question as to what is "current good manufacturing practice." That is a term which was developed and used in the Food and Drug Act over a period of years, so it is presently a term that has been a part of the basic legislation and therefore has by precedent and by administration become a part of this program and understood by both those administering the law in the agency and the industry involved.

Two, requirement that new drugs be shown to be effective as well as safe.

You have heard a great deal about this question of "efficacy" and "effectiveness." There has been a lot of talk and publicity about it. It seems that the Government agencies that deal with this problem want this provision in the law, and they want it pretty bad. The industry which is greatly concerned raises all kinds of questions and they think it ought not to be included on the ground that it is giving entirely too much authority to the Government agency. The Senate committee used the words "effective" and "effectiveness" in lieu of the words efficacy and efficacious. I gave some attention to this during the course of the hearings and asked a good many questions. I asked the staff to look up the definition as well as the derivation of these terms to try to see how we might resolve this. So help me, I am unable to find that there is any difference at all in the definition or meaning of the two terms.

It may be that a usage has developed in the industry and it may be that there is some connotation involved. But, we are writing legislation here and I think we understand the English language. Therefore, we see no difference in the meaning of the two terms and, consequently, we use in this legislation the words "effective" and "effectiveness" instead of the terms "efficacy" and "efficacious." In my judgment, it does not make any difference and I see no reason why we should spend so much time on it.

The third item we have given consideration to here is the keeping of records and furnishing of reports in connection with safety and effectiveness of new drugs and antibiotics.

Fourth. We deal with procedures to be followed in the testing of investigational drugs including the patient's consent. There is one matter that you have heard a great deal about from your doctors and the industry.

The gentleman from Maryland [Mr. FRIEDEL] offered an amendment in the course of the marking up of this legislation providing that before an investigational drug can be used by a doctor, the doctor had to inform the patient or his representative and get consent. Now this is all rather an emotional thing. It is only natural to say, if you are going to give me an experimental drug that I am going to take into my system, I should be advised as to what it is. And there is a lot to be said for that viewpoint. If you are going to give somebody honey, why should you not let them know they are getting honey? If you are going to give them vinegar, which they might not like, why should they not know about it? So there is a lot of feeling in connection with this matter.

The committee adopted the amendment. Personally, I thought it was not the wise thing to do and I so expressed myself to the committee. I think some thought has been given to this question since then, but I am not going to be one of those who is going to try to modify or attempt to modify it here today. I think we should go on with it and, after we get all the information together and the various viewpoints and facts that we should have, we might modify that provision in the conference.

Mr. COOLEY. Mr. Chairman, will the gentleman yield for a question?

Mr. HARRIS. I yield to the gentleman.

Mr. COOLEY. What would be the situation in the event the patient is unconscious?

Mr. HARRIS. His representative or a member of the family could give consent.

Mr. COOLEY. Suppose he has no representative.

Mr. HARRIS. We would have to assume that somebody represents him.

Mr. COOLEY. A man may be far away from home and rendered unconscious; what about such a situation?

Mr. HARRIS. That is one of the problems that was raised during the course of consideration of the amendment, I personally think it is not the thing to do. I can say that one of the scientists who had a lot to do with the development of two of the three antidepressant drugs for mental cases advised me that if there had been such a restriction in the law at that time he was fairly certain that these drugs would never have been developed. But those are the things we want to develop and I think we can handle it in conference and work it out. The author of the amendment, I understand, would be agreeable to it. I do not think he is present right now.

Mr. PIKE. Mr. Chairman, will the gentleman yield?

Mr. HARRIS. I yield.

Mr. PIKE. The gentleman touched lightly upon a point I wanted to ask about. There was some question in regard to people who are mentally incompetent. Is there any provision for consent to be provided in the case of people who are mentally incompetent?

Mr. HARRIS. In that case in accordance with the amendment that is included in this bill the doctor would have to get the consent from a representative.

Mr. HOLIFIELD. Is it not true that such a person would be a ward of the State or county and that the State could exercise the right? I am speaking now of a mentally incompetent person, who might not have a legally appointed guardian.

Mr. HARRIS. I think that would come into play; yes.

Mr. HOLIFIELD. I would like to ask the gentleman if this provision applies to new drugs or to all drugs?

Mr. HARRIS. The use of new drugs; yes. It is experimental drugs; I will put it that way.

Mr. HOLIFIELD. Does not the gentleman believe that if a person is going to be experimented on with some type of new drug that he should know about it? It just seems reasonable to me. If a doctor is going to do any experimenting on me I would like to know that it was an experiment. I might agree and probably would if my doctor said: "Now, we do not know what the result of this will be, but we think it will be good, we are hopeful."

Mr. HARRIS. That was a point that was developed during the hearings. There were a number of other facts brought to our attention, that maybe under certain conditions the doctor himself should make the decision on a professional basis as to whether or not the person should know or be made aware of it. That is just one of the things that is involved here and that is why I think we should sit down around the table and try to work it out.

Mr. HOLIFIELD. The question is whether it should be made mandatory.

Mr. HARRIS. I think the author of the amendment has in mind that a modification might be appropriate or desirable.

Mr. ROGERS of Florida. Mr. Chairman, will the gentleman yield?

Mr. HARRIS. I yield to the gentleman from Florida.

Mr. ROGERS of Florida. I just want to say to my distinguished chairman that I agree with him. I think at the present time ethics require a doctor to notify a patient before he uses an experimental drug. However, there are cases that have been pointed out where there may be a situation that consent cannot be obtained in an extreme emergency. Again, for instance, the person might have cancer and the doctor not want to tell the patient what the drug is or what it is used for, because such knowledge might do the patient harm. There are instances, I think, where this provision would be too stringent, and, as the chairman has said, modification certainly would be in order.

Mr. HARRIS. Then also we considered and dealt with here the procedures and prescribed what the agency shall follow in approving new drugs. We have heard a lot about that in the last few months, I would say, and certainly weeks. We deal with that problem, and we think adequately here.

Sixth. We improve procedures in connection with the summary suspension of new drugs where there is an imminent hazard to public health.

Seventh. The withdrawal of new drugs when their safety or effectiveness is no longer assured. We have developed a lot about that and could cite numerous examples if time permitted.

Eighth. Certification of all antibiotics for man. The present law requires only certification of certain antibiotics.

Then there is the very sticky and difficult subject of factory inspection of establishments manufacturing prescription drugs. We deal with that and I think we have worked out a very satisfactory solution to it, one that will meet the problem.

Then we deal with drug advertising. That problem will come in for some discussion a little later on. Apparently some efforts have been made to resolve some of the controversy in the different views here. As I understand it, maybe we will work that out during the course of consideration of the bill under the 5-minute rule.

Finally we deal with simplifying drug nomenclature.

I shall comment on some of these items.

ADEQUATE MANUFACTURING CONTROLS FOR ALL DRUGS

The manufacturing of drugs is a business that requires highly qualified and trained personnel, and special laboratory and other facilities and most careful internal manufacturing, packaging, and labeling controls. These requirements are necessary to the assurance that the drugs will be safe for the user and will have, and so far as possible retain, the identity, strength, quality, purity, and effectiveness that they purport to have.

Except in the case of those drugs for which the Federal Food, Drug, and Cosmetic Act requires premarketing clearance—that is, new drugs, certain antibiotics, and insulin—and except for drugs prepared or held under insanitary conditions, nothing can be done under the present act if these essential requirements demanded by good manufacturing practice are not met, until a particular shipment of drugs is marketed and the Food and Drug Administration can prove that the drug itself is deficient. This is not adequate assurance of consumer protection. People with inadequate experience, equipment, and technical competence can, and do, enter the business of making drugs.

Section 101 of the reported bill would amend section 501(a)(1) of the Federal Food, Drug, and Cosmetic Act to deem a drug to be adulterated if the methods, facilities, or controls used in its manufacture, processing, packaging, or holding fail to conform to, or are not operated or administered in conformity with, good manufacturing practices as determined in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare which are designed to assure that the drug is safe and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess. The phrase "operated or administered in conformity with current good manufacturing practice" encompasses key technical and professional personnel responsible for the safety of the drug, and its identity, strength, quality, and purity characteristics.

The promulgation of these regulations would be subject to opportunity for hearing and judicial review. Thus, legal action could be brought against firms failing to abide by these standards and against the products they ship.

PREMARKETING PROOF OF EFFECTIVENESS OF NEW DRUGS

Section 505 of the Food, Drug, and Cosmetic Act prohibits interstate shipment of a "new drug"—that is, one that is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof or one that has not been used to a material extent or for a material time other than in safety investigations—unless it is first cleared for safety through the filing of a new-drug application by the manufacturer.

The scientists of the Food and Drug Administration may and sometimes do have serious reservations about the ability of the drug to accomplish the therapeutic benefits claimed for it. However, except where the question of the drug's effectiveness is a consideration in passing on its "safety"—as in the case of toxic drugs claimed to be valuable in the treatment of a disease, or in the case of drugs offered for treatment of life-threatening diseases—proof of effectiveness is not required before a product is marketed. Even where the effectiveness of a new drug enters into determining its "safety," the Food and Drug Administration cannot, if it finds the drug "safe," refuse clearance because the claim of effectiveness is exaggerated. Rather, the Administration would have to stultify itself by allowing clearance and then causing court action to be brought for misbranding. The Administration claims that many new drugs that have cleared the safety requirements of the law are marketed with unproved claims of therapeutic effectiveness. As a result, good medical practice is hampered, and the consumer is misled until, perhaps years later, the Government has gathered the necessary evidence to sustain its burden of proving the violation in court.

Section 102 of the reported bill would require all new drugs to be proved effective as well as safe for use under the conditions prescribed, recommended, or suggested in the labeling, before they may be marketed. The definition of "new drug" would, correspondingly, be revised so that drugs not generally recognized as safe and effective, or not used materially except in safety and efficacy investigations would be considered "new drugs."

DRUGS FOR INVESTIGATIONAL USE

The clearance of a new drug is necessarily based on the scientific data then before the Department of Health, Education, and Welfare. Regardless of the competence and integrity of the scientists whose investigations produced these data, unexpected adverse effects from the drug may develop in actual clinical experience—effects that might call for warnings to physicians to exercise special caution in using or prescribing the drug, or might even justify its withdrawal from the market. Thus, it is highly important for the Department to keep informed about all such developments. The Department claims that it often learns of adverse reactions attributed to new drugs along after the manufacturer has received complaints about them from physicians, hospitals, pharmacists, consumers, or others. An adequate procedure is particularly needed to permit the Department to determine immediately when a new drug, thought to be safe, presents an unsuspected hazard and thus should be taken off the market.

Similarly, the Department needs to be informed promptly as experience, particularly adverse experience, develops with respect to the effectiveness of such products.

Existing law directs the Secretary to promulgate regulations providing for exempting new drugs from preclearance for safety on condition that they are labeled and intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs.

Present regulations require that the investigational drug be labeled "Caution: New Drug—Limited by Federal Law to Investigational Use." Such drugs may be shipped only to persons qualified by scientific training and experience to investigate the safety of new drugs who have certified to the drug manufacturer that they are properly qualified and have adequate facilities for the investigation. These investigators are required to maintain records on the investigation.

The reported bill—section 103 and 106—would enable the Department to require a manufacturer to establish and maintain records and reports of data relating to clinical experience and other data and information and to advise the Secretary of Health, Education, and Welfare promptly of reports of adverse reactions attributed to his new drugs, and to keep the Department informed of clinical experience with the drugs which has a bearing on their safety or effectiveness.

Furthermore, the reported bill provides that the Secretary may establish regulations for conditioning the exemption of a new drug upon the submission to the Secretary before any clinical testing is undertaken of reports by the sponsor of such drug of preclinical tests which, in the opinion of the Secretary, would be adequate to justify clinical testing. Such regulations may also provide for conditioning the exemption upon the sponsor of a new drug proposed to be distributed to investigators for clinical testing that the sponsor obtain a signed agreement from each investigator that the patients to whom the drug will be administered will be under his personal supervision or under the supervision of the prime investigator and that he will not supply such drug to any other investigator or to clinics for administration to human beings.

Such regulations would effectively prevent another thalidomide tragedy

which occurred abroad that we have been hearing so much about lately.

The bill also provides that the sponsor will require investigators to notify the patients that they are being given drugs in an investigational program, obtaining their consent, and certifying to the sponsor that consent has been obtained.

The same requirements as to records, reports, and experiences apply to antibiotics.

NEW DRUG CLEARANCE PROCEDURE

The committee bill eliminates the provisions of existing law under which a new drug application becomes effective automatically at the expiration of 60 or 180 days if the Department does not take positive action to prevent this. Under the bill, a new drug application is not effective unless it has affirmative approval both for safety and effectiveness.

The Secretary would have 180 days, after filing of a new drug application, to approve the new drug application or to give the applicant notice of an opportunity for hearing. The applicant has 30 days after notice to accept the opportunity for hearing. The hearing must start within 90 days, unless a different date is agreed upon, and it must proceed on an expedited basis. The Secretary has 90 days, after completion of the hearing to issue his order. There are other provisions dealing with denying, revoking, or suspending approval of a new drug application and with judicial review.

SUSPENSION OF NEW DRUG APPLICATIONS

Under existing law, an application with respect to any new drug must, after notice and opportunity for a hearing, be suspended if experience shows that the drug is unsafe or that the application contains any untrue statement of material fact. The Secretary of Health, Education, and Welfare cannot terminate a clearance of a new drug on the basis of a lack of substantial evidence of the drug's safety. Rather, he must prove affirmatively that the drug is unsafe before he can terminate its clearance.

The committee amendment provides, in addition, that approval of an application will be withdrawn if new evidence shows that the drug is not safe, or if new information, evaluated together with other evidence, indicates that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have.

In the event the Secretary or Acting Secretary of Health, Education, and Welfare finds that there is an imminent hazard to public health, he may suspend the approval of an application immediately, but he must give the applicant an opportunity for an expedited hearing.

Under the committee amendment, the Secretary may also withdraw approval of an application if he finds that, first, the applicant has failed to establish an adequate system for maintaining the required records or has refused to permit access to those records; or, second, that new information shows that the methods used in manufacture of the drug are inadequate and are not corrected promptly; or, third, that new information indicates that the labeling, based on a fair evaluation of all material facts, is false or misleading, and is not properly corrected.

CERTIFICATION OF ANTIBIOTICS

Presently, the requirement of batch-by-batch certification of antibiotics applies only to drugs composed wholly or partly of one of five specified antibiotics—penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or their derivatives.

Under the committee amendment, antibiotic drugs not previously subject to the certification requirement, and already on the market after clearing the new drug safety requirements of present law, would not initially require an affirmative finding that the drug is effective with respect to the conditions of use prescribed, recommended, or suggested in the labeling covered by the new drug application. However, the Secretary could later amend or repeal the regulations on certifications on the ground of lack of efficacy of the drug under such conditions of use, on a finding that there is a lack of substantial evidence that the drug has the effect it purports or is represented to have under such conditions of use.

ANIMAL FEED

The committee amended the anticancer clause of the food additives amendment and the color additive amendment of the Federal Food, Drug, and Cosmetic Act by making this cause inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals if the Secretary finds first, that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended; and second, that no residue of the additive will be found—by methods of examination prescribed or approved by the Secretary by regulations—in any edible portion of the animal after slaughter or in any food such as milk or eggs yielded by or derived from the living animal.

STANDARDIZATION OF DRUG NAMES

The committee bill would authorize the Secretary of Health, Education, and Welfare to promulgate regulations establishing a single standard name for a drug whenever, in his judgment, such is necessary or desirable in order to achieve usefulness and simplicity of drug nomenclature, or because two or more names exist for the same drug, or because the common or usual name of a drug is misleading, confusing, or not sufficiently informative, or because there exists no common or usual name for a drug. Such regulations could include any related or additional information which, in the Secretary's judgment, is desirable to facilitate the correct and effective use of such standard name. In no event, however, shall a standard name be established so as to infringe upon a valid trademark.

This amendment will facilitate better understanding of drug nomenclature and facilitate the prescribing of less expensive drugs.

AMENDMENTS AS TO ADVERTISING

The Federal Food, Drug, and Cosmetic Act does not presently apply to drug advertising, except when it is used as labeling. The Federal Trade Commission Act does not, with respect to the advertising of prescription drugs, require adequate information to appear in each advertisement.

The committee amendment would deem a prescription drug to be misbranded unless all advertisements for the drug contain the established name of the drug, printed prominently and in type at least half as large as that used for the trade name of the drug, the quantitative formula of the drug, and such information relating to side effects, contraindications, and effectiveness as the Secretary of Health, Education, and Welfare would require by regulation. This jurisdiction over prescription drugs would be exercised by the Secretary and not by the Federal Trade Commission. However, where the advertisement fails to give the quantitative formula or information about side effects, contraindications, or effectiveness, the drug advertised would not be deemed to be misbranded if such information were freely available in labeling materials distributed to licensed practitioners upon their request to the advertiser and if the advertisement contains a conspicuous statement of such availability. The drug labeling, whether distributed in the package or separately is presently required to make full disclosure of such information.

Mr. Chairman, in recent years there has been a spectacular growth in the development of new drugs, particularly new prescription drugs. A very large number of drugs now on the market did not exist 10 or 20 years ago. The rapid development has created some problems with which the existing Federal Food, Drug, and Cosmetic Act is not adequate to cope. Therefore, we have brought this legislation to the House. The Committee on Interstate and Foreign Commerce gave this bill very careful consideration and recommends its passage. The pharmaceutical industry generally speaking supports this legislation. It is not a perfect bill in all respects but realizing that we are dealing here with many controversial issues, the results we obtain are the best obtainable under the circumstances.

With this bill enacted into law we will take a great step forward in the protection of public health. This bill is very much in the public interest.

Mr. YOUNGER. Mr. Chairman, will the gentleman yield?

Mr. HARRIS. I yield to the gentleman from California.

Mr. YOUNGER. The question has been raised, and I will ask, is it not true that under the present law the FDA inspector going into a pharmacy does not have the right to inspect prescriptions?

Mr. HARRIS. Yes. The Food and Drug Act of 1938 originally dealt with that. Then in 1953, if the gentleman will remember, we dealt with that subject, and very impressively and clearly explained the provisions of the law and

just what authority was extended. This is the law today. As a matter of fact, my attention has been called on several occasions to a statement I made at that time. But it was a fact. We did not extend authority to the agency to go into the prescription formula and so forth, and we do not change that procedure here.

Mr. YOUNGER. This bill does not change that procedure?

Mr. HARRIS. No; it leaves it as it is insofar as prescriptions in the drug stores are concerned.

Mr. WAGGONNER. Mr. Chairman, will the gentleman yield?

Mr. HARRIS. I yield to the gentleman from Louisiana.

Mr. WAGGONNER. First of all I would like to commend the chairman of the committee for making, as he always does, a good presentation of anything he brings to the floor. Earlier the gentleman made the statement that as the committee considered this in its deliberations it became aware of the fact that the Government agencies very much wanted this legislation, at least those agencies which are affected and which would be charged with the responsibility of administering this particular act. However, by contrast, industry itself was opposed to it. They were opposed to it because they felt it involved too much Government regulation or interference. At this point I take neither of those positions. But I do take the position that I am concerned very much with protecting the health of the average American in the street today and I am wondering, without trying to provoke anything of scare proportions, if the chairman could very briefly tell the committee, so that we might better understand this problem, just exactly what is wrong with present legislation and what has happened that makes this legislation necessary. I feel that a brief statement along that line will be helpful to all the Members of the House.

Mr. HARRIS. First, permit me to thank the gentleman for his very fine compliment. We always like to hear compliments.

I have just taken most of 25 minutes to call to the attention of the members of the committee very briefly the things which we think need improving. If the gentleman would get the report and read those 11 points that I have pointed out to the committee, it will give the gentleman the exact information.

The facts are that we have about 200 to 300 new drugs every year that go on the market. It has been acknowledged by most everyone, including doctors who have written me, as well as representatives of the industry who have talked to me about it, and those in the agencies who have anything to do with it, that there are certain loopholes and procedures that need to be closed. I have explained what these are.

Mr. WAGGONNER. I have read the report and listened attentively to the chairman of the committee, and perhaps I phrased my statement in the wrong way. I perhaps could have asked a simple question, and that is this:

Is it the opinion of the chairman of the Committee on Interstate and Foreign Commerce, as well as the committee, that there have been too many ineffective and faulty drugs reaching the market, which have worked to the detriment of the health of the public in times gone by and for that reason you feel this legislation is necessary? Am I correct?

Mr. HARRIS. I say to the gentleman I do not think there is anyone, regardless of whether he is in manufacturing or distribution or testing who does not feel that there are some improved procedures which are necessary. The only controversy which has arisen has to do with the question of how much tightening up should be done.

Mr. WAGGONNER. If the gentleman will yield further, the point in controversy which arises is how much tightening up should be done in the regulations?

Mr. HARRIS. I do not think that is a real controversy. As a matter of fact, we have got this down to where it is acknowledged by most everyone who knows what we are dealing with, that it is pretty well worked out, with one exception, and that has to do with advertising of drugs. But the rest of the bill has been worked out fairly well insofar as the industry is concerned—that is, with both the Senate and the House bill—and insofar as the agencies are concerned and everyone who has anything to do with it.

I do want to say that I think in some respects the Senate might have some provisions in its bill that would be more desirable than the House bill.

I think in some respects the House bill might be more desirable than what is included in the Senate bill. You are well aware how these things work. But basically the same problem is dealt with in both bills. I do not say that this is the answer. I am sure that there will be, as time goes on, other matters that will develop with which we will have to deal, but I do say to you, Mr. Chairman, that I think, generally speaking, we have done a fairly good job with this important and difficult problem.

Mr. BENNETT of Michigan. Mr. Chairman, will the gentleman yield?

Mr. HARRIS. I yield to the gentleman from Michigan.

Mr. BENNETT of Michigan. Mr. Chairman, I wish to commend our distinguished chairman for the excellent statement he has made on this bill. As the gentleman from Louisiana [Mr. WAGGONNER] has pointed out, he always makes an excellent, clear-cut explanation of the issues of the legislation reported from our committee. I think the House recognizes and appreciates that fact.

I want to ask the gentleman a question or two in the interest of clarification. If you will refer to the bill, section 101, on page 34, we adopted some language that was different in some respects from the original House language. The language to which I wish to direct attention concerns the word "personnel." That means the personnel of the drug manufacturing concern. In section 101 there is no mention of personnel. But if you will turn to page 2 of the committee report in the explanation of section 101 you will find this language—and I am quoting from the committee report.

Mr. HARRIS. What page?

Mr. BENNETT of Michigan. Page 2, near the bottom of the page, explaining section 101.

> The phrase "operated or administered in conformity with current good manufacturing practice" encompasses key technical and professional personnel responsible for the safety of the drug, and its identity, strength, quality, and purity characteristics.

Since there is no mention of the word "personnel" in the section of the bill itself my question is this: Is not the reference in the committee report, particularly the word "encompasses" ambiguous and likely to lead to misinterpretation and misunderstanding of what the language in the bill actually intends in that regard?

Mr. HARRIS. The gentleman has expressed some interest in this provision heretofore and I am aware of his concern. I feel, however, that it is our responsibility and duty to be perfectly frank and in all candor express what we think this language does encompass. If we did not do so I think we would not be doing our duty to bring information to the Members of this House. If the gentleman will refer to the language of the bill as reported by the committee on page 34, line 11:

> (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packaging, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice * * * to assure that such drug meets the requirements of this act—

And so forth. I think in all candor that that language includes the technical personnel insofar as the word "administer" is concerned.

Mr. BENNETT of Michigan. The word in question is the word "encompasses." I agree with what the gentleman has said.

Mr. HARRIS. Let us say it includes this. If there is any question about the word "encompasses," that may very well include it.

Mr. BENNETT of Michigan. Is it not a fact that what we actually intended by this language was to give the Food and Drug Administration the authority to test the performance and the operations of the drug concern, and of course to that extent the performance and operations would include the work performed by personnel. But I do not believe we intended here to include the right of the Food and Drug Administration to determine the qualifications of the specific personnel to do the job that they were required to do.

Mr. HARRIS. When we struck out the general authority on personnel, which is on page 3 of the bill originally introduced, we proposed to give the Food and Drug Administration authority over the personnel of these manufacturing industries. That we struck out. We said, no, they should not have that authority.

Then in order to get to what we thought and what was thought in this language would be necessary, in my judgment, the language which I read would include all those elements that go into the operation and administration in conformity with current good manufacturing practice. If I did not give my best judgment on what this would mean and how it would be interpreted in its administration, I think I would be derelict in my responsibility here, and I feel I should let the Members of the House know.

Mr. BENNETT of Michigan. My reason for calling it to the gentleman's attention——

Mr. HARRIS. I am going to let the gentleman take some of his own time to discuss this.

Mr. BENNETT of Michigan. I will yield the gentleman time.

Mr. HARRIS. I would rather do that later. I would be glad to talk to the gentleman about this. Let me yield to others who want to talk about it. I have given the gentleman my best judgment. That is what I think it is.

Mr. BENNETT of Michigan. Very often in these matters—and I have seen it happen and I know the chairman has, too—language in a committee report supersedes the language of the bill itself.

Mr. HARRIS. I cannot agree that that is a fact, because if you go back to the natural gas bill, which we fought over around here for a good many years, I think you will find the Supreme Court paid no attention to that at all. They put their own language in there. The gentleman was on the other side of that issue.

Mr. ROBERTS of Alabama. Mr. Chairman, will the gentleman yield?

Mr. HARRIS. I yield.

Mr. ROBERTS of Alabama. Was it not the intention of the committee that in no event would this apply to technical personnel?

Mr. HARRIS. Only technical personnel that are necessary in connection with the language which spelled it out very explicitly and clearly. I repeat, Mr. Chairman, that we do not claim that we have all the answers here, but we do feel that we have closed some loopholes, the closing of which is badly needed. The thalidomide situation is one of those that helped to emphasize this. I have some personal feelings about that. I think in the administration of it there could have been some positive action taken. It may be that the way the thing worked out was best for our people. Nevertheless, it did point up, as it did in other examples that we had presented to us, the need for some action to be taken. We feel we have done as good a job as we could under the circumstances and with the information we had and with the advice and counsel we had. I strongly urge the House to approve this legislation.

The CHAIRMAN. The time of the gentleman has expired.

Mr. BENNETT of Michigan. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, I do not want to belabor this point about the language of the committee report on the question of personnel. On the other hand, I do think it is important. I say that not as one who has come on this committee recently, because I have been a member for a good many years and have participated in some of the prior amendments, including the Humphrey-Durham amendments, which were enacted by this Congress, I think, in 1951, or before that time.

I say the language in the committee report is important and sometimes in spite of what my distinguished friend, the chairman of our committee, says to the contrary, I still say that very often, in fact too often, the courts in interpreting the provisions of a bill which we in the Congress enact here use the language of the committee report as being the proper and correct explanation of what is in any particular section of the law and what the Congress intended when it passed the bill.

I do not think it was intended here to give the Food and Drug Administration authority to tell a drug manufacturer whom he could or could not employ. I think the intention is to give the Food and Drug Administration the authority to supervise the operating practices of the manufacturer in the manufacturing processes of his product. But operating practices and personnel qualifications are two entirely different subjects and ought not to be confused.

What our primary purpose has been here, and everything else has been subordinate to that, is to tighten up and strengthen the provisions of existing law insofar as they relate to the testing of experimental drugs and to the placing of new drugs on the market. Heretofore there has been a question as to the real extent of the authority of the Food and Drug Administration to require, in connection with the testing of experimental drugs, that the agency has been given reports of preclinical tests adequate to justify clinical testing. Furthermore, what we sought to do here is to make clear in a case where the Secretary of Health, Education, and Welfare finds that a new drug is imminently dangerous to the public health it can be taken off the market immediately.

Thereafter the drug concerns would have their day in court, but pending the investigation of this situation, because it involves human life, this authority is given in this legislation to the Secretary of Health, Education, and Welfare; and I think very properly so.

Mr. COLLIER. Mr. Chairman, will the gentleman yield?

Mr. BENNETT of Michigan. I yield.

Mr. COLLIER. Let me say to the gentleman from Michigan that I share the same concern, that legislative history is always made as part of the committee report, and I questioned our staff as to the reference to personnel. I feel that perhaps where the justification might come in is in the use of the language in title 1, starting in line 13, page 34, "or holding do not conform to or are not operated or adminstered in conformity with."

I think when we get to the word "administered," there is an implied inclusion of personnel. And I might say to that end I intend to offer an amendment to the factory inspection authority of the bill, title 2, and I hope to point out at that time there should be some restrictions as to the intent of the legislation insofar as it affects personnel and the qualifications of technical and professional personnel.

Mr. BENNETT of Michigan. As I was saying, Mr. Chairman, the prime intent of the legislation is to tighten up, to give the Food and Drug Administration and the parent agency, HEW, greater authority in the area of protecting the public from dangers flowing from experimentation with drugs not yet approved or from the sale of new drugs which are placed upon the market and which later are found to be dangerous. To that end I think the legislation is excellent, and I think it does its job.

There are other parts of this bill that need not have been included, but that is the case with all legislation that is written here. I believe, generally speaking, we have come up with a good bill.

My original inclination was to support the bill passed by the Senate as the best way that would resolve this problem during this session, but I frankly feel that the bill our committee has reported is better than the Senate bill, and I think that from the conference we will probably come back with a bill substantially similar to our committee bill.

Therefore, Mr. Chairman, I am happy to join my distinguished chairman of the Committee on Interstate and Foreign Commerce, the gentleman from Arkansas [Mr. HARRIS] in urging prompt passage of the committee amendment to H.R. 11581. The gentleman from Arkansas has very ably stated in detail the provisions of this bill and there is no need for me to repeat all that he said.

I would, however, like to comment on some parts of the bill. As I see it, one of the most important provisions relates to preclinical testing of new drugs. Until the present time, new drugs developed by the pharmaceutical companies have not been required to get a clearance for safety if they are intended only for investigational use. The only requirement, and this is a requirement by regulation of the Food and Drug Administration, is that such investigational drug be labeled as follows: "Caution: New Drug—Limited by Federal Law—To Investigational Use." And with this label the drug may be shipped all over the United States to qualified doctors and scientists for experimentation on humans and animals. There is no present requirement of any proof of its safety or effectiveness.

I believe this is a wrong practice. It would seem to me that there should be some showing by the manufacturer or sponsor of the new drug, that the drug is safe for use on humans before he may be permitted to use them, even on an experimental basis. No one knows for sure how extensive these experiments may be.

They may involve thousands of doctors and scientists and hundreds of thousands of patients.

We have heard a lot of talk about thalidomide lately. Very fortunately for us, the citizens of this country did not

suffer the horrible experiences of people in Europe where the drug was widely used. But we now find that although thalidomide was not yet approved as a new drug until the new drug clearance procedure of the Federal Food, Drug, and Cosmetic Act, thanks to the Food and Drug Administration, nevertheless it apparently was distributed in fairly large quantities to physicians all around the country for investigational purposes.

The bill would provide for the American public a large measure of protection in this area. It provides that with respect to drugs intended solely for investigational use, the Secretary of Health, Education, and Welfare may exempt them from meeting the stiffer requirements which apply to commercial drugs sold on the market. But he may condition this exemption upon the submission to him of reports on preclinical tests adequate to justify the use of this new drug in clinical testing. Also, the Secretary may require the manufacturer of a new drug being proposed for clinical testing to obtain signed agreements from his investigators that the patients who will undergo the clinical testing will be under his personal supervision and that he will not supply this drug to any other investigators.

If the authority being granted to the Secretary of Health, Education, and Welfare will be used and enforced it would eliminate the sad spectacle we witnessed with the investigational use of thalidomide in this country when it was found that many doctors had possession of this drug and, apparently, were prescribing it to patients without the knowledge of the distributor of this drug. Certainly such loose practices should be drastically curtailed, if not eliminated.

The Secretary could also require, as a condition for granting an exemption, the maintenance of records by the investigator of the results of the experiments on investigational drugs and furnishing such reports to the Secretary. It would seem elementary that an investigator using an experimental drug on patients should be required to establish and maintain records on his experiment.

Another important provision of the bill is the requirement that new drugs be required to pass the test of effectiveness as well as safety which is presently required. The test of effectiveness means that the sponsor of the drug will henceforth have to prove that he has "substantial evidence" to prove that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in the labeling. This is a fair requirement.

If a drug is represented as being a remedy for a given ailment, the sponsor should be able to furnish substantial evidence that his claim can be supported. New drugs which have already been approved will also be subject to this new test of effectiveness.

Another key provision is the one which authorizes the Secretary of Health, Education, and Welfare to suspend the approval of a new drug immediately if he finds that there is an imminent hazard to the public health. If this should happen the sponsor of the drug would be afforded an opportunity of an expedited hearing on the revocation.

The bill requires the maintenance of records and reports. It imposes additional requirements with respect to manufacturing controls on drugs to assure that manufacturing methods are in conformity with "current good manufacturing practices." It provides that new drug applications will require affirmative approval by the Secretary before they could become effective. Presently these applications become effective automatically after the expiration of 60 or 180 days unless the Secretary takes positive action to prevent this. It authorizes increased powers over factory inspection of prescription drug manufacturing plants.

All these proposals—and there are others in the bill which I have not mentioned—will strengthen existing law and are in the public interest. I shall vote for the bill, and I hope it will pass.

Mr. HARRIS. Mr. Chairman, will the gentleman yield?

Mr. BENNETT of Michigan. I yield.

Mr. HARRIS. I would not want the RECORD necessarily to have what I said earlier regarding the history to stand without further comment. I agree with the gentleman that the purpose of the report is to make an effort to further explain what is intended by the committee. I agree with the gentleman that agencies administering these programs and the courts themselves should take into consideration the legislative history, not only the report, but also the debate such as we are engaging in here today.

I also recognize finally that a court when it construes the language, taking into consideration what is said, must finally and does finally give its own opinion as to what a particular line, phrase, or language says and means. So that is the reason I say in the language I read here with reference to this provision I could not feel anything else but what it would be interpreted for this limited purpose only and technical personnel would be included.

Mr. BENNETT of Michigan. I thank the gentleman.

The CHAIRMAN. The time of the gentleman from Michigan has expired.

Mr. BENNETT of Michigan. Mr. Chairman, I yield 15 minutes to the gentleman from Ohio [Mr. SCHENCK].

Mr. SCHENCK. Mr. Chairman, the Committee on Interstate and Foreign Commerce, of which I am proud to be a member, worked hard and diligently on the bill which the committee has brought to the floor of the House today. We had lengthy and thorough hearings on this subject beginning several months ago and more recently extending over a period of 2 weeks including several night sessions when everyone who had the desire to testify and express views on this subject was afforded the opportunity to do so.

We started out with two bills, H.R. 11581 and H.R. 11582, both introduced by the distinguished chairman of the committee, the gentleman from Arkansas [Mr. HARRIS]. As I understand it, these bills were recommended to the Congress by the former Secretary of Health, Education, and Welfare, the Honorable Abraham Ribicoff, and they encompassed the entire scope of legislative recommendations in this field recommended by the President in his consumer message to the Congress. H.R. 11581 deals with drugs and factory inspection; H.R. 11582 has to do chiefly with cosmetics, therapeutic devices, and so forth.

The bill, H.R. 11581, which the Committee on Interstate and Foreign Commerce presents to you here today deals only with drugs. It is a good and workable bill which merits your support. We did not have sufficient time to give to the other subjects in this broad area, and it is my understanding the chairman of our committee has indicated that these remaining subjects will be given consideration in the next Congress.

Mr. HARRIS. Mr. Chairman, will the gentleman yield?

Mr. SCHENCK. I yield to the gentleman from Arkansas.

Mr. HARRIS. I am glad the gentleman reminded me of the matter he just mentioned. We thought we should advise the membership of the House on that subject. These are important matters with reference to drugs that the committee felt should be given more consideration. One of those important problems involves barbiturates and another involves biologicals. We thought they were of such importance to the health and welfare of our people that further consideration should be given. If I have anything to do with it, it is my purpose to see that further hearings and consideration will be given to the matter perhaps by the subcommittee headed by the gentleman from Alabama [Mr. ROBERTS] and the subcommittee of which the gentleman from Ohio is a member. Then, of course, the cosmetics field is another one. Those will be considered in the next Congress.

Mr. SCHENCK. I thank the gentleman for his clarification.

Mr. Chairman, it is my firm conviction and considered judgment that the doctors, medical scientists, and all other scientific personnel in the field of human health here in the United States are by far the best trained and most expert professional men and women in the entire world.

Tremendous advances and great progress have been made in the treatment of the ills and health problems of all kinds. Tremendous and continuous progress is being made in the development of new drugs. These drugs are very properly referred to as miracle drugs because the helpful results are often unbelievable. Literally millions of people are living active, happy, and productive lives today as the result of recovery from illnesses which only a few years ago were nearly always fatal. Thus we owe a very great debt of gratitude to the dedicated men and women in all the professions connected with the medical and health sciences.

Mr. Chairman, our Nation also has the best food and drug laws in the world today and these laws are on the books for

only one reason—to protect the health and safety of each and every citizen.

Occasionally, of course, these laws need to be updated and strengthened to meet new conditions and situations as they arise. No nation in the world today has anything like the controls over drugs of all kinds which are exercised in the United States for the protection and safety of the health and well-being of its citizens. In fact, in any number of other nations very potent drugs can be bought over the counter by anyone while in the United States these same drugs can be obtained only as the result of a written prescription signed by a qualified physician.

Recently here in the United States a great deal of consternation properly arose because of the experimental use of a drug which caused children to be born with malformed bodies. Information was developed also that another drug which had been given approval by the Food and Drug Administration was showing side effects harmful to human health. The Food and Drug Administration took prompt action, however, in immediately stopping the use of the experimental drug and also took immediate and successful steps in withdrawing approval and stopping the use of the other drug which had been previously approved. Thus it was shown conclusively that the Food and Drug Administration had the authority, the means, and the determination to protect the safety and health of our citizens. The Food and Drug Administration is to be commended for promptly taking the actions it did in these instances.

Mr. Chairman, food and drug legislation is always complex and complicated and careful judgment must be exercised to make sure that proper legislative controls and authority are available to adequately protect the public health and safety and yet also maintain the degree of flexibility which is so necessary to encourage the research and development of new drugs to meet the challenges of the day. This is indeed a very fine line of demarcation to draw and observe. On the one hand the health and safety of the people is at stake and must be adequately protected, and if we are to err we must err on the side of safety. On the other hand, if we discourage and stifle research and development in new life-saving drugs and treatments, many lives will be needlessly lost. Thus we must legislate with great care and wisdom to provide the Food and Drug Administration with all the authority necessary to properly discharge its responsibilities in the public interest without granting the authority to control just for the sake of controls through the creation of ever-increasing Federal bureaucracy. All of the legislatures and the administrations in each of the 50 States of our Nation are also fully aware of their responsibilities in the field of human health. Many very helpful State laws are in effect; many such laws in some instances are even stronger than Federal laws for the protection of human health in the public interest. We here in the Congress should take no action to interfere with these strong and effective laws already approved by State legislatures and doing very effective work in this important effort to protect and improve human health.

At the conclusion of our hearings, the committee went into executive session and gave the bill, H.R. 11581, a great deal of careful attention. We had before us not only the House bill but also the Senate bill (S. 1552) which had been approved in the other body. The bill which the committee reported is a composite of the House and Senate bills and I am convinced it is sound legislation which I heartily recommend to the House. It will give added protection to the consumer in areas where it is most needed. We provide in the bill many of the things that our colleague, the chairman of the committee, so well stated.

The chairman of the committee, the distinguished gentleman from Arkansas [Mr. HARRIS] has already gone into a detailed explanation of these items, and I do not believe it necessary for me to repeat what he has already stated except for the purpose of emphasis we provide in this bill, H.R. 11581, for the following:

First. Controls of manufacture of drugs to assure that manufacturing methods are in conformity with current good manufacturing practices.

Second. Requirement that new drugs be shown to be effective as well as safe.

Third. Requires the keeping of records and furnishing of reports in connection with safety and effectiveness of new drugs and antibiotics.

Fourth. Provides procedures to be followed in the testing of investigational drugs.

Fifth. Outlines agency procedures to be followed in approving new drugs.

Sixth. Provides for summary suspension of new drugs where there is an imminent hazard to public health.

Seventh. Provides for the withdrawal of new drugs when their safety or effectiveness is no longer assured.

Eighth. Certification of all antibiotics for man—present law requires only certification of certain antibiotics.

Ninth. Factory inspection of establishments manufacturing prescription drugs.

Tenth. Requires that manufacturers make available complete and adequate scientific and factual information concerning safety and effectiveness of drugs to physicians.

Eleventh. Simplifying drug nomenclature.

The recent disclosures in the press in regard to thalidomide have impressed upon me the fact that the present Federal Food, Drug, and Cosmetic Act is deficient in regard to the procedures involved in the testing of drugs for investigational use. The only requirement under the present act—and this is done by regulation of the Food and Drug Administration—is the requirement that the experimental drug be labeled to indicate that it is a new drug for investigational use only. With that labeling requirement met, the pharmaceutical companies could proceed to distribute it to physicians and other investigators for testing on humans and animals.

It seems to me that more is required in the way of protection for the public in the use of experimental drugs. I, therefore, proposed an amendment to section 103(b) of the bill which was approved by the committee and which provides:

Such regulations may provide for conditioning such exemption upon—

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests of such drug adequate to justify the proposed clinical testing;

(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

(3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b).

My amendment authorizes the Secretary of Health, Education, and Welfare to issue regulations for the testing of experimental drugs on humans upon the condition that before any tests are undertaken on humans, the Secretary may require the submission of reports to which I have referred.

This language, it seems to me, is necessary to protect the health and safety of people and is a perfectly reasonable requirement to have in the new law. It does not compel the Secretary of Health, Education, and Welfare to do these things and is permissive, but it grants him authority to proceed if he thinks it appropriate and necessary.

I also offered an amendment to section 101 of the bill having to do with adequate controls in the manufacture of drugs.

My amendment to section 101 of the bill, which was approved by the committee, provides simply that the drug will be deemed to be adulterated and subject to seizure if the methods, facilities, or controls used in the manufacture of the drug do not conform with current good manufacturing practice, as determined in accordance with regulations promulgated by the Secretary.

The purpose of this provision is to enable the Secretary to require all companies producing drugs to observe the high standards that are now followed by the better manufacturers. It is intended that the Secretary's regulations will define minimum standards of good manufacturing practice, rather than setting forth an exclusive method by which some particular drug product may be made. Manufacturers whose methods, facilities, and controls exceed the minimum standards will not be required to lower their own standards, so long as they can show that their own practices meet or exceed these minimum requirements.

The principal purpose of the provision is to assure that the same high manufacturing standards are followed in making so-called old drugs that the law now requires in the making of so-called new drugs. Before any manufacturer is permitted to make a new drug he must file complete details of his manufacturing process with the Food and Drug Administration. It is not intended that the regulations issued under section 101 will apply to the manufacturer of new drugs insofar as concerns the methods, facilities, or controls used in making these new drugs but that the Food and Drug Administration will require that such drugs meet the requirement of this act as to safety, and has the identity and meets the quality and purity characteristics which it purports or is represented to possess.

The committee adopted an amendment which would make the formal rulemaking procedures of section 701(e) of the Federal Food, Drug, and Cosmetic Act applicable to regulations referred to which may be made pursuant to the above amendment.

I am opposed to the amendment in section 101(b) of the bill which would require the Secretary to hold a formal hearing under section 701(e) of the Federal Food, Drug, and Cosmetic Act in order to issue regulations as to what constitutes "current good manufacturing practice." I favor the approach adopted by the Senate under which this determination is made pursuant to section 701(a) of the act. This procedure permits the Secretary to issue such regulations as he desires and their scope and effect will be the same as that of other regulations issued under such general authority. This procedure is more flexible. Numerous regulations have been issued under this section and they have been the subject of consideration and application in the courts in actions arising under the various provisions of the act not now subject to formal rulemaking procedures.

I am also opposed to the interpretation on page 2 of the committee report which states that the phrase "operated or administered in conformity with current good manufacturing practice" encompasses key technical and professional personnel. It seems to me that this means the performance of the personnel so used. I do not believe that the Food and Drug Administration should have the authority to set the standards for industrial personnel and pass upon the qualifications of such personnel. This prerogative should remain with the industry. Good manufacturers of quality drugs are already using the greatest care and have established very high standards for well-qualified personnel.

I trust, Mr. Chairman, that the House will approve this bill by an overwhelming majority, because it is good, sound legislation in the best public interest and for the protection and well-being of the citizens of our great Nation.

Mr. YOUNGER. Mr. Chairman, I yield 10 minutes to the gentleman from Illinois [Mr. COLLIER].

Mr. COLLIER. Mr. Chairman, dealing with any legislation of a highly technical and complex nature is, in itself, one which demands considerable soul searching on the part of any conscientious legislator; and to deal with this type of subject matter in an atmosphere of emotion and frenzied hysteria was the situation our committee faced in the bill before you today. Hence the thalidomide episode only added to the grave difficulty of an already tough problem.

Hearings on this bill were begun by the committee late in June. The original legislation was indeed broad in its scope and reached far beyond the areas of the legislation before us today. Less than a month after these committee hearings began, the tragic thalidomide story hit the front pages of newspapers across the country. However, at this very time, the story of thalidomide and its effects upon newborn babies was old news overseas for the British press had already aired these findings many months ago.

Be that as it may, the pressure mounted to provide the Food and Drug Administration with sweeping new powers. Some of these powers were prescribed with frightening vagueness—and I might add that we have by no means removed from H.R. 11581 certain areas of vagueness, particularly in the factory inspection section identified as title II of the bill. And while I repeat that this bill as reported has been vastly improved over its original form, we must realistically accept as fact that legislative and regulatory sanction cannot promptly provide a solution to all of the associated problems of drug evaluation and the side effects.

Certainly no one in this Congress or in the industry denies the need for tightening up drug practices.

Dr. Louis C. Lasagna, associate professor of medicine and associate professor of pharmacology and experimental therapeutics at Johns Hopkins University School of Medicine, summed the situation up as concisely and clearly as anyone was able to do during the hassle on this issue when he said, and I quote, "What really needs emphasis is that any required modifications in existing laws and regulations should be made after appropriate deliberation and discussion with clinical investigators and pharmaceutical firms and not as a quick-change act performed in the purple spotlight of hysteric and sensational news headlines." He warned, and I again quote, "The basic rights of patients must not be infringed upon, to be sure, but the passage of laws requiring written or verbal agreement before the administration of any new drug may retard medical progress in unpredictable ways."

In other words, while we are charged with the responsibility of providing the Food and Drug Administration with the tools necessary to protect the public and prevent abuses and misuse of drugs in this country, we must also be fully aware of the public welfare to the extent also that we do not act to retard the development of drugs that are life prolonging or lifesaving. Thus, public welfare becomes a two-way street; one which provides protection from abuses on the one hand and the other which provides the continued advantages to which the public is entitled through the research and development of new and effective drugs.

Earlier in my statement, I mentioned that there are vague areas of new authority granted to the Food and Drug Administration in this legislation. It will be argued that Congress cannot spell out to the letter of the law the authority of an agency which must deal with the complex and technical phases of food and drug administration. With the exception of the factory inspection authority of this bill, I think the committee has done a good job as did the other body. But I must remind the House that Justice Douglas, in the Supreme Court case of United States against Cardiff said:

> The vice of vagueness in criminal statutes is in the treachery they conceal either in determining what persons are included or what actions are prohibited.

For this reason, I intend to offer an amendment to title II to clarify an area of vagueness which I think is essential to improving this section of the bill.

I feel that I would be remiss if I did not at this time compliment the chairman of the committee who worked diligently and long in bringing to us a bill, late in the session though it is, to meet the prime needs for authority for the Food and Drug Administration; and it is my further hope that the bill before us will be unanimously passed.

Mr. HARRIS. Mr. Chairman, I yield 10 minutes to the gentleman from South Carolina [Mr. HEMPHILL], a member of the committee.

Mr. HEMPHILL. Mr. Chairman, before I discuss the particular part of this legislation in which I am greatly interested I want to thank and salute my chairman for the leadership he gave in bringing this legislation here before the end of this session of Congress. I think the committee has done a good job under his leadership and I am proud to have been a part of it.

I think one of the greatnesses of this country lies in the fact that we have such legislation as the Food and Drug Act. If you will take the report you will see that we have tried to spell out the purpose of the legislation. We have covered the needs in the bill as we could leaving out anything that would be obnoxious to the manufacturer of good safe drugs.

I want to turn now to a part of the legislation I was particularly interested in. When the legislation was scheduled for hearing I was besieged with a great many letters and other communications from people in the cosmetology profession saying that this bill, if passed, was going to put them out of business. Naturally I was interested in keeping this segment of our American professional effort in business. I was interested in the fine testimony given by our colleague from Missouri, the gentlelady from St. Louis, who is here in the chamber today, and none of us wanted to take any step which would in anywise hurt these people who are in a very necessary and productive business.

So by leave of the committee I inserted into the legislation—this appears on page 57—a provision, line 6:

> SEC. 509. This chapter, as amended by the Drug Amendments of 1962, shall not apply to

any cosmetic unless such cosmetic is also a drug or device or component thereof.

So if you go back home and are asked what effect it has you can tell them that in the bill we have provided here that where the item or the particular things used by a cosmetologist are not of such nature or used in such way that it might be a drug or device or component thereof they are perfectly safe. We have spelled out that the legislation recognizes the needs of the hairdressing profession in this area of safety and effect, and we give legislative intent and direction that the products are pure. The hairdressers want that, but they want a minimum of interference and my amendment provides this.

We have provided that the ladies who go to the beauty parlors in the future will be absolutely safe because of the provisions of this bill so far as any drugs are concerned. The people who are in the business of hairdressing or cosmetology, I know, depend on the manufacturers to give them a measure of protection through this kind of legislation, and I feel, after talking to them, that they are thoroughly in accord with the committee sentiments. The cosmetics that do not contain any drug or component thereof are exempt. We are talking about drugs, because the word "drugs" has a connotation. It has a common application of doing something different to you. Years ago we had a particular drink that we called a "dope" because people thought that that particular drink affected you in some way. It was a suspicion that was not justified in any way.

Here we have an obligation. These people are considerably worried. I do not know who went to the hairdressers and cosmetologists and told them we were trying to put them out of business, but I hope whoever told them now has the integrity to commend this committee and the Congress for this legislation, for it is an effort not only to protect the people who patronize that industry but it is an effort to protect the ladies and gentlemen who practice that profession. We have done that here in this particular legislation.

Let me dwell on one other feature of the legislation that is not included in the committee amendment, which I hope we are going to pass today. Perhaps you have had some letters, as I have, on the question of whether or not we were going to back into the manufacturer's place of business and try to find out his formulas. The committee felt that was not proper. We want it safe, we are going to insure it is safe. We want it effective and we use the word "effective." But the real meaning of this particular legislation is honesty. If you say you are marketing something that will do human beings some good, then it will do them good. If you say it will do them good and it does not do them good, then you are violating the law. That is so necessary because we have no intimate knowledge of internal medicine.

All of us recognize in hospitals as well as the home the practice of internal medicine and, because the scientific progress we have made has become significant, a large part of the American public depends on the medicines, pills, and the other injections it receives in order to sustain health or bring somebody back to health. So, what I feel we are doing here today, I am hoping we are doing it, is doing something for every single person in the United States. We are saying to them: "Your Congress is concerned, your Congress is determined, that honesty shall be the byword and the password and the purpose insofar as the advertisement and use of drugs in this country are concerned."

Mr. HARRIS. Mr. Chairman, I yield 10 minutes to the distinguished gentlewoman from Missouri [Mrs. SULLIVAN].

THE DRUG CONTROL BILL

Mrs. SULLIVAN. Mr. Chairman, I wish this were the Sullivan bill, H.R. 1235, which we were considering here today. Instead, it is the Washington Post bill. By that, I mean, that if it had not been for the dramatic news story carried in the Washington Post some months ago about Dr. Frances E. Kelsey of the Food and Drug Administration blocking the sale of thalidomide in this country, I imagine we would have had no bill at all this year. The one we have before us is limited strictly to drug control, as a means of providing the kind of safeguards we should have had in the law before Dr. Kelsey's long fight with thalidomide. It meets none of the other serious deficiencies in the Food, Drug and Cosmetic Act—none of them. I could list them all here, but it is probably unnecessary, since I have been doing that, off and on, here on the House floor ever since January 3, 1961—nearly 21 months ago—when I introduced the first omnibus bill since 1938 to close all of the major loopholes in the 1938 Act.

It took from January 3, 1961, to March 15 of 1962 for the Administration to decide on the extent to which it wanted to go in seeking changes in the Food, Drug and Cosmetic Act. The President in his consumer message of that date endorsed nearly all of the major features H.R. 1235 was intended to cover. But then there was another long delay—until mid-May—before two bills were sent up as Administration bills to carry out the same major objectives as H.R. 1235. Many of the provisions were identical, down to the last comma and semicolon. I went to former Secretary Ribicoff many months before that to ask that he accept H.R. 1235, or modify it, as a vehicle for seeking these terribly long overdue changes in our law. If that had been done, I think we could have begun work on this problem long in advance of the timetable which was followed.

Perhaps, if we had acted earlier without the spur of the thalidomide incident, the final legislation might have been less effective in drug control. But I believe it would also have covered cosmetics and therapeutic devices and amphetamines and barbiturates and fake cancer cures and all of the other things which are in H.R. 1235 and the two administration bills but which were dropped by the wayside in the adjournment rush.

So, while I am disappointed at the delays which occurred in HEW in getting to this problem and coming forward with strong recommendations for legislation along the lines of H.R. 1235 until a year and a half after my bill was introduced, perhaps, as I said, we are better off, in getting stronger drug control legislation than would otherwise be feasible. Who would have predicted a few months ago that the Senate Judiciary Committee would recall the bill it had reported and completely rewrite it, and that it would pass the Senate 78 to 0? Not I.

The tragedy of all this is that the facts which formed the basis for the dramatic Washington Post story about Dr. Kelsey were known to many people in the drug industry at the very time they were bitterly fighting effective controls. Dr. Helen Taussig of Johns Hopkins back in April had brought back word from Europe of the thalidomide deformities. There were news stories on it. The regulations within the Department of Health, Education, and Welfare for control over experimental testing of new drugs were being studied to determine whether they should be revised in the light of the thalidomide experience. The industry knew all this. Few of us outside of the industry, however, knew much about the extent of the thalidomide tragedy. I inquired about this in April but had no reason to think our escape was as narrow as it turned out to be.

But some of us knew—and strongly urged at the June hearings of the committee—that our new drug laws must be strengthened because they are full of holes, and particularly the provision of present law which requires the Government to prove a drug is dangerous in order to stop its use once it has been approved. That was one of the key points in my testimony before the committee.

The most important thing we do here in this bill is to close that loophole. Anything else we do is extra—a dividend. The real harvest here is the ability to act quickly to protect the public when a drug in use—previously approved for use—turns out to be dangerous.

The next most important thing is the requirement for proof of effectiveness of new drugs. The antibiotics batch-testing is important, too. The authorization for tighter controls covering experimental testing will also help the consumer and particularly the sick. So we are doing a vital thing in passing this bill. It is too bad it took the shock of a dramatic news account about a heroic woman doctor—a personalized story—to make us act.

That is why I say this should be called the Washington Post bill. The news account which prompted—which inspired it—deserves the Pulitzer prize. Other articles have been written on this subject of equal significance, but this article was the trigger—it appeared at the right time in the right place, in a newspaper most Members of Congress and most of the top leaders of Government read.

And it came at a time when the best we could hope for in consumer protection legislation was a watered-down bill which may or may not have passed the Senate, with no House action of any kind scheduled.

Mr. Chairman, I applaud the staff work on the House Committee on Interstate Commerce on this legislation. The materials provided the committee and some of us who requested it were comprehensive and very useful. I applaud the members of the committee for coming back to Washington in August while the House was virtually in recess, and putting in 3 solid hard days of day and night hearings to move this bill forward, when the previous intention had been, following the week of hearings in June, to let it go over until next year.

Congress does not always move as fast as we would like or as fast as it should or as fast as it can. But when there is widespread public awareness of a problem, Congress can do wonders in moving quickly to meet it.

The Washington Post did not create the problem—but it created the interest in it. I am deeply grateful.

ASSOCIATED PRESS STORY OF APRIL 12 QUOTING DR. TAUSSIG

Mr. Chairman, some months before the Washington Post story appeared disclosing the heroic battle waged by Dr. Kelsey to keep thalidomide off the market in the United States, the Associated Press carried a warning report from Philadelphia—which I read in the Washington Post of April 12—quoting Dr. Taussig of Johns Hopkins on the gaps in our regulations dealing with the experimental testing of new drugs. That article was as follows:

EXPECTANT WOMEN WARNED: PILLS MAY CAUSE DEFORMITY

(By James V. Lamb)

PHILADELPHIA, April 11.—Dr. Helen Brooke Taussig, a prominent Baltimore physician, warned today of the dangers pregnant women face by taking new drugs before they have been adequately tested.

She backed up the warning with a report on an increase of congenital abnormalities in Europe known as phocomelia.

Dr. Taussig, who gave a special report to the American College of Physicians last night, said stricter controls on drug testing are needed in the United States.

Dr. Taussig, professor of pediatrics at Johns Hopkins Hospital, told a news conference that in West Germany figures indicate there will be between 3,500 and 5,000 babies born in 1962 afflicted with phocomelia—shortening and deformity of the limbs. Often the hands and feet are gone, or look like the extremities of a seal. About one-third die.

She said there "is extremely strong circumstantial evidence" that the abnormality could be traced to the use of drugs containing thalidomide—a sedative—by women in the first 2 months of pregnancy.

It is not for sale in this country.

She said that before the advent of the drug, the number of cases were rare. A physician "might see as many as 10 cases in his lifetime." Now, she said, there are thousands of cases. In Westphalia, Germany, medical experts predict there will be as many as 2,000 cases by year's end.

Dr. Taussig is just back from Europe where she studied many of the cases.

The drug was withdrawn from European markets last December. It had been on sale since 1958. The drug sold for a while in Canada, but has been dropped there, too, she said.

She said it is possible under present Food and Drug Administration regulations for a drug like thalidomide to be publicly sold. "We do not require testing of all drugs on pregnant animals," she said.

"We must strengthen our food and drug regulations," she added.

She also said her medical colleagues should exercise more care in prescribing new drugs, "especially for young or expectant mothers."

INQUIRY TO FOOD AND DRUG ADMINISTRATION

Mr. Chairman, I then directed the following inquiry to Dr. Larrick at FDA to determine whether it was true that under our regulations a drug like thalidomide could be placed on sale in this country and, if so, whether my bill would cover this situation adequately or whether amendments would be necessary to cover this point:

HOUSE OF REPRESENTATIVES,
Washington, D.C., April 18, 1962.

Mr. GEORGE P. LARRICK,
Commissioner, Food and Drug Administration, Washington, D.C.

DEAR MR. LARRICK: I am sure you must have seen the enclosed news article which appeared Thursday in the Washington Post on the consequences alleged to have occurred in Germany from use by pregnant women of a sedative pill not sanctioned for use in this country. What interests me in this is the statement attributed to Dr. Taussig in the article that it is "possible" under present FDA regulations for a drug like this to be publicly sold, and her further comment, "We must strengthen our food and drug regulations" presumably to cover that kind of situation.

May I ask if you know of the existence of the kind of danger Dr. Taussig mentioned, particularly in relation to her statement that: "We do not require testing of all drugs on pregnant animals." Furthermore, I would appreciate knowing—in case there is a gap in our new drug laws such as she indicates—whether H.R. 1235 would close it or whether additional wording would be necessary. I was under the impression our new drug laws were sufficiently tight to cover any and all eventualities in connection with the right to sell a drug for the first time; it was my further impression that the main gap in the new drug provisions lies in the grandfather's clause which protects them from delisting without overwhelming proof.

Naturally, I will appreciate your best advice on this.

Sincerely yours,

LEONOR K. (MRS. JOHN B.) SULLIVAN,
Member of Congress, Third District, Missouri.

REPLY FROM DR. LARRICK ON THALIDOMIDE

Dr. Larrick's reply on April 26, as follows, reassured me that the new drug law provided adequate authority for requiring, by regulation, whatever testing was necessary to assure the safety of a drug before marketing:

DEPARTMENT OF
HEALTH, EDUCATION, & WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C. April 26, 1962.

Hon. LEONOR K. SULLIVAN,
House of Representatives,
Washington, D.C.

DEAR MRS. SULLIVAN: We had seen the news article referred to in your letter of April 18 about the tragic results in Europe following use of a sedative pill not sanctioned for use in this country.

The thinking of the medical experts in this country and abroad about the types of tests that should be made to establish the safety of a new drug has been undergoing revision ever since the new drug section became a part of the law in 1938. While we do not at this time require the testing of all new drugs on pregnant animals, it is the practice of our medical officers to ask for results of such tests in all new drugs that are to be offered for use by pregnant women. We have been calling for this type of information for some time now.

You will be interested in knowing that the same drug that was allowed in Germany, thalidomide, was under consideration in this country. A manufacturer submitted a new drug application for the product in September 1960. However, we found that the information submitted was incomplete in a number of respects and did not establish the safety of the drug. From time to time during the next several months, the firm submitted additional information. During this period, however, we noted in the British medical literature reports about side effects (neurological toxicity) of the product which raised further questions about its safety.

Also, because the product was to be recommended in its labeling for use by pregnant women, we asked for data to show that it was safe in pregnancy.

Before all of the questions were answered, the manufacturer advised us that the product had been withdrawn from the German market because of the reports that it caused birth defects in infants whose mothers were taking the drug during pregnancy, and the firm withdrew its application for safety clearance.

Answering now the specific inquiry in your letter, I do not believe that further legislation is required to permit us to require the testing of a new drug on pregnant animals. We have the authority in the present new drug section to require any test that is necessary to demonstrate the safety of a new drug under its proposed conditions of use. Certainly, the foreign experience with thalidomide is permitting us to take a new look at our own requirements to be sure that they do call for all of the tests that should be requested in evaluating a drug before it may be marketed.

We do of course need additional legislation to deal with efficacy.

With best personal regards.

Sincerely yours,

GEO. P. LARRICK,
Commissioner of Food and Drugs.

TESTIMONY BY CONGRESSWOMAN SULLIVAN ON FOOD AND DRUG BILLS

Mr. Chairman, the above exchange reassured me that there was adequate authority under present law for revising our regulations, and those regulations now are in the process of revision. But as events have proved, and as I advised the House Committee on Interstate and Foreign Commerce in my testimony on the various pending bills when I testified on June 20, not only the drug portions of our law but the food and cosmetics and therapeutic device sections are in woeful need of overhaul. This bill we are passing today is a good step in the right direction, but it meets only part of the overall problem.

Mr. Chairman, under permission granted by the House, I submit at this point the testimony I gave on H.R. 1235 and the administration bills, out of which the bill now before us was drafted:

AN OMNIBUS BILL TO REWRITE THE FOOD, DRUG, AND COSMETIC ACT

(Testimony by Congresswoman LEONOR K. SULLIVAN, of Missouri, before House Committee on Interstate and Foreign Commerce, June 20, 1962)

It is certainly no criticism of this committee when I say that this is a moment I have been waiting for—impatiently—for a year and a half, or at least since the opening day of the 87th Congress on January 3, 1961, when I introduced H.R. 1235, an omnibus bill to rewrite the Food, Drug, and Cosmetic Act

to bring it up to date in terms of today's needs and problems in protecting the American consumer. It is still the only measure pending in either House which would combine in one bill provisions for closing all of the major loopholes in consumer protections under the Food, Drug, and Cosmetic Act.

Chairman HARRIS and I discussed the importance of having the formal departmental reports from the Department of Health, Education, and Welfare and other Government agencies affected by or interested in the many complex and technical provisions of the bill before hearings could be scheduled.

Unfortunately, except for a "no comment" report from the Federal Trade Commission (subsequently clarified in an exchange of correspondence between me and FTC Chairman Dixon), none of the executive departments or agencies directly or indirectly affected by H.R. 1235 ever did file the requested reports to this committee on the specific provisions of the bill.

PRESIDENT ENDORSES MANY PROVISIONS INCLUDED IN H.R. 1235

On March 15, however, the President sent his comprehensive consumer message to the Congress which contained a formal endorsement on behalf of the administration of many of the changes in the law which are contained in H.R. 1235; and last month, as you know, Chairman HARRIS on behalf of the administration introduced two separate bills directed to those recommendations—H.R. 11581 dealing with drugs, and H.R. 11582, dealing with cosmetics and therapeutic devices. Together, these bills contain many of the features of H.R. 1235, but not all of them, and also contain some provisions not in H.R. 1235.

I suppose I wouldn't have minded the long delay nearly as much if, after all this time, the administration had reported that the approach in H.R. 1235 was completely wrong and impractical. However, now that most of the provisions of the administration bills are shown to be identical to, or at least very similar to, H.R. 1235, I am indeed sorry we couldn't have gotten to this matter a year or more ago, and thus with a better chance of final action in this Congress.

On Monday, I placed in the CONGRESSIONAL RECORD a detailed breakdown prepared for me by Mr. Raymond J. Celada, of the American Law Division of the Legislative Reference Service in the Library of Congress, showing in comparative tabular form all of the similarities and all of the differences when comparing H.R. 1235 with the two Harris bills, and also as compared with the widely discussed Kefauver-Celler bill. I felt it would be helpful to the committee and to all of your witnesses to have this material available prior to the start of the hearings for a better understanding of the technical points in the various bills. All of the bills share the one common objective of protecting the American consumer; all differ, however, in some significant respects.

The Kefauver-Celler bill is not before this committee, of course, since, as introduced, it is directed primarily at changes in the antitrust laws and the patent laws applying to drugs, and thus comes within the jurisdiction of the Judiciary Committee, even though it also contains many provisions amending the drug provisions of the Food, Drug, and Cosmetic Act. But I thought it would be useful to have the comparative breakdown of the various bills include this one, too, even though it is not officially before you.

GREAT CHANGES IN FOOD, DRUG, COSMETIC TECHNOLOGY

You are faced here in this committee with an assignment of great magnitude, in an area of supreme importance to the lives and health and safety and well-being of the American people, in connection with the purchase and use of the most personal and intimate of products—all of the foods we eat, all of the drugs and devices we use for health purposes, all of the cosmetics used not only by women but in increasing numbers by men, as well. In many respects, you are facing the same problem which confronted your predecessors on this committee a quarter century ago when it became obvious that the Wiley Act of 1906—a great legislative achievement in its time—was woefully out of date and replete with loopholes permitting practices which visited fraud, deceit, poisoning, blinding, and death upon untold numbers of trusting American consumers.

From 1906 to 1938—a period of 32 years—Congress amended the Wiley law in a number of very important respects to protect consumers but never quite succeeded in making the law as effective as we know it should have been. Congress in 1912, 1913, 1919, 1923, 1930, and 1934 closed loopholes as they became glaringly evident—just as this committee since 1938 has initiated many, tremendously important improvements in the 1938 act—the factory inspection bill, the pesticides bill, the food additives bill, etc. But the time has come now, just as it did in 1938, for a complete rewriting of outmoded provisions—a modernization and updating of the whole statute based on far-reaching changes in food, drug, and cosmetic technology and the dangers created for consumers by omissions in the law, or by court decisions, or by studied evasions and easy violations which are often almost impossible to prevent because of shortcomings in the law.

CATASTROPHE SHOULD NOT BE ONLY SPUR TO ACTION

So it is my hope, as I know it is the hope of every American consumer concerned about the health and safety of our people, that you will now do what was done in 1938—rewrite the statute from beginning to end, keeping what is good but replacing what is obsolete or ineffective. It required a series of horrible episodes to stir the 75th Congress finally to pass the basic statute now on the books, after the 73d and 74th Congresses had extensively discussed and debated similar legislation but let it die in squabbles over special interest amendments and exemptions. By the time the 75th Congress finally acted, it had before it a sickening parade of horror cases—of young women blinded by eyelash blackeners; of many Americans paralyzed by a poisonous substance in Jamaica ginger—the infamous "Ginger Jake" scandal; of at least 73 Americans dying from the use of a new prescription drug, elixer sulfanilamide at first considered a great medical breakthrough until horrified doctors watched many of their patients die in prolonged agony from its use.

No such mass poisoning or blinding or paralyzing or killing episodes have occurred, thank God, in recent years. I hope it never again requires such incidents to persuade Congress to act on a broad level to improve the Food, Drug, and Cosmetic Act. However, as we all here know, most of the changes and improvements in the act since 1938 have been on a piecemeal, limited approach basis. I complained of this in 1960 when the color additives bill was being considered. I felt if we were going to bail out the lipstick makers on the use of other than harmless colors, we should insist on something-for-something—that is, on a requirement for pretesting for safety of all ingredients used in cosmetics, not just the coloring matter. In fact, I felt so strongly about that aspect of it that even after you agreed to amend the hastily passed Senate bill to include an anticancer clause, I voted against the bill in the House.

COSMETICS NOT PRETESTED FOR SAFETY

Since 1938, when it first came under Government regulation, the cosmetic industry has had comparatively gentle treatment. Unlike drug manufacturers marketing a new product, or food manufacturers using a new ingredient, the cosmetic industry does not have to prove safety of a new product prior to marketing. If the product is believed unsafe, furthermore, the Government must furnish legal proof of danger to the consumer in order to force the item off the market. This is the situation which previously existed in connection with the use of food additives, and which we changed in 1958—relieving the Government of the obligation of proving a product dangerous in order to take it off the market. We now require, instead, that the manufacturer prove his additive is safe before putting it on the market.

As a result of our lax cosmetics controls there have been occasional cases of extremely painful injury to cosmetic users, and frequent cases of allergic reaction, because the cosmetic manufacturer is not required to pretest the product for safety or even to identify the ingredients in the product.

Of course, I do not maintain or believe that major cosmetic manufacturers are anxious to poison, or disfigure, or denail, or scalp, or burn, or otherwise injure the American consumer. Certainly, there is no profit in that, and these are firms anxious to make a profit by pleasing, not harming, the customer. But the competitive situation in the cosmetic industry is such, and the ease of entry of new firms into the field of processing cosmetics is such, that new products hit the market accompanied by a wave of high pressure advertising and promotion, and each firm tries to beat the other to the drug store or department store counter or supermarket shelf with the latest magic potion for making us attractive.

Cosmetics are as old as history, and the basic ingredients used are well known in the trade. So sales spurts must often depend upon mysterious "gimmick" additives—turtle oil to promote skin rejuvenation or tighten chin muscles (but did you ever see a turtle's skin?); shark oil, queen bee royal jelly; chick embryo extract; horse blood serum, pigskin extract—yes, these are all ingredients which have been introduced in face and skin creams to form the basis for extravagant claims of beauty in a jar.

INGREDIENTS NOT DISCLOSED EVEN TO FDA

They are seldom dangerous—but if they are, we never know about it until a lot of gullible consumers—or consumers who have assumed the product must be safe or it couldn't be sold—have been hurt. That has been the situation in cosmetic regulation for 24 years.

Since the 1938 act does not even require cosmetic manufacturers to identify ingredients in their products, the Food and Drug Administration must analyze new products to determine their content, in case it suspects the presence of a dangerous ingredient. It cannot even go to the firm and legally demand to know what is in the product. Consequently, the consumer never knows—has no way of knowing except by painful trial and error—whether an attractive cosmetic product contains an ingredient to which she knows she is allergic. And, even worse, if a child swallows a cosmetic, the parents and doctor have no way of knowing for sure what ingredients it contained and what antidote may be necessary.

These loopholes in the law applying to cosmetics should have been closed when we rescued the cosmetic industry from the color crisis in 1960. But we didn't do it then. We just dealt with color additives and nothing else.

It was after that experience—of seeing another blowout patch being placed on the old Food, Drug and Cosmetic Act to meet only a limited problem situation, just as we previously passed the factory inspection bill, and the pesticides bill and the food additives bill and the citrus red bill and so on, that I decided late in 1960 to draft a single

bill to rewrite all of the obsolete provisions of the basic law. That resolve resulted in the introduction of H.R. 1235 the following January.

WHILE DIFFERING, HARRIS AND SULLIVAN BILLS COVER SIMILAR GROUND

As the Legislative Reference Service report points out, the two administration bills, H.R. 11581 and H.R. 11582, and my bill, H.R. 1235, cover substantially similar ground, while differing to some extent in language, approach, or, in a few instances, in content.

For instance, H.R. 1235 and H.R. 11581 both require more adequate controls over drug manufacturing to assure the quality of the product output, thus, for one thing, making it more likely that physicians would feel safe in prescribing by common names instead of the often more expensive trademark names; both require new drugs to be proved efficacious as well as safe for the purposes intended; both permit recall of previously approved drugs in case of substantial doubt of their safety; both require batch-by-batch testing and certification of all of the 30 or more groups of antibiotic drugs rather than just the five so-called wonder drugs in existence a dozen years ago; both call for extensive controls over the manufacture, distribution, sale and possession of habit-forming barbiturates and stimulant drugs to curb the flagrant bootlegging of these powerful and dangerous and death-dealing drugs; both clarify the existing factory inspection laws as they apply not only to drugs but also to foods and cosmetics.

Similarly, H.R. 1235 and the other Harris bill, H.R. 11582, both require pretesting of cosmetics for safety before marketing, including a Delaney anticancer clause; both require that therapeutic devices be proved safe—closing a serious and dangerous loophole—and also that therapeutic devices be proved effective for the purposes for which they are offered for sale; both bills repeal the provision in the present law which permits the sale of coal tar hair dyes containing poisonous or deleterious ingredients which may be injurious to the user (the present law merely requires a label warning of possible danger).

H.R. 11581 and H.R. 11582 have some other provisions in them which are not contained in H.R. 1235 and which are worthwhile. For instance, there is a tighter provision in H.R. 11582 than in H.R. 1235 on the record-keeping requirements for cosmetic manufacturers after a new product has already been approved for sale, and in case consumer complaints or experience should indicate the existence of danger in the use of the product. H.R. 1235 contains such reporting and recordkeeping requirements on drugs and should have included cosmetics.

H.R. 11581 has a provision amending the Public Health Service Act requiring tests for efficacy of biological drugs—the provision the President referred to when he said hogs, sheep, and cattle receive somewhat greater protection in this respect than humans.

The same bill also proposes the assignment of standardized names by the Secretary of Health, Education, and Welfare in cases where such names do not already exist or there is a dispute over a particular name. Of course, as I said earlier, many doctors will not use generic names in prescriptions unless and until factory inspection authority is so strong that there is no chance of fly-by-night operators turning out inferior drugs for sale in the prescription departments of pharmacies.

However, I have strong doubts, I must admit, over the retreat on the Delaney anticancer clause on feed additives, as contained in H.R. 11582, particularly in view of the Government's experience several years ago with the hormone-treated chickens. It cost us $10 million to remove from the market the fowl treated with a drug considered safe for the purpose—after it was learned that there were residues of the cancer-inducing substance in the skin of the chickens. Too often for complacency, new testing methods disclose the existence of harmful residues which had not shown up in earlier tests, but by then the damage is done.

ADDITIONAL FEATURES OF H.R. 1235

Now, I would like to discuss some of the provisions of H.R. 1235 which are not in either of the administration bills and which I strongly believe should be made part of the Food, Drug, and Cosmetic Act.

First of all, there are the sections dealing with fake cancer remedies and useless dietary ingredients. If the law were strengthened in all other respects, as has been recommended, perhaps the FDA would then be able to reach the cancer quacks and put them out of business quickly. But I think the provisions of H.R. 1235 would be of invaluable assistance in this respect. As to the special dietary food section of H.R. 1235, it does not aim at legitimate dealers but at the charlatan who evades the law by making oral claims of special benefits to be derived from the inclusion of some exotic or unusual ingredient with no known nutritional value whatsoever.

H.R. 1235 also gets an exemption in the law for common carriers responsible for causing an article in commerce to become misbranded or adulterated. Carriers should be held accountable, I believe, for violations of the law, for which they are responsible. Under present law they are apparently exempt from responsibility for adulterated products in transit, even if the carrier's own neglect caused the violation.

A very important provision of H.R. 1235 which is not included in either administration would facilitate oversea inspection by U.S. officials of factories shipping substantial quantities of foods, drugs, or cosmetics into the United States. Importation could be refused any product from a manufacturer who would not permit reasonable inspection of his facilities on request. According to the testimony of Commissioner Larrick on the FDA appropriation bill, we import about $6 billion worth of foods, drugs, and cosmetics a year, of which only a fraction can be inspected on arrival. It is significant that nearly one out of every three sample analyses and wharf examinations uncover violations of the Food, Drug, and Cosmetic Act. Mr. Larrick acknowledged that this high rate of violations results from the selective nature of the inspection work—in other words, the inspectors pick out those shipments they suspect of violations, rather than depending upon a random sample. While there is at present no elaborate plans for sending inspectors overseas, yet it seems to me the authority should be there to require those foreign firms which ship substantial amounts of food, drug, or cosmetic items to the United States to give our inspectors the same right of entry on request as an American firm is required to do.

SPECIAL INTEREST LOOPHOLES ADOPTED IN 1938

Another loophole H.R. 1235 alone among the pending bills would close involves the label exemption under the present law for butter, cheese, and ice cream in revealing the presence of artificial color. This was a deliberate special interest provision written into the law in 1938 to quiet protests from the dairy interests, even though some Members of Congress said at the time there was no good reason for it. By law, coloring matter cannot be used unless it is safe, so why not let the consumer have this information if it means anything to him? Some people just don't like to buy artificially colored butter or cheese or ice cream—but at the present time, they have no way of indulging their wishes in this regard. All other food items must acknowledge on the label the existence of artificial coloring. So why not ice cream, butter, and cheese, too?

Another special interest exemption written into the 1938 act, and which H.R. 1235 would repeal, is the provision which declares that soap is not a cosmetic.

It is not a food, of course. Except in the relatively few instances in which certain therapeutic values are manufactured into—or claimed for—a soap product, it is not a drug, either. The law defines cosmetics as, among other things, "articles, including components of any such articles, intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance."

Soap is certainly intended for cleansing, and it is used by most of us also, if not consciously for beautifying, at least for promoting attractiveness in the removal of dirt from face and hands. Some soaps presumably will do far more for our appearance than that. Nevertheless, by law, soap is not a cosmetic. Under the Food, Drug, and Cosmetic Act of 1938, then, it is a nothing—it is not subject to the law in any way unless therapeutic values are claimed for it as a drug.

I am not so much concerned over the money spent trustingly and hopefully by women who are led to expect beauty miracles from the soap they buy, although the economic waste may perhaps be significant. What I am concerned about is that a complexion soap can be adulterated with unsafe chemicals or unsafe color additives, and the Food, Drug, and Cosmetic Act cannot touch it. And regardless of how fraudulently it might be packaged, there is not even a requirement that the size or net weight or anything else of an informational nature be printed on the label for the consumer's guidance. Why should soap be above the law?

READ THE LABEL—IF YOU CAN FIND IT

Unlike soap, products subject to the Food, Drug, and Cosmetic Act must carry certain label information, but the language of the law, and the rulings of the courts, are such that this information is often almost impossible to find. Just the other day, the FDA seized 16,000 plastic tubes of a well-known firm's deodorant product because, while the required information was printed somewhere on the product, the printed matter was the same color as the plastic container and was almost impossible to find and read.

H.R. 1235 provides for an effective attack on the labeling problem in foods, drugs and cosmetics by providing the Government with authority to spell out, in regulations, the degree of prominence required for certain label statements, including statements of the quantity of contents of foods, drugs and cosmetics, the common or usual names of drugs, and the ingredients in foods and cosmetics.

The present law prohibits labeling which is "not prominently displayed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."

But, as the Senate Anti-Trust Subcommittee hearings brought out last year, you often need a magnifying glass to find the required label information on quantity and contents—before you get out the slide rule to figure the cost per ounce. As a nonlawyer, the present law seems very strong, to me, but apparently the courts have held it to be vague. That is why we now need the same authority in the Food, Drug, and Cosmetic Act to specify size and location of labeling information as you provided in the Hazardous Substances Labeling Act.

PREFERENCE FOR A SINGLE OMNIBUS BILL

If we are going to change the law on food, drugs, and cosmetics, then let us write a model law and close all of these loopholes.

I believe H.R. 1235, or a similar omnibus bill, would best serve as the vehicle for accomplishing this purpose. I see no valid reason for having two separate bills—one on drugs and the other on cosmetics and devices. They are part of the same overall problem—and under the jurisdiction of one agency. If there are omissions in H.R. 1235 based on the administration's 18-month study of the issue since I introduced that bill, it should be an easy matter to incorporate them into a single omnibus measure along the lines of H.R. 1235.

For instance, while H.R. 11581 provides for requiring proof of the efficacy as well as the safety of all new drugs, a similar provision dealing with therapeutic devices is contained in the different Harris bill, H.R. 11582. Since the pre-testing requirements for both drugs and devices would be similar, and are often intended for the same people, why not cover them in one piece of legislation? If you go through the detailed breakdown of H.R. 11581 and H.R. 11582, you find that substantially similar provisions in those two bills deal separately with drugs and devices. I am not a lawyer, but I suspect lawyers would have a field day over the years finding hidden meanings and significance in the fact that Congress used duplicate wording but in separate bills applying to different products in providing for pretesting for efficacy as well as safety of drugs and therapeutic devices. Obviously, some lawyer, some day, will argue, and perhaps successfully, that Congress didn't really mean to have these products treated alike in their safety requirements, or it would have placed them in the same bill rather than passing separate bills. Do I just imagine this?

Furthermore, while H.R. 11581 applies primarily to drugs—every specific provision applies only to drugs—yet it also would have the effect of amending the factory inspection laws applying to "any articles subject to" the Food, Drug, and Cosmetic Act, including, of course, food and cosmetic products. I think this is to the good—our factory inspection laws need strengthening, for food products and cosmetics as well as drugs. But why put a food inspection provision in what is exclusively a drug law? Why put a cosmetic inspection provision in a drug law, and leave it out of the proposed new cosmetic law? Obviously, there must be some rhyme or reason for dividing up the proposed improvements in the law in separate bills in this fashion, but I do not understand the value of it.

The use of H.R. 11582, primarily a bill dealing with pretesting of cosmetics and therapeutic devices, as a vehicle for amending the Hazardous Products Labeling Act dealing with household products, and also to amend the animal feed additives and food additives laws is, I believe, further evidence that we should have a single omnibus bill and not two separate bills, each covering one major area and a variety of unrelated ones.

Mr. Chairman and members of the committee, I appreciate your courtesy in hearing me. The subject matter of these hearings is of paramount importance to me from a legislative standpoint—and has been ever since I came to Congress in 1953 and introduced a safe cosmetic bill to carry out the recommendations of the Delaney investigation. I have introduced safe cosmetics bills in every Congress since then. I have supported this committee in every proposal it has made to strengthen the Food, Drug, and Cosmetic Act, and have opposed it in the few instances I thought the legislation would weaken consumer protections.

It would be a relatively simple matter for the committee at this late date in the final months of the life of the 87th Congress to pick out one of the many major areas of inadequacy in the law and recommend another blowout patch to tide us over temporarily. I hope you will not do that—that you will recommend legislation to close all of the major loopholes in the act.

In 1938, after attempts in two previous Congresses to replace the 1906 act had failed, the House Committee on Interstate and Foreign Commerce, in a report filed in the House on April 14, 1938, said of the Wiley law of 1906:

"While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions."

After two dozen years, the same words are exactly applicable today to the law passed in 1938. I hope this same committee will shortly file a report with the House containing those words, or similar words, in connection with a legislative accomplishment in 1962 as far reaching as that of 1938 in the field of consumer protection.

Mr. HARRIS. Mr. Chairman, I yield 5 minutes to the gentleman from Alabama [Mr. ROBERTS].

Mr. ROBERTS of Alabama. Mr. Chairman, I shall not use all of the time which has been yielded to me. However, I simply would like to take a little time to thank the gentlewoman from Missouri [Mrs. SULLIVAN] for the gentlewoman's statement and for the gentlewoman's devoted interest in this problem. The gentlewoman appeared before our committee with reference to this legislation. She made a fine contribution. I am sure I bespeak the feelings and sentiments of all members of the Committee on Interstate and Foreign Commerce when I say that we are grateful to her for all the help she has given us.

Mr. HARRIS. Mr. Speaker, I yield 10 minutes to the gentleman from New York [Mr. SANTANGELO].

Mr. SANTANGELO. Mr. Chairman, I support this bill, H.R. 11581. I think it is a great step forward for the protection of the health of the people of our country. Last week I was gratified when the chairman of the Committee on Appropriations appointed me as a member of the House Appropriations Subcommittee on the Department of Health, Education, and Welfare. I look forward to working with the gentleman from Rhode Island, JOHN FOGARTY, who has done so much in the field of health, education, and welfare.

I have introduced today a bill and I intend to introduce an amendment to this bill, H.R. 11581, which will correct a defect which I think has been overlooked. This bill is quite complete and I am satisfied with it. But what we lack today are the means and the methods whereby we can disseminate the information which we obtain to all the practicing physicians of the United States and throughout the world.

The bill which I seek to introduce is going to try to establish within the Department of Health, Education, and Welfare a worldwide Medical Information Bureau which will disseminate to all physicians the vital current medical information from worldwide scientific sources concerning drug safety, efficacy, disease, and treatment. The Bureau would consist of a Director appointed by the Secretary of Health, Education, and Welfare. In addition, two physicians will be selected from each of the following groups: The American Medical Association, the Food and Drug Administration, the pharmaceutical industry, and two editors from the various medical journals. This Bureau may utilize the experience of recognized medical groups and journals to assist the efforts of the Bureau.

We are proud of the advances of our research institutions, our institutes and our universities and private clinics. But the information does not go out to the thousands of doctors who practice and minister to the needs of our people. There exists an adequate means of rapidly disseminating to the practicing physicians the vital medical information from worldwide sources.

It is a well-known fact that the doctor's time for reading information is limited and it is impossible for him to read the thousands of journals and articles of scientific importance. Medical authorities are in agreement that if the latest revisions on safety, efficacy and treatment were readily accessible to the doctor, he could better treat his patients and avoid future thalidomide tragedies.

Mr. Chairman, I have been working with Senator HUMPHREY along these lines since the thalidomide case broke. We find that among the present agencies and publications now contributing various facets of this drug information are about 9 or 10. But they are not complete and they do not reach everyone. And they have a limited source of distribution. Among the agencies and publications now contributing various facets of this drug information are:

First. The American Medical Association Council on Drugs publishes annually "The New and Non-Official Drugs." This reviews briefly the new drugs in general use not yet accepted by the U.S. Pharmacopoeia and National Formulary.

Second. The U.S. Pharmacopoeia and National Formulary catalog drugs approved by Federal Food and Drug Administration. This provides limited information only on accepted drugs.

Third. The "Modern Drug Encyclopedia and Therapeutic Index" with the monthly supplement lists drugs in common usage. It summarizes the manufacturers' presentation.

Fourth. "The Medical Letter" is a biweekly which reviews a very small number of new drugs.

Fifth. "The Physicians' Desk Reference" is an annual publication of manufacturers' product information of drugs with a quarterly supplement.

Sixth. "Operation Mediphone," now nonexistent, was a telephone service of drug information available upon request to subscribers only.

Seventh. The "Psychopharmacology Service Center Bulletin" and "Abstracts" are sponsored by the National Institute of Mental Health. These are distributed only to research investigators of psychopharmacology and are not considered part of the scientific literature.

Eighth. "Excerpta Medica" is a publication of abstracts of the worldwide medical literature not confined to drugs. It does not evaluate or compare relative merits of drugs.

Ninth. "The Compendium of Neuropsychopharmacology" is published in

the bimonthly Journal of Neuropsychiatry. The compendium appraises psychiatric and neurological preparations based upon the worldwide drug literature. It is presented in chart form to provide the physician with readily accessible information concerning safety, efficacy, and treatment. This service has been proven to be useful and timesaving to the subscribers in its specialty. Doctors in other specialities, upon reading the compendium, requested of the editor that he provide an expanded service to include all fields of medicine. As a result a new publication of great potential is about to be launched, called "The Physicians' Drug Manual." This will appraise preparations that are extensively used in the various specialities and the general practice of medicine.

Of all these, the Physicians' Drug Manual seems to best meet the needs as a source of quick, concise medical information as to drug safety, efficacy, disease, and treatment. Its editor is a brilliant young doctor, Albert Laverne, of New York, the head psychiatrist of Bellevue Hospital in New York City.

The creation of this bureau, with the adoption of a source material such as the Physicians' Drug Manual, will be extremely favorable to the national and international prestige. It will enhance the Government politically in the eyes of the average American and may prevent drugs such as thalidomide from reaching an unsuspecting public through an uninformed medical profession.

Mr. Chairman, I hope this bill which we have before us today passes unanimously.

Mr. HARRIS. Mr. Chairman, I yield such time as he may desire to the gentleman from New Jersey [Mr. RODINO].

Mr. RODINO. Mr. Chairman, the question of revising drug legislation has been with us for several years. It has been with us since the previous administration. Over these years we have heard a great deal about drug prices, about patents for drugs, about all sorts of things. Some of these issues are important. And some of the arguments they have engendered have struck me as particularly cogent. They have, however, opened up a wide field of disagreement. But I think all of us can agree on one thing. Patents and profits, important as they may be, cannot be compared in importance with drug safety.

This is why I think all of those who played a part in writing the legislation we are considering are to be congratulated. They have come up with a measure which puts first things first. I do not think we need to be particularly proud that it took an international catastrophe to make us realize that the first thing with drugs is safety. But we have learned this lesson. And when this bill finally becomes law, that too often forgotten individual—the consumer—is going to receive a vital additional measure of protection.

The record shows that we have been sitting on our hands for years when it comes to drug safety. Now that—under a Democratic administration—we are at last to get the needed legislation in this crucial field, let us be grateful that it goes directly to the heart of the matter. Let us be grateful that the Government of the United States is about to give a real added degree of protection to the one customer in the world who has no choice in what he buys: the sick person who must purchase prescription medicines.

Mr. HARRIS. Mr. Chairman, I yield 10 minutes to the gentleman from Michigan [Mr. DINGELL].

Mr. DINGELL. I want to pay tribute to the chairman of the committee for his able, conscientious, and sincere handling of this measure and I want to point out to my colleagues that were it not for the real leadership on his part and were it not for the extraordinary cooperation on the part of each member of the committee with our distinguished chairman that we might, perhaps, have had no drug bill because the committee worked under the most arduous of circumstances but worked rapidly and well in achieving what is substantially a good piece of legislation in the public interest. Mr. Chairman, I rise in general support of this measure as being a measure which is in the public interest. I rise also to point out a specific defect of rather grave concern to each Member of the House of Representatives who is interested in seeing to it that we have in this session of the Congress meaningful drug legislation.

I refer specifically to the changes to the Senate portion of the bill which were adopted in the committee.

I want to treat with one section. I refer my colleagues to the language which appears on page 58 of the amendment to the bill, lines 15 through 22. I wish to point out to my colleagues that this language taken together with the language in the four lines preceding to all intents and purposes completely eliminates any Federal concern over false and misleading advertisement of prescription drugs. The simple answer to perfecting this bill is to strike and to eliminate the language to which I refer. This language taken together with the elimination of Federal Trade Commission jurisdiction over prescription pharmaceutical advertisements appearing in the language immediately above, when it is read in context, stating that no prescription drug shall be deemed misbranded under the provisions of this paragraph if it simply advises a doctor that information is readily available from another source, allows a manufacturer to make extravagant and unfounded claims with regard to efficacy; enables a manufacturer to make extravagant and unfounded claims with regard to side effects; and enables a manufacturer to make extravagant and unfounded claims with regard to safety.

It enables the doctor to look at an advertisement and be assured of safety, efficacy, and the absence of side effects when, in fact, there really is a most dangerous situation with regard to the drug.

I would like to refer my colleagues, in this brief time that I have, to some language which appeared in the Senate report on this subject. I refer to the treatment of diabetes by a certain pharmaceutical house in this country. In its advertisements the manufacturer said that Diabinase was well tolerated with minimal side effects or almost complete absence of unfavorable side effects. The manufacturer went on to say, "In other instances, it provided more effective control of diabetes and it was generally safe."

Whereas, in effect, one of the manufacturer's own investigators, and this was known to it and brought out in the Senate hearings, reported a 27-percent incidence—a 27-percent incidence—among cases investigated of hepatitis, jaundice, and liver damage, if you please. The doctor who investigated for the manufacturer showed in a total of 1,922 cases investigated, 27 percent reported 1 or more side effects. This fact was concealed in advertisements to medical practitioners.

The effect of the language, as it is in the bill, will be to offer a sanctity to this kind of advertisement to go on confusing, to go on offering inadequate or untrue information to the American medical profession. What it says, in effect, is that you can offer an advertisement making extravagant and unsafe claims and statements with regard to a drug stating that there are no side effects or ignoring the fact that the drug creates dangerous side effects, things like extreme exfoliation of the skin or spreading of cancer, that it might perhaps cause falling hair, or baldness, or change the color of the hair, or cause any of the side effects that might occur, or that it might be dangerous to give to a patient who suffers from a severe heart condition, or that it might offer danger to a patient who has cancer, or who has virus infections, or that it might cause bone damage in specific instances, so long as the manufacturer states in his advertisement that further information is available to the medical profession upon request.

Mr. NELSEN. Mr. Chairman, will the gentleman yield?

Mr. DINGELL. I yield.

Mr. NELSEN. I listened with interest to the gentleman's comments relative to the provision on page 18 and the language in lines 15 to 22. I believe an amendment can be worked out—the gentleman and I have discussed it to some extent—an amendment to meet the gentleman's objections without at the same time imposing too great a demand on the advertising of a drug which becomes a burden. I think the language could be changed and an amendment added, which I intend to offer at the proper time. We have discussed it. There has been some disagreement as to what section of the law should be amended, but I shall offer the amendment at the proper time that I think will meet the objection of the gentleman from Michigan.

Mr. DINGELL. I am delighted to hear my colleague, for whom I have the highest regard, in agreement with me with regard to a need for a change in the section I have been referring to. I, too, have an amendment which I propose to offer.

Let me go on with this dissertation upon their advertising. This is not a field in which doctors have any protection other than the requirement of the law. Let us take the advertisement in the case of a drug called Medrol, of which

I had photostats made. I was surprised to find in my study of material involving one medical practitioner that an ad appeared in one of the standard publications on the subject showing two photographs of a patient who allegedly suffered from colitis. I was further surprised to find in my additional study that this so-called reputable manufacturer who was advertising had actually gone so far as to use two X-ray photos of persons who had not received the drug. These two different photographs of two different patients appeared in the ad with statements in the advertisement purporting to indicate that it was the same patient on a before and after treatment basis, before and after he had received the drug Medrol.

This is the kind of advertisement that the amendment to the drug advertisement section tries to correct, to assure that the doctor shall receive to the fullest extent possible the fairest and most complete statement of side effects, contraindications and efficacy of the drug in a simple form.

Over and above this there have been studies made including one which was made by the American Medical Association. In this study it was surprising to note that doctors pointed out that perhaps the largest source of information to practitioners was the advertisements they received in the several medical journals.

Mr. SCHENCK. Mr. Chairman, I yield 5 minutes to the gentleman from New Jersey [Mr. GLENN].

Mr. GLENN. Mr. Chairman, I want to pay my respect and honor to our chairman, the gentleman from Arkansas, OREN HARRIS. Now that we are nearing the end of the session it becomes apparent how much passed legislation has come from our Committee on Interstate and Foreign Commerce. And it has been due to the capable leadership of our chairman and his devotion to duty that has resulted in all this passed legislation. I marvel at his ability to digest and debate on so many complex subjects as we have had but he has done it in a masterly manner.

Mr. Chairman, in the consideration of H.R. 11581 it must be kept in mind that drugs have become a most important branch of medicine within the past decade. With the advent of the wonder drugs, which have become so important in the prevention and cure of disease and the saving of lives, comes also a certain amount of risk. Medicine has never been and never will be an exact science. Every human body is different in many ways from that of another. The Food and Drug Administration, therefore, has one of the most important assignments in our system of public health. It must weigh a balance between safety and efficaciousness on one side and to derive the benefits of derivatives and new drugs as soon as possible on the other side. In the final analysis it is the personnel of the Food and Drug Administration who must make the determination which is so vitally important to the American people. For instance, as it is now, the average time on testing a new drug may run 2 to 4 years. Under this bill, which adopts the test of efficaciousness, the time element of testing may run even longer, or from 3 to 6 years. This is a safeguard to the public, but at the same time lengthening the period of testing may cost lives which otherwise could have been saved. If the drug tested is finally found to be safe and an exact preventative and cure of certain diseases or ailments, some people suffering from such ailments or diseases will not have the benefit of the drug if the test time is to be extended to prove efficaciousness.

Therefore, even though we draft the law by the use of these words, it is incumbent on the Food and Drug Administration to apply these words in the most reasonable manner, weighing the factors which I have heretofore recited and which may mean the difference between life and death on either side. The bill as reported from the committee is as good as any that could be developed in the rush toward adjournment, but in the final analysis in dealing with such difficult factors as the committee has had to contend with, it will be in the application of the law where the real test will be made, and I have every confidence that the Food and Drug Administration will accept it in this light.

Mr. HARRIS. Mr. Chairman, I yield 5 minutes to the gentleman from North Carolina [Mr. KORNEGAY].

Mr. KORNEGAY. Mr. Chairman, the merits of this legislation have been thoroughly discussed and adequately brought to the attention of the House by other members of the committee and Members of the House who are interested in it.

This is a good bill, it is a bill that has been brought out of committee after a great deal of time in hearings and executive sessions. As the junior member of the committee, I would not take the time of the House to further comment on the bill or its merits. However, I would like to take this opportunity to congratulate the chairman of our committee for the wonderful leadership he has displayed and the swiftness with which he has brought to the floor this fine piece of legislation.

He is an amazing individual. It is a gratifying experience to me, as a member of the committee, to observe him in action and to witness his great knowledge about the many and divers propositions which are presented to our committee.

I again congratulate him and wish to say it is a real pleasure and honor for me to serve with him and under him on our Committee on Interstate and Foreign Commerce.

Mr. HARRIS. Mr. Chairman, I yield 5 minutes to the gentleman from Maryland [Mr. FRIEDEL].

Mr. FRIEDEL. Mr. Chairman, I, too, wish to congratulate the chairman of our committee for his patience and for his diligent work and effort in bringing out a very good bill that protects all of the people.

I strongly favor the bill as reported by the Committee on Interstate and Foreign Commerce. In view of the detailed explanation given by the distinguished chairman of the committee, the gentleman from Arkansas [Mr. HARRIS], I shall not go into detail but I would like to discuss one amendment to the bill which I sponsored in the committee and which the committee adopted.

The amendment provides that the sponsor of a new drug being used experimentally on humans shall require the doctor or investigator using it to notify the patient or his representative that an experimental drug is being administered and to obtain the patient's consent or the consent of his representative.

Mr. Chairman, this great and wonderful country has always operated on the theory that the citizen has a right to know what is going on. We want an informed public opinion on all matters. That makes for good government.

The Government tells us about the dangers of atomic testing, radioactive fallout, war and threats of war, the great slaughter that occurs daily on our highways from automobile accidents, and other dangers to life and limb. We are informed about deposits of radioactive strontium in milk and other radioactive fallouts. Yes, we have even been told about the dangers of thalidomide, MER–29, and other dangerous drugs that have appeared on the market.

I feel that any patient has a right to know what the doctor is doing to his body. If he is to be used as a guinea pig, he ought to be informed. I feel that the doctor should not try out any experimental drugs on the patient without his consent or the consent of his representatives.

One thing to remember about this is that an experimental drug is one which has not yet been tested sufficiently to arrive at a firm scientific conclusion that it is safe and effective. Since this conclusion has not yet been reached, the patient should have the choice of either taking it or not taking it.

The Judicial Council of the American Medical Association has stated its position in regard to patient's consent very clearly. This appears in the form of a question and answer and is printed in the Journal of the American Medical Association for March 30, 1957, page 1158. Here is what the Journal says:

Question. In the use of new drugs or new procedures still in the experiment stage what ethical limitations are placed on the physician?

Answer. In order to conform to the principles of medical ethics of the American Medical Association, three requirements must be satisfied: (1) The voluntary consent of the person on whom the experiment is to be performed must be obtained, (2) the danger of each experiment must have been investigated previously by means of animal experimentation, (3) the experiment must be performed under proper medical protection and management.

In a later issue of the Journal of the American Medical Association, September 15, 1962, page 1022, there appears the following question and answer:

Question. Is a physician required to advise a patient as to what the possible side effects of a drug may be before giving that drug?

Answer. A physician has a legal obligation not to undertake any treatment of a patient without the patient's consent. The consent of a patient may not be valid and effective to protect the physician, if the physician

withholds information about the treatment which might affect the decision of a patient to consent or not to consent to a particular treatment. If a particular drug is known to have side effects which may prove dangerous to the patient, the physician should make a reasonably full disclosure to the patient of the risks involved before obtaining the consent of the patient to the administration of the drug.

There you have the position of the American Medical Association on this subject. My amendment would make certain that the practice of obtaining patient consent is carried out.

I feel that the doctor-patient relationship is always a very important consideration in therapy. If the patient has sufficient confidence in the doctor and the doctor suggests to the patient that the use of an experimental drug will be helpful to him, either to alleviate or cure the ailment, I feel certain that the patient would gladly give his consent to the use of such experimental drug on him.

If sufficient confidence in the doctor is lacking, the patient may not give his consent but since it is the patient's body that the doctor is administering to, except for most unusual circumstances, the patient certainly ought to know and to give consent.

Mr. SCHENCK. Mr. Chairman, I yield 3 minutes to the gentleman from Illinois [Mr. HOFFMAN] and ask unanimous consent that the gentleman from Illinois be permitted to speak out of order.

The CHAIRMAN. Is there objection to the request of the gentleman from Ohio?

There was no objection.

Mr. HOFFMAN of Illinois. Mr. Chairman, today is the 20th day of a strike which has caused the people of the 14th Congressional District, which I have the honor to represent, as well as countless others who live in the nine-State area served by the country's third largest railroad in point of mileage, much hardship, inconvenience, and economic loss. I am referring to the strike which was called on August 30 against the Chicago & North Western Railway by the Order of Railroad Telegraphers in an effort by the union to compel the railroad to include the following rule in its contract:

No position in existence on December 3, 1957, will be abolished or discontinued except by agreement between the union and the railroad.

An impartial emergency board which was appointed by the President to investigate the facts rejected the demands of the union as unreasonable, inefficient, and a hindrance to the managerial functions of the railroad. The emergency board also recommended that the railroad should provide a comprehensive program of employee protection.

The North Western accepted the recommendations of the Presidential emergency board. The union has not—although in a similar case on the New York Central Railroad—another Presidential emergency board recommended that the union withdraw its demand for a job freeze—just as the Presidential emergency board in the North Western case had done previously.

Mr. Chairman, I call your attention to the admonition of the President at his September 13 news conference to the aerospace industries to accept the recommendation of the Presidential emergency board in that case as the union had done. Why did he not at that same news conference request both parties in the North Western case to accept the recommendation of his emergency board and thereby have expedited the settlement of unnecessary work stoppage. Surely we cannot have one set of rules for the unions and another for management.

The arbitration panel which the President suggested on September 17 has still not been appointed. Why? Why does the President permit this strike to go on day after day jamming the expressways and streets of the Chicago area with commuters—displaced from their regular Chicago & North Western commuter trains—endeavoring to get to their place of employment?

This strike, as I have pointed out, is now in its 29th day. It should be settled without further delay. The prestige of our President should be brought to bear on both parties—just as it was in the steel price situation—and end this unnecessary hardship and inconvenience to the people who depend on the Chicago & North Western Railway for their passenger and freight transportation requirements.

Mr. BEERMANN. Mr. Chairman, will the gentleman yield?

Mr. HOFFMAN of Illinois. I shall be glad to yield to the gentleman from Nebraska.

Mr. BEERMANN. Mr. Chairman, the strike against the Chicago & North Western Railway has halted all freight transportation in many areas of nine Midwestern States for 29 days. Not only have nearly 16,000 empolyees been out of work because of the strike of 1,000 telegraphers, but the entire region is suffering. The Chicago & North Western is a $600,000-a-day operation; already nearly $175 million has been lost to the economy of these States. Every day that the railroad is closed down further depresses the well-being of the people in these States.

A Presidential emergency board set up under provisions of the Railway Labor Act has made specific recommendations to settle the strike. The railroad has accepted these recommendations. The telegraphers union has not.

The President has failed to use the prestige of his office to end this strike. He did not hesitate to say in his press conference on September 13 that four aerospace industries should accept the recommendations of a similar factfinding board, which were acceptable to the unions but not to management. Yet in the same press conference he failed entirely to refer to the recommendations of his emergency board in the North Western case but simply stated:

I am hopeful that both sides will make sufficient concessions, if that is the word, to permit an agreement, because the public interest suggests an agreement is due.

The President is a great expert on the public interest. He used his interpretation of the public interest to force the steel companies to rescind price increases. He invoked the public interest in demanding that Congress pass the $900 million standby public works bill. He pleaded in the public interest in trying to pass a farm bill. In fact, the public interest—as interpreted by the President—is used time and time again to get legislation through the Congress.

Mr. Chairman, do the midwestern farm States not get consideration when talking about the public interest? Is not a strike that is creating economic hardship in the breadbasket important enough to get at least a word or two of support for the recommendations of the President's own factfinding board?

Or does the President invoke the public interest for his own political purposes and not for the people?

Republican Congressmen represent most of the districts served by the Chicago & North Western Railway. Is this why it is so difficult for the President to determine that settling this strike is in the public interest?

When the administration set up the trial areas for the food stamp plan, 25 of the 26 were in districts represented by Democrats. Is this another example of the President playing politics when the public interest is involved?

Or is it because of the antibusiness attitude of the administration? Is this another application of the double standard used in dealing with labor and industry? Unions liked the closed-shop recommendations of the emergency board in the case of the aerospace industries. So the President made it clear that the blame for tieups in the vital missile field would rest on industry. Why does he not give the same kind of support to the recommendations of this emergency board?

Regardless of the reasons for the President's reluctance to act in this strike, the fact remains that a very important region of the country is suffering needlessly because the President is not using his influence to end a disastrous strike.

Mr. COLLIER. Mr. Chairman, will the gentleman yield?

Mr. HOFFMAN of Illinois. I yield to the gentleman from Illinois.

Mr. COLLIER. Mr. Chairman, I would like to associate myself with the remarks which have been made by my colleague, the gentleman from Illinois [Mr. HOFFMAN], and point out that there are 35,000 commuters, thousands from my district, who have been using this service, who are placed under a terrific hardship in getting to and from work. I would like to also point out the sickening impact this strike has had on the economy of the area served by the Chicago & North Western Railway.

Mr. SCHENCK. Mr. Chairman, I have no further requests for time, and reserve the balance of my time.

Mr. HARRIS. Mr. Chairman, I yield 5 minutes to the gentleman from Oklahoma [Mr. JARMAN].

Mr. JARMAN. Mr. Chairman, I rise to propound an inquiry in respect to one provision of section 102 which will sharply modify long-established relationships between industry and the Food and Drug Administration.

I refer to page 36 of the bill, lines 14–16, and page 39, lines 5–11.

The distinguished chairman of our committee will recall that, when we substituted the Senate-approved language for the original provisions of section 102, included in that language was an entirely new provision which gives the Secretary of Health, Education, and Welfare a new basis for disapproving a new-drug application, even when the drug is unquestionably safe and unquestionably effective. Under section 102, lines 14–16 on page 36, the Secretary may now disapprove a new-drug application on the ground that a proposed labeling is "false or misleading." A parallel provision, appearing on page 39, authorizes the Secretary to withdraw already-approved applications on the same ground.

Today, where the safety of a drug is clearly established, compliance with the broadly phrased statutory rules on labeling remains the manufacture's responsibility. A charge that any label wording is "false or misleading must be judicially determined on objective facts produced in open court. Under this bill, however, a manufacturer can be stopped from marketing a new drug, not because the drug is unsafe or ineffective, but because the proposed label of an acknowledgedly safe and effective drug is considered "false or misleading."

Now, in committee we recognized that the granting to FDA of a new authority of this kind could open the door to possible administrative abuse. To meet this contingency, we adopted an amendment requiring that a finding that a proposed label is "false or misleading" have an objective base—that is, the finding by the Secretary must be based on a fair evaluation of all material facts.

The question I now raise with the distinguished chairman of our committee is our intent in adopting this amendment. I construe it to mean this—that we have precluded a refusal of a new drug application or a revocation of an effective application on false or misleading grounds if the departmental objection is merely a subjective interpretation of a proposed label or any particular word appearing therein. We have required that there must be, to warrant a disapproval or a revocation, objective facts of record which make the proposed labeling demonstrably false or demonstrably misleading.

May I inquire of the distinguished chairman of our committee if this construction of this particular amendment fairly and accurately explains what our committee has sought to do?

Mr. HARRIS. Mr. Chairman, will the gentleman yield?

Mr. JARMAN. I am happy to yield to my chairman.

Mr. HARRIS. Mr. Chairman, if I understand correctly the question of the gentleman I would answer in the affirmative. However, I think if you read the language it is self-explanatory. The language provides a new basis for refusing to approve a new drug application. The gentleman quoted the language correctly "based on a fair evaluation of all material facts." I think that woud be the prevailing language in the interpretation. It is true that to warrant a disapproval or a revocation of the application objective facts of record which makes the proposed labeling is false or misleading would be necessary—demonstrably false or misleading. That is true. That must be a part of the consideration which would be given to this particular problem.

Mr. JARMAN. The concern that I have had, Mr. Chairman, is the danger that the departmental objection might be merely a subjective interpretation. My own understanding of the words that we put into the bill with this amendment is that we intended that it be based on objective facts of record that are clear and more definite than simply a matter of individual interpretation.

Mr. HARRIS. We must presume and certainly the Congress expects any Secretary of Health, Education, and Welfare administering this program to be fair in his decisions and the administration of the law. The gentleman raises the question of subjective decisions and objective decisions. We expect the Secretary to have wide latitude in his decisions. Certainly we do not expect by this language for any Secretary in the administration of the law to be arbitrary in his decisions but to be objective, after consideration of all the material facts, then to make the best decision objectively that he can make on it.

Mr. JARMAN. I thank the chairman for his clarifying remarks. I know they will be reassuring to the drug manufacturers, who have been concerned about the interpretation of this amendment.

Mr. HARRIS. Mr. Chairman, I yield 1 minute to the gentleman from Illinois [Mr. YATES].

Mr. YATES. Mr. Chairman, I think there ought to be some clarification in connection with the colloquy between the gentleman from Oklahoma and the gentleman from Arkansas. There is always difficulty when an effort is made to draw a hard and fast line between subjective and objective showings. Can it be said that Dr. Kelsey's appraisal of thalidomide was entirely objective?

Mr. HARRIS. It was my understanding she never made a formal decision because the application was never completed.

Mr. YATES. It is my understanding that she never made a formal decision, but she certainly never approved the application as requested by the Merrill Co. Subsequent to the thalidomide disclosures, the Merrill Co. withdrew the application for the drug.

Mr. HARRIS. My understanding of the facts is that the Merrill Co. was trying to get a decision and the good Dr. Kelsey kept advising that she did not have enough information, and she kept asking for more information.

Mr. YATES. That is right.

Mr. HARRIS. During the interim all this publicity about thalidomide came out, and the company withdrew it.

Mr. YATES. But according to the story that was reported in the press of these activities, the reason Dr. Kelsey kept asking for additional information was that she was not satisfied that the drug would perform as the company intended. This was in great measure a subjective interpretation, was it not?

Mr. HARRIS. It might have been, but she did not make a formal decision. If she had made a formal decision on it, it might have been something different. She was not satisfied that the information that had come to the Department was complete enough for the Department to put its stamp of approval on it.

Mr. YATES. The only point I am making is that it seems to me you cannot try to draw a sharp and fast line between the terms "objective" and "subjective." It seems to me that the gentleman is right in referring the gentleman from Oklahoma to the language in the bill as he did which required the Department to act on the basis of a fair evaluation of all material facts.

Mr. HARRIS. I do not think we intend here that any administrator should be arbitrary in his decision.

Mr. YATES. I agree. There should be no arbitrary action by an administrator.

Mr. HARRIS. That is exactly what I intended in my efforts to explain this question to the gentleman from Oklahoma.

Mr. YATES. Apparently we are in substantial agreement. Nevertheless, I still think it would be better to rely on the section requiring action to be based on a fair evaluation of all material facts.

Mr. HALPERN. Mr. Chairman, I would like to express my support for the bill presently before the House. I feel that it is a desirable and necessary step toward more effective regulations of the drug industry and for meaningful protection of the public.

H.R. 11581 is the very least necessary if the public health of our Nation is to be safeguarded effectively. I have long been concerned with the needs of fully protecting our citizens in this area, and was a House sponsor of the original Kefauver bill. I offer my complete support for the provisions of this bill which are designed to provide the public with safer and more effective drugs and also enable our doctors to be informed more adequately concerning the many new drugs which we are marketing daily.

Laudable as this bill before us is, there are still areas of deficiency which have not been met by it, or by the watered-down Kefauver bill which was approved by the other body. Mr. Chairman, the areas of deficiency to which I am referring are those relating to licensing and patenting provisions. Provisions in these areas were embodied in the bill I introduced several months ago, and while heartily supporting the great strides to greater drug safety and efficacy embodied in H.R. 11581, I am convinced that licensure and patent requirements are necessary to the achievement of more realistic drug price and a greater degree of drug safety.

The excessively high prices of drugs as revealed by the Kefauver investigations point out the pressing need of patent laws which do not allow drug production monopolies. Lifegiving drugs should not be prohibitive in price.

Finally, I feel that a program of licensure to insure "the continued chemical structure, strength, quality, purity, safety, and efficacy" of the products of drug companies and the revoking of

licenses of companies not meeting the standards would be a more effective and efficient form of enforcement for maintaining the standards upheld by this bill than the method of seizure proposed in the present form.

Of course, I offer my complete support to this bill which should provide the public with greater safety and improved use of new drugs as they are developed.

At the same time, I wish to emphasize that I had hoped for a bill that would go further along the lines I have mentioned concerning patents and licensing. I shall continue my every effort, along with the distinguished Senator from Tennessee [Mr. KEFAUVER], to get these measures passed into law.

Mr. Chairman, I strongly urge the overwhelming approval of this bill as a broad forward step in an area where legislation to fully protect the public has been long overdue and vitally needed.

Mr. FOGARTY. Mr. Chairman, several months have passed since the first reports that a drug was associated with the death or deformity of newborn babies in Germany and in other countries where the drug was released for general use.

It is now possible to view that event in some perspective—and it is necessary for us to do so because of its relevance to the legislation that is before us.

I do not need to recapitulate the story of thalidomide here. I am sure every Member of the House knows full well the details of the tragedy as reported to a shocked nation * * * a nation that was also stunned at the narrow margin by which Americans had been spared a human disaster that could have dwarfed earlier setbacks in man's efforts to control disease by medicines. The dedication to duty and to the public interest by Dr. Frances Kelsey and her colleagues in the Food and Drug Administration will long be remembered as illustrative of the best traditions of service by Federal employees.

In the public attention that has been given to thalidomide, one fact has tended to be obscured: The fact that the tragedy in other countries was not repeated here. It is as President Kennedy said in his comment at the time:

> The United States has the best and most effective food and drug law of any country in the world.

But he felt our law could be even better. The President went on to acknowledge the need for tighter controls on the investigational use of drugs. He urged the enactment of the bill before us, a bill that had been introduced by the distinguished gentleman from Arkansas [Mr. OREN HARRIS]. And he established twin national goals of drug safety and progress against disease—goals that are shared by all of us in this Chamber who must today record our judgment on the merits of a bill that represents a major step toward the fuller achievement of both goals.

I urge that our vote be a unanimous endorsement of the legislation. For health, like national defense and national security, is not and cannot be a partisan issue. When our Founding Fathers set "life, liberty, and the pursuit of happiness" as inalienable rights of the American people, they did not mean simply life as opposed to death. They meant an abundant and healthy life, as free as possible from pain and suffering and the specter of premature death. All of us recognize that advances in the practice of medicine and of public health are dependent upon advances in knowledge derived from research. By broadening and strengthening the powers of Government to regulate the industry that develops and produces and markets the medicines prescribed by physicians, the bill before us further assures life for all Americans in the years that lie ahead.

I would not have anyone think that the bill is a panacea. Man is a complex biological organism. The drug that helps 99 people may harm the 100th. The drug thought to have inconsequential side effects over a period of several years may suddenly cause problems that argue for its withdrawal from general use. There are no absolutes in medicine, no 100 percents, no sure cures. Our goal is to reduce the relative risks to the barest minimum. H.R. 11581 provides a greater margin of assurance of safety in that its long-term effect will be to establish high standards and raise the level of performance by the pharmaceutical industry as a whole toward the responsible levels of which the most reliable companies are demonstrably capable.

The House is fortunate in being able to act with knowledge of the careful consideration given this measure by a committee that has distinguished itself by its perceptive and realistic approach to health legislation. Mr. HARRIS and his colleagues and staff again deserve the commendations of the Congress and of the American people for their deliberations and their actions on this bill.

I speak as one who has dedicated nearly two decades of his adult life to serving the interests of the American people in the field of health. My colleague in the House and my constituents in Rhode Island have special reason to know the shape and direction that dedication has taken. For 22 years I have been a member of the committee responsible for appropriations to the health, education, welfare, and related activities of the Federal Government. For 12 years, I have been chairman of that committee. Since the Food and Drug Administration comes within the province of the committee, I am intimately familiar with the details of its operations—with its accomplishments and its remaining problems, with its strengths and its failures. The record will show that I have always been an advocate of building a regulatory body that increasingly has the authority and the manpower and the resources to meet the increasingly complex challenges presented by rapid advances in science and technology. During the 1950's and thus far in the 1960's, I have consistently sought appropriations for the Food and Drug Administration in excess of the President's budget request for that agency. Although I have been criticized in some quarters for my position, I am happy to stand on that record here today.

My extensive experience with the Food and Drug Administration I think gives me a certain prerogative to speak on the merits of H.R. 11581. I trust it will also give a certain weight to my judgment as the measure is on the floor to be voted on by the House. Let me simply say, without equivocation, that I believe there is need for broader consumer protection in the field of prescription drugs, that I am confident the bill provides such protection, and that I strongly urge its enactment before this session of Congress adjourns.

Lest there be any misunderstanding, let me emphasize that H.R. 11581 deals only with that part of the FDA's responsibility that has to do with the safety and usefulness of drugs prescribed by physicians. The bill does not deal with nonprescription drugs, with cosmetics, with food additives and food contamination, with deceptive packaging and labeling, with any of the other diverse fields of consumer protection that are the agency's province. In total, the American people pay some $117 billion each year for the products that are under the agency's purview. More than 100,000 commercial establishments produce these products and distribute them in interstate and foreign commerce.

Prescription drugs, in contrast, are but a small part of this increasingly complex regulatory responsibility. But they are a vital part, and it is well to single them out for the kind of special legislative attention that is reflected in the broadened statutory power in the bill before us. In so doing, we should be conscious of the fact that broadened powers are a hollow gesture unless the agency also has the resources to exercise those powers in the public interest.

We have tried, in the committee I chair, to foster continuing and orderly growth in the Food and Drug Administration. But it has still not kept pace with the challenges and responsibilities that lie ahead. While I point with pride to the record of our committee and to the recent action of the administration to increase the FDA staff by 25 percent, I also remind you that the job is not finished. I hope and confidently expect that all interested groups, including those whose actions are regulated by the FDA, will do everything they can to assure that the FDA progressively acquires the staff, the facilities, and the other resources it needs to administer effectively the amendments to the law that are here proposed and that certainly should be enacted.

In this connection, let me express a view on the well-intentioned proposal made in some quarters that the National Institutes of Health should serve as a testing ground for the FDA in establishing the safety and usefulness of new drugs. While I agree that everything possible should be done to facilitate the exchange of information between these two agencies, I am unalterably opposed to the concept that one agency should serve the other in a formal sense. Their missions are different, their philosophies are different, their procedures are different. The function of the FDA is regulation of consumer products. The function of the NIH is medical research.

The answer to the FDA's problems is not to superimpose burdensome and peripheral responsibilities on a sister agency, but rather to provide the FDA with those resources it needs and should have in order to carry out its own mission.

The need for such added resources is demonstrated in part by the almost incredible proliferation of new drugs in recent years. During the past year, for example, nearly 700 new drug applications were filed with the Food and Drug Administration—an average of almost two a day. This is a tremendous responsibility, particularly when one remembers that in each case, the decision to permit or not to permit marketing is a matter of judgment rather than simply of fact.

The number of new drugs is a reflection of advances in knowledge. It is also a reflection of advances in the application of knowledge through industrial technology. For the biochemical explosion has been accompanied by a comparable industrial explosion. The handful of drug manufacturers before World War II has grown to some 1,200 today. It is understandable if the industry has some growing pains. But since it has demonstrated no particular capacity to be self-regulating, and since the American people cannot and will not tolerate marginal or submarginal performances in matters so directly affecting their health and well-being, it is necessary for the regulatory agency of the Federal Government to act strongly in the public interest. And I for one feel strongly that they should have both the authority and the capacity to do so.

In dealing with the question of prescription drugs, we are seeking answers to questions which may affect every one of our constituents—questions of health and disease, comfort and pain, and—quite literally—life and death. Our duty, as I conceive it, is to make assurance doubly sure that we here in the United States may never be the victims of a tragedy of the magnitude of the one associated with the use of thalidomide in Germany and Great Britain. Whatever inadequacies now exist in legislation covering this vital field must most certainly be taken care of promptly, so that we may rest secure that the very medicines which hold out such bright promise of our ultimate freedom from disease do not themselves become a new cause of fear.

Safety is, of course, only one of our responsibilities in health matters. As the gentleman from Arkansas [Mr. HARRIS] has pointed out in calling also for progress against disease as important as providing all possible assurances of safety, is our obligation to maintain a legislative framework in which the benefits of new drug discoveries can be brought rapidly to those who need them. I wish it lay within the power of this body to legislate cancer or heart disease out of existence. If it were, I know that every one of you gentleman would join me in making this our first order of business. But, unfortunately, that is beyond our power. Nor can we legislate out of existence the elements of risk inherent in progress. We, as legislators, cannot hope to foresee every scientific contingency.

Let us consider for a moment the testing of a new drug before it is available on a physician's prescription. To start with, scientists emphasize that preclinical animal tests, no matter how exhaustive, cannot invariably predict all the effects of a drug on people. That is one of the reasons for clinical testing. I know that there have been expressions of shocked disbelief that human beings are involved at all in the test pattern of a new drug. Indeed, some have asked: Why test at all in humans? and then have suggested: Let us forbid the testing of a new drug in humans.

To this reaction there is, of course, only one answer: it is necessary to test in humans if we are to have new drugs. If this testing does not occur before a new drug is permitted to go on the market, then it must in effect take place afterwards, when the first physicians write the first prescriptions for it after marketing. Someone, somewhere, has to be the first human being to take a new drug.

Those who have seen the benefits of new drug therapy do not question the necessity of clinical testing. It is a procedure which has been repeated over and over again as our scientists in public and private institutions have brought forth new agents for the conquest of disease. The sulfa drugs, the vitamins, the antibiotics, the antiinflammatory drugs, the hormones, the vaccines, the mental health drugs, the drugs against heart disease—all have been made possible and available to prolong life and to preserve health because clinical testing provided an accurate evaluation of their benefits and their shortcomings.

And what of the so-called guinea pigs—the first patients to receive these new drugs?

The first patient in the United States to receive penicillin—discovered in England but developed as a therapeutic agent chiefly in this country—was a woman with blood poisoning who had undergone three operations, six transfusions and treatment with other drugs. Her temperature of over 105° was brought down to 98° within 12 hours with penicillin—and her subsequent recovery was called uneventful.

The first patient to receive streptomycin therapy was a young woman with far-advanced pulmonary tuberculosis. From a situation which at the time had looked hopeless, she recovered and has gone on to a full and active life which includes marriage and the bearing of three children.

And yet another young woman, the first patient to receive cortisone treatment, was confined to a hospital bed with painful arthritis which virtually immobilized her. Yet, a week after cortisone therapy was started, she was able to embark on a 3-hour shopping trip.

These three cases, each one dramatic in its effect not only on the patient but also on the subsequent course of medicine, are not isolated ones. They demonstrate clearly, I think, that the first persons to receive a new drug are anything but guinea pigs; they are, above all, patients who stand to benefit from a new medical discovery.

But this is behind us—all this lies in the past. We must look to the future—to the hope which burns in each of us that medical research will find a way to choke off the grim specter of cancer or of heart disease. The flow of new drugs to roll back even further the ravages of disease must continue—it must be encouraged to continue. We cannot overcome disease by keeping drugs off the market—by erecting well-nigh impossible barriers against bringing these agents of hope to those who need them.

Let us strengthen the Food and Drug Administration, but let us not make the mistake of overburdening that agency with responsibilities and decisions which properly belong to the relationship between the physician and his patient. Such a mistake would be doubly harmful, for it would not only impair the effectiveness of the FDA—which has served us so well—but would also tend to impose a stultifying straitjacket on the practice of medicine itself. Our Nation's doctors must have adequate freedom to exercise their professional judgment in the best interests of those whose health lies in their safekeeping.

Proposed new regulations recently issued by the FDA and a section of the bill before us seek to assure high standards of ethics and performance by clinical investigators and sponsors of clinical trials while drugs are being tested and before they are placed on the market. I believe this is a principle we can all endorse.

I want to point out, however, that in addition to the precautions taken by those who create new medicines, which are to be double-checked by the FDA under the new regulations, the first physicians to administer a new drug are guided by their own scientific code together with their own special knowledge of their patients. They know the probable limits and limitations—the effects to look for. And they do not use the drug capriciously—it is administered only to those patients who can be expected to benefit from it.

Despite all these precautions, we must acknowledge that risks remain in bringing a new drug to market. But we must also acknowledge that a far greater risk to health and to life itself would result from taking steps which would have the effect of preventing new drugs from reaching the market—and the patient who needs them. Our goal should be to encourage the maximum in medical progress with the minimum of risk to any human being.

Both the bill that is before us and the new regulations that are being proposed by the administration remind us that we are legislating and regulating in a most complex and sensitive area of human relationships and human endeavor.

While we must do what we can to strengthen the law and to stimulate optimum performance by the individuals and groups concerned, we must not forget that no one individual and no one group is—or can be—isolated. It is through interdependence, not independence, that research leads to discovery, and discovery to development, and devel-

opment to testing, and testing to manufacture, and manufacture to distribution, and distribution to the ultimate purpose of a new drug use in man, on the basis of prescription by physician.

The paramount responsibility in this chain of progress, of course, is that of the physician. No act of Congress and no regulation of an executive agency extending and interpreting the law can or should contravene the fundamental responsibility of the physician to treat and if possible to help his patient.

All those who help to shape the environments in which medical care and medical research are carried out have special responsibilities, too—including responsibility to set standards that reflect the best in ethical and procedural considerations bearing on the welfare of patients.

The Government has very direct and clear-cut responsibilities to protect the public interest and improve the public health. It does not exercise this responsibility by assuming or usurping the powers and authorities of others, unless it finds that the job is not being done satisfactorily by the usual and normal channels. Thus, a part of the Government's function in this field is to foster the capacity and desire of nongovernmental groups, including medicine and industry, to meet their responsibilities without Government interference or control.

Finally, a word about the pharmaceutical industry. It seems to me it has a special obligation to act responsibly. It cannot assume unto itself the full range of rigid free enterprise prerogatives that may be characteristic of a maker of toys, for example, or clothing, or adornments of various kinds. What the industry produces has the power of giving or taking away health. The people who buy prescription drugs, for a variety of good and sufficient reasons, do not have free choice. If a doctor prescribes, they buy, and, if they value their life and health, they do not challenge the physician's professional judgment on what medicines they should use to get or stay well.

This is only one reason why the drug industry cannot consider itself the same as other industries. Another is that they are the direct commercial beneficiaries of a tremendous national medical research effort that has come into being during the past two decades. The people are the ultimate beneficiaries, of course. But in our society, which I trust will be perpetuated in strength and in freedom, products are made by the private, rather than the governmental, sector. The pharmaceutical industry contributes greatly to the national medical research effort by investing substantially of its own funds, derived from the profits on its products. But there is no question in my mind that the number and variety and value of new drugs have been increased tremendously by the knowledge derived from medical research supported by the tax and voluntary funds. The American people and the Congress of the United States look to the U.S. pharmaceutical industry to act responsibly—and this includes setting responsible prices—because of these factors.

The controversies of the past several years about drugs may tend to undermine public confidence in medicine and public health. I do not hold such gloomy views of the future. I am certain that abuses will be corrected, misunderstandings eliminated, and issues resolved, so that those who search for new medical knowledge and those who apply that knowledge for the benefit of mankind can move swiftly and certainly forward toward the achievement of health goals that are visible clearly on the horizon today.

While I am on the subject of responsibility, I want to comment briefly on a situation that has just been brought to my attention by my constituents in Rhode Island.

The situation is that we simply cannot get the influenza vaccine needed to protect the aged, those afflicted with chronic diseases, and other high-risk groups. And the little vaccine that is available is reported to be priced considerably above last year's price—when, if my memory serves me right, there was also a shortage of flu vaccine.

I have asked the Surgeon General to give me a report on the vaccine supply picture nationally, and on the prices being asked by manufacturers and by retailers, so I can find out whether the people of Rhode Island are being discriminated against.

But let me make this point here and now. Science has given society the tools with which to prevent and control influenza. I am sure many of my colleagues here in the House can remember, as I can remember, when the word "influenza" would strike terror in every household; today, we have vaccines to prevent it, better drugs to treat it, and better medical care to reduce its aftermath. But we must use these tools to the fullest. And we are not doing so.

I do not know yet where the responsibility lies. Federal, State, and local public health authorities appear to be doing their part. Medicine is cooperating. The public is responding to appeals to protect themselves. And I see by the papers this morning that the flu vaccine manufacturers claim to have increased their production this year to almost double last year's levels. You would think there would be enough vaccine for everyone who needs and wants it. But there isn't.

In my own State, responsible efforts have been made to organize key groups to assure their protection against influenza—including certain key industries whose work is closely related to the national interest, and other groups such as firemen, policemen, and teachers, whose ranks must not be thinned unnecessarily by disease. They have done their part, and it is ironic, yes, and potentially tragic, that vaccine cannot be widely available, and at a reasonable price, to protect them.

It seems to me that in those fortunate instances when we have everything we need to make good use of an advance in public health—a receptive public, a willing profession, a productive industry, and a Government that has led in stimulating use of the vaccine in the national interest—there is no excuse for failure. And I call upon everyone involved to redouble their efforts to achieve maximum protection against influenza before the flu season is upon us in full force.

Mr. RYAN of New York. Mr. Chairman, throughout our Nation today there is a new concern with the effects of drugs upon the public health of every citizen. Realization of this concern and safeguards for alleviating many of its causes are expressed in the bill before us. It is our responsibility to see that these necessary safeguards are enacted; we must realize the dire need of strengthening our drug laws to insure the people of the United States that their medicine cabinets will contain the means of enhancing, rather than endangering, good health.

Although our country's drug regulations have been praised as the most comprehensive standards of any country in the world, it has become evident that they are not sufficient for our needs. Since the enactment of the Food, Drug, and Cosmetic Act in 1938, the pharmaceutical industry has grown by leaps and bounds. However, the law has not grown with them; legislation has lagged behind as the drug and medicine production has forged ahead at a terrific momentum.

The extensive 2-year investigation of the drug industry by the Senate Antitrust Committee indicated the existence of this lag, and as a result of these hearings Senator KEFAUVER introduced the drug industry antitrust bill (S. 1552) in an attempt to tighten the existing law. The recent and highly regrettable thalidomide tragedy has left no doubt that the need for such strengthening exists.

It is not enough to hope that the thalidomide pills which were received by approximately 1,073 U.S. doctors for experimental use and pills obtained by Americans from European sources will not result in tragedies similar to those experienced throughout Europe. We must realistically evaluate existing regulations and act to prevent future threats to public health. This bill provides safeguards which are essential to this end.

Under this bill drug manufacturers will be required to register with the Government. Thus we will eliminate the existing situation wherein a totally untrained person can manufacture a number of drugs without adequate facilities and controls. To insure the continued maintenance of high standards of manufacturing the bill authorizes more extensive drug factory inspection, including records of technical and professional personnel to ascertain their qualifications.

Once a company is registered and deemed qualified to produce drugs, the Food and Drug Administration must be given substantial evidence that each drug produced is effective as well as safe. Under present law a company could stick a name on bottled water and attempt to sell it for medicinal use simply because it is not harmful. This has been one of the greatest defects in our existing law; a producer should be required to show that his product will do what is claimed of it. When a person pays his money at the drug counter, he should have some degree of assurance of the efficacy of the product he buys.

I feel strongly that the drug companies should provide information relating to side effects resulting from use of the drug.

Drug advertisements should be required to give similar information.

Because of the rapidity with which new drugs appear on the market, medical practitioners cannot keep abreast of extensive medical articles on each drug. This information must be easily and readily accessible to them. Neither can the FDA, with its tremendous workload, be expected to establish the side effects of each drug without the cooperation of the drug companies. Therefore, these provisions are essential for preventing possible disasters resulting from unknown side effects, and they would enable the medical profession to more fully and knowledgeably utilize the large and continuously changing drug supply.

I regret that H.R. 11581 contains language—lines 15 through 22, inclusive, on page 58—which nullifies the effect of section 131. It provides that the information need not be included if such information on a drug's side effects be "freely available * * * upon request." Mr. Chairman, I will support the amendment to strike this language which the gentleman from Minnesota [Mr. BLATNIK] intends to offer. I hope that this escape hatch will be closed.

Advertisements along with drug labels will also be required to show the generic name of the drug. This requirement promotes the interests of doctors and consumers by simplifying drug terminology and classification. Furthermore, by standardizing the drug name and eliminating the confusion, the physician could intelligently prescribe by the generic name and thus allow free market factors to determine more realistic drug prices.

H.R. 11581 also extends the present 60-day drug approval time of FDA to 180 days and states that no drug be allowed on the market until the Secretary has approved it. Not only is the approval time inadequate in the present law, but also the possibility of a drug entering the market with no form of approval is highly detrimental to the unsuspecting public.

One of the strongest provisions for safeguarding the public against the dangers that might occur from unforeseen effects of a drug after it has been placed on the market contained in the bill authorizes the Secretary to remove a drug from the market immediately if it poses a hazard to public health. This authority would back up the preventive measures of the bill in the event that all precautions failed to protect the consumers from suffering ill effects produced by a drug. Such removal would be of national consequence, and thus it could be achieved rapidly and effectively only by a Federal agency.

H.R. 11581 strengthens the controls over drug manufacturing, raises the standards of drug safety and efficacy, requires that the FDA, doctors, and the public be more fully informed and protects the public from harmful drugs.

Mr. Chairman, I support this bill and urge my colleagues to approve it.

Mr. REUSS. Mr. Chairman, there is for consideration before this body a bill intended, and I quote in part:

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs.

I refer, of course, to H.R. 11581 introduced by the gentleman from Arkansas [Mr. HARRIS]. Quite generally, this bill would give the Food and Drug Administration greater responsibilities than it has had in the past in the area of drug protection and it would provide greater authority for the Food and Drug Administration to act on behalf of all of us who, at one time or another, must depend upon a drug product to protect our health or to preserve our lives. I want to go on record as strongly urging the passage of this bill which will go a long way in assuring our Nation that its drug products maintain the highest quality and are safe, reliable, and effective in their purposes.

I have had a continuing interest and concern for the safety of our Nation's drug products. Recent events have shown me, as they have shown us all, that this is no idle concern. I refer, of course, to the tragic results from use of the drug thalidomide by pregnant women in Europe. There is no means now of consoling these mothers for the birth of their deformed children, nor for turning back the clock and preventing these sorrowful births.

But, we in this country can thank the Food and Drug Administration and that agency's Dr. Kelsey for preventing the same harsh happenings in our Nation and can help in a great measure to assure that such tragedies never occur here through passage of H.R. 11581.

So, as the thalidomide tragedy has shown, the Food and Drug Administration does now have limited authority that can prevent a major disaster resulting from the wide use of an unproven, insidious drug. But, the limited authority FDA now has is not enough to assure the high standards of quality, the reliability, and the effectiveness that our citizens have a right to expect in the drugs they take.

All of the provisions in H.R. 11581 are important and necessary for the public good, but if I should point to one as being most important, it would be the provision that new drugs be proved effective before they are marketed.

A dismal proportion of consumers' resources are spent on worthless drug products. This unnecessary and wasteful extravagance might not be so bad if it were not coupled with the deplorable fact that ineffective drugs can mean the difference between a man's health and sickness or his life and death. The bill before us would help to assure our sick that the drugs they take will in fact be effective in their purpose.

The bill is seriously defective in one respect. The last sentence of section 131(a)—lines 15–22, inclusive, on page 58—would make the proposed tighter control of prescription drug advertising a mockery. It would allow advertisers to avoid giving full and honest information in prescription drug advertisements by inviting doctors to write in for further information, a thing overworked doctors just are not going to do. This sentence should be stricken.

In summary, let me record my vital interest that the public's health be protected by adequate and meaningful drug legislation; and my endorsement of the Drug and Factory Inspection Amendments of 1962, H.R. 11581 when properly strengthened.

Mr. FOUNTAIN. Mr. Chairman, I want to commend the able chairman and his committee for adopting the amendment to section 202, which I proposed at its hearings. The amendment provides that nothing in the Food, Drug, and Cosmetic Act "shall authorize the withholding of information from the duly authorized committees of the Congress." This amendment was strongly supported by the distinguished gentlemen from California [Mr. MOSS] who in addition to being on your committee, is also chairman of the Special Government Information Subcommittee of the Committee on Government Operations.

This amendment was necessitated by the original language of section 202 of the bill which extended the confidential treatment presently afforded only to trade secrets under section 301(j) of the Food, Drug, and Cosmetic Act to all information obtained by the Food and Drug Administration under specified sections of the act. As chairman of a Subcommittee of the Committee on Government Operations, I had seen the Food and Drug Administration use the trade secrets proviso of section 301(j) to withhold from the subcommittee access, not only to trade secrets, but to their entire files.

One such situation which I described in my testimony on this bill involved the withdrawal from the market of two drugs due to the discovery of dangerous and injurious side effects. One of the drugs in question caused cataracts, skin disorders, and falling or graying hair. The other is known to have caused 54 cases of hepatitis resulting in 15 deaths.

Since both drugs had been cleared for safety by the Food and Drug Administration, the subcommittee, in an effort to determine whether that agency had fully and effectively met its responsibilities, requested access to the files containing the new drug applications for these two drugs.

This request was denied on two grounds. The first ground was the trade secrets proviso of section 301(j). Such denial was a misuse of that section. The second was a Food and Drug Administration regulation providing that all information submitted in connection with new drug applications will be treated as confidential. This regulation has no basis in law and its use to withhold information from the Congress was a further abuse of FDA's power. The original language of section 202 of H.R. 11581 was a thinly disguised attempt by FDA to provide a statutory basis for this regulation, thereby enabling the agency to withhold any and all information from the Congress at will. The amendment which I proposed, if sustained in conference, will prevent such withholding action.

As I have tried to demonstrate, occasions do arise when it is both desirable and necessary for committees of the Congress to examine all information in an agency's files in order to properly evaluate that agency's administrative performance. Yet, such a request can and has been denied under the guise of protecting trade secrets. It is my position, therefore, that the Congress should reserve to itself this right.

I sincerely hope that when this legislation goes to conference, the conferees on the part of the House will insist upon the language of section 202(3) as approved by the House.

The question has been raised in some quarters as to whether section 202 of the bill as reported would deny to the press and the public the kinds of information which have heretofore been available from the Food and Drug Administration. I do not believe this is the intent or the effect of the legislation. To confirm this, I would like to read a letter which the gentleman from California [Mr. Moss] today received from Commissioner Larrick of the Food and Drug Administration on this subject:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, FOOD AND DRUG ADMINISTRATION,
Washington, D.C., September 27, 1962.

Hon. JOHN E. MOSS,
House of Representatives,
Washington, D.C.

DEAR MR. MOSS: In response to a telephoned request yesterday from Mr. Archibald of your staff, we are pleased to give you our interpretation of section 202 of H.R. 11581 as reported by the Committee on Interstate and Foreign Commerce.

In our view, there is nothing in section 202 that would derogate from the authority given to the Secretary by section 705 of the Food, Drug, and Cosmetic Act to collect, report, and illustrate the results of investigations of the Department.

As originally introduced, section 202 of H.R. 11581 contained a provision recommended by our Department which amended section 301(j) of the Food, Drug, and Cosmetic Act so that it would prohibit the using of information obtained under the factory inspection section of the law and certain other sections, other than as authorized by law. This would apply whether or not the material involved concerned a method or process which, as a trade secret, is entitled to protection. We suggested this change in order to make it perfectly clear that, under the expanded factory inspection proposed in the bill, there would be adequate safeguards against the using of material obtained by inspection to the advantage of one of the Department's employees.

It would be our purpose, if H.R. 11581 is enacted as reported by the House committee, to continue under authority of section 705 the public information functions of the Food and Drug Administration which are in the public interest so that the American people would continue to have, as they have had in the past, a full reporting of those facts relating to the activities of the Food and Drug Administration which are in the public interest.

Sincerely yours,

GEO. P. LARRICK,
Commissioner of Food and Drugs.

This letter should put at rest any fears by the press.

Mr. Chairman, I would like to include for the benefit of the House and Senate conferees the following statement which I made before the Committee on Interstate and Foreign Commerce relative to section 202 of H.R. 11581:

STATEMENT OF HON. L. H. FOUNTAIN

Mr. Chairman and members of the committee, my purpose here today is not to take a position on the general merits of H.R. 11581, but to express my objection to a particular section thereof which would, in my opinion, seriously hamper the work of the congressional committees which have responsibilities with regard to food, drug and cosmetic legislation or the operations of the Food and Drug Administration. I refer to section 202 of H.R. 11581, amending section 301(j) of the Federal Food, Drug, and Cosmetic Act.

As section 301(j) is presently written, it prohibits "the using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this act, any information acquired under authority of sections 404, 409, 505, 506, 507, 704, or 706 concerning any method or process which as a trade secret is entitled to protection."

The effect of the amendments proposed in section 202 of H.R. 11581 would be to extend this confidentiality beyond "trade secrets" to include any information acquired by the Food and Drug Administration under the stated sections of the Food, Drug, and Cosmetic Act.

Since only the officers and employees of the Department and the courts are given access to confidential information under section 301(j), passage of section 202 in its present form would, in my opinion, make it virtually impossible for the congressional committees which have responsibilities in connection with food, drug, and cosmetic legislation or the operations of the Food and Drug Administration to obtain the information necessary for the effective discharge of those responsibilities.

Under the rules of the House, the Committee on Government Operations has the duty of "studying the operation of Government activities at all levels with a view to determining its economy and efficiency."

The responsibility for studying the operations of the Food and Drug Administration, as well as those of a number of other Federal agencies, has been delegated by the Committee on Government Operations to its Intergovernmental Relations Subcommittee, of which I am chairman. Our past experience in trying to fulfill this responsibility has shown that on occasion the Food and Drug Administration has used section 301(j) as a basis for withholding access to information which the subcommittee deemed necessary for the proper discharge of its responsibilities to the full committee and to the House. I have copies of two letters of recent date which will, I believe, demonstrate this problem. I would like to read them at this time.

They relate to a situation which arose in late April of this year when two prescription drugs were withdrawn from the market due to the discovery of dangerous side effects. Both drugs had previously been approved by the Food and Drug Administration under its new drug procedure and had been on the market for some time. In an effort to determine whether the Food and Drug Administration had fully and effectively met its responsibilities in the clearing of these two drugs for the market, the subcommittee sent the following letter to Commissioner Larrick:

MAY 2, 1962.

Hon. GEORGE P. LARRICK,
Commissioner, Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C.

DEAR MR. LARRICK: In connection with its responsibility for studying the activities of the Food and Drug Administration with respect to efficiency and economy of operation, the Intergovernmental Relations Subcommittee wishes to obtain information concerning two drugs which were recently withdrawn from the market due to the discovery of dangerous side effects. They are MER-29, manufactured by Richardson-Merrill Co., and Flexin, manufactured by McNeill Laboratories.

Will you please arrange for Mr. Donald Gray of the subcommittee's staff to examine your files containing the new drug applications for these two drugs and any other information you may have concerning them.

Your cooperation in this matter will be greatly appreciated.

Sincerely yours,

L. H. FOUNTAIN,
Chairman, Intergovernmental Relations Subcommittee.

I received the following letter from Mr. Larrick in reply:

MAY 10, 1962.

Hon. L. H. FOUNTAIN,
Chairman, Intergovernmental Relations Subcommittee, Committee on Government Operations, House of Representatives, Washington, D.C.

DEAR MR. FOUNTAIN: We have your letter of May 2, 1962, requesting us to arrange for Mr. Donald Gray of the subcommittee staff to examine our files covering the new drug applications for Mer-29 and Flexin.

We want to be as helpful as possible to your committee. However, the Federal Food, Drug, and Cosmetic Act imposes certain restrictions on us which we must respect. Under the law, we are forbidden to disclose any information submitted in connection with a new drug application that is entitled to protection as a trade secret. Our regulations further emphasize the fact that all information submitted in connection with new drug applications will be treated as confidential. The reason for these restrictions is to encourage manufacturers to make as full a disclosure as possible when they submit their new drug application, including information involving doctor-patient relationships.

We have uniformly declined to make the files on new drugs available to anyone except employees of the Food and Drug Administration. We are confident, however, that we can prepare a summary of these new drug applications that will contain all pertinent information. We will undertake the preparation of these summaries promptly and they will be sent to you as soon as they are completed.

After you have had an opportunity to review them, we will be glad to arrange for a meeting between Mr. Gray and our personnel who are familiar with these files to clarify any questions you may have. We should point out that even though these drugs have been removed from the market, we are actively investigating both of these cases to determine whether false statements were made in connection with the new drug applications or whether there was a failure to disclose material facts.

We hope that our suggested handling of your request will be satisfactory. Again let me say that we want to furnish you with all information that we possibly can within the limitations imposed on us by the statutes.

Sincerely yours,

GEO. P. LARRICK,
Commissioner of Food and Drugs.

Following receipt of this letter, members of the subcommittee staff talked with Assistant Commissioner Rankin and Mr. William W. Goodrich, the Department's Assistant General Counsel, Food and Drug Division. The staff assured Mr. Rankin and Mr. Goodrich that neither they nor the subcommittee were interested in seeing any information

entitled to protection by law as a trade secret. I might point out that Mr. Larrick incorrectly states in his letter that his agency has uniformly declined to make the files on new drugs available to anyone except employees of the Food and Drug Administration. The fact is that our subcommittee staff has examined such files in the past, and FDA had not previously in our experience claimed confidentiality for these records.

The subcommittee staff was then assured by Mr. Rankin that, in view of these facts, our request would be reconsidered by the Food and Drug Administration. However, despite numerous telephone inquiries from the staff, no further action has yet been taken on the request; nor have the summaries which Mr. Larrick promised in his letter of May 10 been received.

I have gone into these details merely to demonstrate the difficulty which our subcommittee has encountered in obtaining certain information from the Food and Drug Administration under the existing section 301j. I believe that the amendments proposed in section 202 of H.R. 11581 translate into law the interpretation which the Food and Drug Administration has already placed upon section 301j, as outlined in Mr. Larrick's letter of May 10, and which I believe to be incorrect.

In view of the experience which our subcommittee has had under the existing section 301j, I believe that enactment of section 202 of H.R. 11581 in its present form would be most undesirable and would make it virtually impossible for the subcommittee to perform its duties in connection with the operations of the Food and Drug Administration. For this reason, Mr. Chairman, I would like to propose for the committee's consideration an amendment to section 202 of H.R. 11581 to read as follows: On page 32, line 25, immediately before the period, insert the following: "and inserting in lieu thereof the following: *Provided*, That nothing in this Act shall authorize the withholding of information from the duly authorized committees of the Congress' ".

This language has been successfully used I understand in the organic act setting up the National Aeronautics and Space Administration and in the legislation setting up an Advisory Committee on Weather Control.

I believe that the adoption of this or a similar amendment would enable our subcommittee and the other committees and subcommittees of the Congress having responsibilities with regard to food, drug, and cosmetic legislation or the operations of the Food and Drug Administration to meet their responsibilities, more effectively and with greater dispatch. To me it is unthinkable that information, other than trade secrets, which is available to officers and employees of the Department of Health, Education, and Welfare, as well as to the courts, should not also be available to the Congress, which passes legislation and appropriates the funds necessary for the Department's operations.

I thank you for the opportunity to be heard on this point which I believe to be of the utmost importance to the Congress.

Mr. YATES. Mr. Chairman, this bill is of vital importance and I strongly urge its passage. I want to congratulate the chairman and the committee for coming in with a good bill.

Several weeks ago our Nation barely escaped what could have been one of the very worst tragedies in its history—a tragedy which other Nations were not so fortunate to escape. In Germany, we are told, there will be about 5,000 children afflicted for life by some of the most hopeless deformities imaginable because their mothers, while in early stages of pregnancy, took a drug known as thalidomide. We are told that in England, in Japan, in Canada, and in various other parts of the world, several thousand additional infants will be added to the list of these grossly deformed individuals. We barely escaped that tragedy here in the United States, thanks to the courage, tenacity and good judgment of Dr. Frances Kelsey and several of her associates at the Food and Drug Administration. I say that we barely escaped this tragedy because, under our present laws, there are really no reliable safeguards to prevent such a tragedy. Dr. Helen Taussig of Johns Hopkins University, recently made this point. Our consumer drug protection laws go back to 1938 and have hardly been changed since then. They were probably all right nearly a quarter of a century ago, but today these laws are unable to provide the American consumer with the kind of protection he deserves and needs at a time when the whole technology and science of drug production and manufacture is changing radically.

Whereas consumers were spending about $150 million each year on prescription drugs back in 1938, today they are spending well over $3 billion. Even in the past one-half dozen years, we have seen the drug industry increase its pharmaceutical research and development expenditures from about $105 million in 1956 to an anticipated $275 million in 1962. On the average, there are about two new drugs developed in the United States of America every single day of the year. For example, in fiscal year 1962, FDA received 693 new drug applications. In addition, drugs already approved by FDA and on the market are constantly being modified. For example, in fiscal year 1962, the Food and Drug Administration received 3,497 requests by the drug industry to approve changes in drugs already available to consumers.

As I indicated, Mr. Chairman, the law of 1938 was written for another age with another set of circumstances. We have moved at a tremendous rate since then, both in population and in technology. No one back in 1938 could have dreamed or imagined in any way the advances that have evolved since then. It is imperative, therefore, that we in this House enact legislation to protect American consumers and provide Americans with a degree of protection which this day and age require.

The bill that is before us, H.R. 11581, will amend the law of 1938, the Federal Food, Drug, and Cosmetic Act, and provide the Food and Drug Administration—through the Secretary of HEW—with much of the additional authority it needs to catch up with the quarter century that has elapsed since 1938 and to confront the challenges facing consumers today. It does this in a number of ways.

Today, the Food and Drug Administration has no authority to require drug manufacturers to open some of their files to FDA inspection. We are not talking here about files that contain financial, sales, and pricing data. We are not talking here about files that contain confidential personnel data. We are not trying in this bill to compromise the competitive position of industry. We are talking about files that contain reports of adverse reactions to drugs. We are talking about files that contain data on the qualifications of those who are doing the research and who pass judgment on new drugs. We are talking about files in which the controls used in the manufacturing process of these drugs are spelled out and elaborated. We are talking about files that contain the qualifications of those individuals who are testing and investigating new drugs for these manufacturers.

This kind of information, the availability of which is not now assured to the Food and Drug Administration, is essential if FDA is to be permitted to remove from investigational channels drugs, such as thalidomide, that could cause tragic consequences. It is information of this nature that can give the FDA's medical officers, such as Dr. Kelsey, information to verify the data that is sent to them by the drug manufacturers. It is this kind of information that can provide FDA with leads to certain drugs on the market that are producing adverse reactions.

This is the kind of authority that the Federal Government must have if it is to provide the kind of protection we all want for the consumers of this Nation. H.R. 11581 proposes to make this kind of information and files available for examination by appropriate authority.

Another provision of H.R. 11581 is to give the Food and Drug Administration the authority to approve not only the safety of a new drug but also its efficacy. It is almost unbelievable that for all these years we have never had a statute to assure the American public that the drugs being prescribed on the market are effective as well as safe. Undoubtedly, each year there are many drugs that reach the market that are quite safe but are probably quite ineffective to relieve the ailment for which they are marketed. Unless the manufacturer of such a drug makes gross overstatements in his labeling and advertising, nothing can be done to prevent a drug from reaching the consumer. Needless to say, this is not only a serious handicap to the consumer's pocketbook, but it can also be a very serious danger. A doctor who prescribes such a drug thinking that it will be effective might seriously jeopardize the health of his patient when another drug on the market, which is truly effective, could have been used. H.R. 11581 would remedy this deficiency.

However, I call attention to a serious gap in the advertising portion of the bill. The so-called Younger amendment which was added in committee, lines 15 through 22 on page 58 of the bill, would, for practical purposes, kill section 131 of the bill. This amendment should be stricken.

Mr. Chairman, I will not elaborate any further on the importance of this legislation we are acting upon today. I have just pointed to some of its many provisions. I could go on and say something about the antibiotics provision that would change the current law so that FDA can approve and certify for safety and potency on a batch-by-batch basis

all antibiotics rather than just a handful of antibiotics as the law now stipulates. I could speak at length about provisions requiring more effective reporting of adverse drug reactions to FDA, doctors, and the public. I could point to the provisions that will greatly strengthen FDA's ability to require drug manufacturers to improve the manufacturing controls they use in the production of drugs, controls that are essential to assure that drugs contain the right ingredients in the right amounts. Sufficient to say, that nearly a quarter of a century after the pure food and drug law was last given a thorough overhaul—years that have witnessed amazing changes in practically all aspects of our daily lives but certainly in our creation, production, and distribution of drugs—we have today an opportunity to strengthen our outmoded drug laws for the protection of all Americans. I sincerely believe that this legislation will be remembered as one of the most constructive and important bills passed by this session of the 87th Congress.

Mr. MACK. Mr. Chairman, I want to join with my colleagues in commending the distinguished chairman of our committee, the gentleman from Arkansas, the Honorable OREN HARRIS, on the great work he has done in the closing days of this session on this bill which amends the Federal Food, Drug, and Cosmetic Act to further protect the public by strengthening and clarifying the present law. This bill comes to the House floor after prolonged hearings by the Interstate and Foreign Commerce Committee and careful consideration in executive sessions.

I am proud to support the provisions of this bill which are designed to protect the public health by imposing additional requirements with regard to the manufacture and distribution of drugs and antibiotics. I feel that this bill will provide additional safeguards which are necessary but it will not have a limiting effect on research or development of new drugs. We must continue to make progress in this field but we must adequately protect the public in the testing of investigational drugs. I am hopeful that this bill will be enacted into law.

Mr. BARRY. Mr. Chairman, certainly no event in the past year so affected the American conscience as the tragedy evoked by the knowledge that the drug thalidomide was causing grotesquely malformed babies. Similar tragedy in the United States was averted by the professional competence of Dr. Frances E. Kelsey, of the Food and Drug Administration. Despite strong pressure, her steadfast determination not to clear the controversial drug remained undaunted. By her heroic effort the drug was precluded from general marketing in this country. This is probably the most cogent reason why this bill is before Congress this session.

In January of this year a poll among my constituents of Westchester and Putnam Counties and their response clearly indicated that they were cognizant of the need for reform of our drug laws. Of those replying to the poll 67 percent were in favor of tighter restrictions on the drug laws.

Hearings conducted this year before the Interstate and Foreign Commerce Committee reaffirmed my convictions of the need for more stringent laws regarding the control, certification, marketing, and effectiveness of drugs for sale to the American public. I favor that information on old and new drugs be disseminated on a wider, more complete, and effective basis. We should not continue to countenance misinformation or an absence of opportunity for our citizens to acquire such knowledge. These deficiencies are among other loopholes remedied in the bill presented to the House.

Mr. Chairman, in legislation of a highly technical nature, pitfalls may arise out of its subsequent implementation. Any legislation which too stringently regulates and restricts—contains the specter of the ramifications of too much control which could diminish research incentive. We must be watchful not to frustrate research and development of drugs which have greatly contributed to our world leadership in medicine and public health. However, it will only be through its application that we can accumulate sufficient evidence to correct deficiencies, if any. I believe this bill avoids the pitfalls of too much control.

Because of the need for a more effective law, and because this bill corrects some of the defects in our present law, I support this legislation. It is necessary for the public health and safety of our citizens, and will not impede the continuation of the role of the United States as a world leader in the most humane of our exports—technical medical skill and medicine.

The CHAIRMAN. Pursuant to the rule, the Clerk will read the committee substitute amendment now in the bill as an original bill for the purpose of amendment.

The Clerk read as follows:

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act, divided into titles and sections according to the following table of contents, may be cited as the "Drug Amendments of 1962".

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TITLE I—DRUGS

Part A—Amendments to assure safety, effectiveness, and reliability

Requirement of Adequate Controls in Manufacture

SEC. 101. (a) Clause (2) of paragraph (a) of section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended to read as follows: "(2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (as determined in accordance with regulations promulgated by the Secretary) to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;".

(b) Section 701(e) of such Act (21 U.S.C. 371(e)) is amended by striking out, in the first sentence, "501(b)" and inserting in lieu thereof "501 (a) or (b)".

Effectiveness and Safety of New Drugs

SEC. 102. (a)(1) Section 201(p)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)(1)), defining the term "new drug", is amended by (A) inserting therein, immediately after the words "to evaluate the safety", the words "and effectiveness", and (B) inserting therein, immediately after the words "as safe", the words "and effective".

(2) Section 201(p)(2) of such Act (21 U.S.C. 321(p)(2)) is amended by inserting therein, immediately after the word "safety", the words "and effectiveness".

(b) Section 505(b) of such Act (21 U.S.C. 355(b)) is amended by inserting therein, immediately after the words "is safe for use", the words "and whether such drug is effective in use".

(c) Section 505(d) of such Act (21 U.S.C. 355(d)) is amended to read as follows:

"(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for

hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term 'substantial evidence' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

(d) Section 505(e) of such Act (21 U.S.C. 355(e)) is amended to read as follows:

"(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority ocnferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (j), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based."

Records and Reports as to Experience on New Drugs

SEC. 103. (a) Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end thereof the following new subsection:

"(j)(1) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section.

"(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records."

(b) Section 505(i) of such Act (21 U.S.C. 355(i)) is amended (1) by inserting "the foregoing subsections of" immediately after "operation of"; (2) by inserting "and effectiveness" immediately after "safety"; and (3) by adding at the end thereof the following new sentences: "Such regulations may provide for conditioning such exemption upon—

"(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests of such drug adequate to justify the proposed clinical testing;

"(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

"(3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that (1) experts using such drugs for investigational purposes inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and obtain the consent of such human beings or their representatives, and (2) such experts certify to such manufacturer or sponsor that such consent will be obtained. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs."

(c) Section 301(e) of such Act (21 U.S.C. 331(e)) is amended to read as follows:

"(e) The refusal to permit access to or copying of any record as required by section 703; or the failure to establish or maintain any record, or make any report, required under section 505 (i) or (j), or the refusal to permit access to or verification or copying of any such required record."

(d) Subsection (a) of section 302 of such Act is amended by striking out "(e),".

New Drug Clearance Procedure

SEC. 104. (a) Section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335(a)), is amended to read as follows:

"(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug."

(b) Section 505(c) of such Act (21 U.S.C. 355(c)) is amended to read as follows:

"(c) Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either——

"(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

"(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after such hearing is completed."

(c) Section 505(f) of such Act (21 U.S.C. 355(f)) is amended to read as follows:

"(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate."

(d)(1) The first four sentences of section 505(h) of such Act (21 U.S.C. 355(h)) are amended to read as follows:

"(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order."

(2) The ninth sentence of such section 505(h) is amended to read as follows: "The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code."

(3) The amendments made by this subsection shall not apply to any appeal taken prior to the date of enactment of this Act.

(e)(1) Section 301(l) of such Act (21 U.S.C. 331(l)) is amended by (1) inserting "approval of" before "an application", and (2) striking out "effective" and inserting in lieu thereof "in effect".

(2) Clause (C) of section 503(b)(1) of such Act (21 U.S.C. 353(b)(1)) is amended by striking out "effective" and inserting in lieu thereof "approved".

(f)(1) Clause (A) of paragraph (3) of section 409(c) of such Act (21 U.S.C. 348(c)) is amended by inserting before the semicolon at the end thereof the following: ", except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (f) and (g)) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal".

(2) Subparagraph (B) of paragraph (5) of section 706(b) of such Act (21 U.S.C. 376(b)) is amended by inserting before the period at the end of the subparagraph a colon and the following proviso: "Provided, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal".

Certification of All Antibiotics

SEC. 105. (a) The heading of section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) is further amended to read "Certification of Drugs Containing Antibiotics", and the first sentence of subsection (a) of such section 507 is amended to read as follows: "The Secretary of Health, Education, and Welfare, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin or any derivative thereof, and of drugs intended for use by man and composed wholly or partly of any other kind of antibiotic substance (including the chemically synthesized equivalent of any such substance)."

(b) Such section 507 is further amended by adding at the end of such section the following new subsection:

"(h) In the case of a drug for which, on the day immediately preceding the effective date of this subsection, a prior approval of an application under section 505 had not been withdrawn under section 505(e), the initial issuance of regulations providing for certification or exemption of such drug under this section 507 shall, with respect to the conditions of use prescribed, recommended, or suggested in the labeling covered by such application, not be conditioned upon an affirmative finding of the efficacy of such drug. Any subsequent amendment or repeal of such regulations so as no longer to provide for such certification or exemption on the ground of a lack of efficacy of such drug for use under such conditions of use may be effected only if (1) such amendment or repeal is made in accordance with the procedure specified in subsection (f) of this section and (2) the Secretary finds, on the basis of new information with respect to such drug evaluated together with the information before him when the application under section 505 became effective or was approved, that there is a lack of substantial evidence (as defined in section 505(d)) that the drug has the effect it purports or is represented to have under such conditions of use."

(c) Section 502(l) of such Act (21 U.S.C. 352(l)) is amended to read as follows:

"(l) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, or a drug intended for use by man and composed wholly or partly of any other kind of substance within the purview of section 507, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507, and (2) such certificate or release is in effect with respect to such drug: *Provided*, That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507 (c) or (d)."

Records and Reports As to Experience on Antibiotics

SEC. 106. (a) Section 507 of such Act (21 U.S.C. 357) is amended by adding at the end thereof the following new subsection:

"(g)(1) Every person engaged in manufacturing, compounding, or processing any drug within the purview of this section with respect to which a certificate or release has been issued pursuant to this section shall establish and maintain such records, and make such reports to the Secretary, of data relating to clincal experience and other data or information, received or otherwise obtained by such person with respect to such drug, as the Secretary may by general regulation, or by order with respect to such certification or release, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to make, or to facilitate, a determination as to whether such certificate or release should be rescinded or whether any regulation issued under this section should be amended or repealed.

"(2) Every person required under this section to maintain records, and every person having charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records."

(b) Section 507(d) of such Act (21 U.S.C. 357(d)) is amended by adding at the end thereof the following new sentences: "Such regulations may provide for conditioning the exemption under clause (3) upon—

"(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests of such drug adequate to justify the proposed clinical testing;

"(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

"(3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application for certification or release pursuant to subsection (a).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that (1) experts using such drugs for investigational purposes inform any human beings to whom such drugs, or any controls used in connection therewith are being administered, or their representatives, that such drugs are being used for investigational purposes and obtain the consent of such human beings or their representatives, and (2) such experts certify to such manufacturer or sponsor that such consent will be obtained. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs."

(c) Section 301(e) of such Act (21 U.S.C. 331(e)), as amended by section 103(c) of this Act, is further amended by striking out "505 (i) or (j)" and inserting in lieu thereof "505 (i) or (j), or 507 (d) or (g)".

Effective Dates and Application of Part A

SEC. 107. (a) Except as otherwise provided in this section, the amendments made by the foregoing sections of this part A shall take effect on the date of enactment.

(b) The amendments made by sections 101, 103, 105, and 106 of this part A shall, with respect to any drug, take effect on the first day of the seventh calendar month following the month in which this Act is enacted.

(c) The amendments made by this Act to the Federal Food, Drug, and Cosmetic Act, insofar as such amendments relate to the effectiveness of drugs (except clause (3) of the first sentence of section 505(e) of such Act), shall not apply to any drug with respect to which an application under section 505 of the Federal Food, Drug, and Cosmetic Act was effective on the day immediately preceding the date of enactment of this Act, so long as amendment of such application is not proposed and approval of such application has not been suspended or withdrawn under section 505 of such Act, as amended by this Act. An application filed pursuant to section 505(b) of such Act which was effective on the day immediately preceding the date of enactment of this Act shall, upon the date of enactment of this Act, be deemed to be an application approved by the Secretary. If an application filed with respect to a new drug pursuant to such section 505(b) prior to the date of enactment of this Act is still pending before the Secretary on such date, the running of the period within which the Secretary must act on such application pursuant to section 505(c) of such Act, as amended by this Act, shall be deemed to have commenced on the day immediately following the date on which such application was in fact filed.

(d) The amendments made by this Act to section 201(p) of the Federal Food, Drug, and Cosmetic Act shall not apply to any drug which, on the day immediately preceding the date of enactment of this Act, (1) was commercially used or sold in the United States, (2) was not a new drug as defined by section 201(p) of the Federal Food, Drug, and Cosmetic Act as then in force, and (3) was not covered by an effective application under section 505 of that Act, when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day.

Part B—Standardization of drug names

Authority To Standardize Names

SEC. 111. (a) The Federal Food, Drug, and Cosmetic Act, as amended by this Act, is

further amended by adding at the end of chapter V the following new section:

"Authority To Standardize Names

"SEC. 508. Whenever in the judgment of the Secretary such action is necessary or desirable in the interest of achieving usefulness or simplicity of drug nomenclature, or because of the existence of two or more nonproprietary names (other than the systematic chemical name) for the same drug (or for two or more drugs which are identical in their active ingredients and substantially identical in their pharmacological action, strength, quality, and purity), or because the common or usual name of a drug is misleading, confusing, or not sufficiently informative, or because there exists no common or usual name for a drug, he may promulgate regulations establishing a single standard name for such drug (or for such identical drugs), together with any related or additional information which in the judgment of the Secretary is desirable to facilitate the correct and effective use of such standard name. In no event, however, shall the Secretary establish a standard name so as to infringe a valid trademark."

(b) This section shall take effect on the date of its enactment.

Name to be Used on Drug Label

SEC. 112. (a) Section 502(e) of such Act (21 U.S.C. 352(e)) is amended by—

(1) inserting the subparagraph designation "(1)" after "(e)";

(2) striking out the words "If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient", and inserting in lieu thereof "If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient";

(3) striking out the words "the name" and inserting in lieu thereof the words "the established name";

(4) inserting therein, immediately after the colon following the words "contained therein", the following: *Provided,* That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs; and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient:";

(5) striking out the words "clause (2) of this paragraph" in the proviso to such paragraph and inserting in lieu thereof "clause (A) (ii) or clause (B) of this subparagraph"; and

(6) adding at the end of such paragraph the following new subparagraph:

"(2) As used in this paragraph (e), the term 'established name', with respect to a drug or ingredient thereof, means (A) the applicable standard name established pursuant to section 508, or (B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient: *Provided further,* That where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homoeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homoeopathic drug, in which case the official title used in the Homoeopathic Pharmacopoeia shall apply."

(b) Section 502(g) of such Act (21 U.S.C. 352(g)) is amended by inserting immediately before the period at the end thereof a colon and the following proviso: *"Provided further,* That, in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail".

(c) This section shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted.

Nonapplicability to Cosmetics

SEC. 113. Chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 111 of this Act, is further amended by adding at the end thereof the following:

"Nonapplicability to Cosmetics

"SEC. 509. This chapter, as amended by the Drug Amendments of 1962, shall not apply to any cosmetic unless such cosmetic is also a drug or device or component thereof."

Part D—Amendments as to advertising

Prescription Drug Advertisements

SEC. 131. (a) Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is further amended by adding at the end thereof the following new paragraph:

"(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor, with respect to that drug a true statement of (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug, and (3) such other information relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) of this Act: *Provided,* That (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisement of prescription drugs, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52–57). No prescription drug shall be deemed to be misbranded under this paragraph by reason of the failure of any advertisement to include information complying with clauses (2) and (3) of the preceding sentence, if information complying with those clauses is freely available in other written materials to licensed practitioners upon their request to the advertiser of the prescription drug, and if such advertisement contains a conspicuous statement of such availability."

(b) No drug which was being commercially distributed prior to the date of enactment of this Act shall be deemed to be misbranded under paragraph (o) of section 502 of the Federal Food, Drug, and Cosmetic Act, as added by this section, until the earlier of the following dates: (1) the first day of the seventh month following the month in which this Act is enacted; or (2) the effective date of regulations first issued under clause (3) of such paragraph (o) in accordance with the procedure specified in section 701(e) of the Federal Food, Drug, and Cosmetic Act.

TITLE II—FACTORY INSPECTION AUTHORITY

Factory inspection

SEC. 201. (a) Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended to read as follows:

"(a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, or establishment in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j) or section 507 (d) or (g) of this Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the Act). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to—

"(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs, or patients under the care of such practitioners in the course of their professional practice and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;

"(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice;

"(3) persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

"(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health."

(b) Section 302(a) of such Act (21 U.S.C. 332(a)) is amended by striking out "(f),".

(c) Nothing in the amendments made by subsection (a) of this section shall be construed to negate or derogate from any authority of the Secretary existing prior to the enactment of this Act.

Confidentiality of information obtained by inspection

SEC. 202. Section 301(j) of such Act (21 U.S.C. 331(j)) is amended by—

(1) inserting "or as authorized by law," after "Act,";

(2) striking out the following: "concerning any method or process which as a trade secret is entitled to protection"; and

(3) inserting immediately before the period at the end thereof the following: ": *Provided*, That nothing in this Act shall authorize the withholding of information from the duly authorized committees of the Congress".

Effective date

SEC. 203. The amendments made by this title shall take effect on the date of enactment of this Act.

Mr. HARRIS (during the reading of the substitute committee amendment). Mr. Chairman, may I say while I personally have no objection to the reading of every line in the bill, I also would like to suggest that each section of the bill amends present law and refers to a paragraph or a subparagraph or a clause in existing law and anyone who just reads what is printed here simply would not get too much out of it. Therefore, I ask unanimous consent that the further reading of the amendment in its entirety be dispensed with, be printed in the RECORD at this point and be open to amendment at any point.

The CHAIRMAN. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

Mr. SCHENCK. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. SCHENCK:

On page 34, line 14, strike out the parenthetical phrase in lines 14, 15 and 16.

On page 34, strike out lines 20, 21 and 22.

Mr. SCHENCK. Mr. Chairman, it would seem to me by striking out this language, it improves the entire situation. I discussed this with our chairman and I wonder if the chairman has any comment to make.

Mr. HARRIS. Mr. Chairman, may I say for the information of our colleagues that this is an amendment which was offered by the gentleman from Ohio. It is taken, in part, from the Senate bill, S. 1552, page 9, lines 11 to 22 of that bill. The gentleman from Ohio advised me of the need not to tie this provision in with section 701(e). I also understood that the gentleman in offering the amendment does not intend to include the language which is in parentheses which was just read.

Mr. SCHENCK. That is correct.

Mr. HARRIS. That being true and since it is the gentleman's own amendment and since he wants it to be as he intended, I think he is entitled to have it that way. Therefore, I have no objection to the amendment.

The CHAIRMAN. The question is on the amendment offered by the gentleman from Ohio [Mr. SCHENCK].

The amendment was agreed to.

Mrs. SULLIVAN. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mrs. SULLIVAN: Page 45, line 13, strike out lines 13 through 24, inclusive, and on page 46 strike out lines 1 through 3 and renumber the succeeding sections accordingly.

Mrs. SULLIVAN. Mr. Chairman, everything in the bill before us, except for two short paragraphs is intended to tighten our laws covering drugs. I have just offered an amendment to knock out of the bill one of the two paragraphs which have no place in this bill because they are not drug items and they weaken instead of strengthen our consumer protections. They are in the wrong bill.

My amendment would delete a provision of the committee bill which is intended to permit more feed manufacturers to add a cancer-inducing substance, stilbestrol, to animal feeds for meat animals. The Delaney clause of the Food Additives Act of 1958 prevents them from using this additive. But some firms which were using it, with Government approval, prior to the passage of the 1958 act, can continue to do so, under a grandfather clause. Now we are being asked to open up this loophole to all feed manufacturers.

If we strike this section from the bill, as I propose, stilbestrol can still be used as a feed additive by the firms now manufacturing such feeds, but new firms could not enter the field. This would appear to be discriminatory. A lot of the feed producers are complaining about it. But here is the point, Mr. Chairman:

So far—up to now—on the basis of present knowledge and test methods—there is no evidence that the cancer-inducing substance stilbestrol leaves any residue in the meat after the animal is slaughtered. So presumably it is safe to use it. Apparently, the meat animals are not permitted to live long enough to develop cancer from the additives, and apparently they do not build up any residue of the cancer-inducing substance in the meat which we eat.

But only a few years ago, we were told the same thing was true about poultry—that stilbestrol pellets used to fatten poultry were perfectly safe because there was no residue in the meat. What a shock it was to all concerned to learn, as a result of improvements in testing methods, that this was not true—that there was a residue, not only in the skin but in the livers and kidneys. It cost the taxpayers of this country $10 million to buy up the stilbestrol-treated chickens, as a condition to obtaining voluntary agreement of the poultry industry not to use this hormone in promoting faster growth of chickens.

Mr. HARRIS. Mr. Chairman, will the gentlewoman yield?

Mrs. SULLIVAN. I shall be happy to yield.

Mr. HARRIS. The gentlewoman is aware of the fact that this does not include the right to feed this material to chickens.

Mrs. SULLIVAN. No; it relates just to meat animals.

Mr. HARRIS. The reference to the chicken situation is not germane. It is simply with reference to large animals such as cattle.

Mrs. SULLIVAN. What I was pointing out was that at the time it was fed to chickens it was said it was not dangerous, but they found out by later methods of testing that it was dangerous. So that is why I say that there might be danger in the future.

Mr. HARRIS. Mr. Chairman, will the gentlewoman yield further?

Mrs. SULLIVAN. I yield.

Mr. HARRIS. The point I wanted the membership to understand that it was decided and determined after very careful research had been made that the chickens where they had put the pellets in the top of the head did affect them and leave a residue that was not gotten rid of but that it was in the skin and in the liver.

But insofar as cattle are concerned and such animals they do not feed this type of feed to. Within a certain period of time, 24 or 48 hours, it has also been determined positively that there is no residue.

Mrs. SULLIVAN. I thank the gentleman.

The hearings of the committee reveal that the industry which now wants this new loophole put in the law doesn't like the prohibition it contains against any residue in the meat. For, as their spokesmen point out, new testing methods may later show there is residue, and then they will automatically have to stop using stilbestrol and they would lose large amounts of money on the feed already prepared or marketed containing an additive later found to be prohibited. So the very people who stand to benefit from the provision of the committee bill to weaken the Delaney clause want it weakened even further—as perhaps could happen in Conference, since this is not in the Senate bill at all. So we would end up with a free-for-all to add cancer-inducing substances to more animal feeds, and the Government would then have to prove the product dangerous in order to move against it.

That is the kind of situation the entire bill before us is intended to end and correct insofar as prescription drugs for humans are concerned.

The proponents of the stilbestrol clause in this bill will argue, I know, that there is a safeguard in the proposal to protect the consumer that in case of residue found in the meat of animals fed this additive, the Government could immediately order an end to the use of stilbestrol even for those manufacturers previously authorized to use it in their product under the "grandfather's clause" of 1958.

Well, let me reassure you on that point: Under the rest of the bill we are considering—under the new drug law

as we will write it in this legislation—the Government will acquire that power in any event. It will be able to move against stilbestrol in animal feeds at the first sign of a residue of this cancer-inducing hormone in our meat supply. We do not need the safeguard written into this section of the bill; we have it in the entire bill. As it is included in this part of the bill, it is only sugar coating to a provision weakening the consumer protections. We are passing a drug law—exclusively.

I do not know why feed producers should get piggyback ride on this bill. The consumers get nothing in it except long-overdue safeguards on drugs. There is nothing in here on barbiturate control, or amphetamine control, or safety or effectiveness of therapeutic devices, or pretesting of cosmetics. We are told only drugs can be covered in this bill.

The stilbestrol clause is special interest legislation for feed manufacturers, and does not belong here. Under permission granted me by the House, I submit at this point the testimony I gave before the subcommittee in opposition to this proposal when hearings were conducted on several bills limited only to this matter, as follows:

STATEMENT BY CONGRESSWOMAN LEONOR K. SULLIVAN, OF MISSOURI, BEFORE SUBCOMMITTEE ON HEALTH AND SAFETY, HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE, AUGUST 6, 1962

Chairman ROBERTS and members of the subcommittee, I have mixed feeling about appearing this morning to oppose a bill introduced by the chairman of this subcommittee, whom I regard not only as a good friend and an outstanding Member of Congress but as one who has probably done more than any single American to protect the safety of the American people on the highways of this Nation. The attack on exhaust fumes and the increasing use of seat belts in automobiles can be attributed largely to the work of this subcommittee and its chairmen. And in the general field of health legislation, hospital construction, and health professions education, this subcommittee has a proud record.

Thus, I would never take the position that this subcommittee, under Congressman KENNETH A. ROBERTS, is interested in weakening the protections of the American consumer from dangerous food products, or that it is interested in undermining, in any way, the effectiveness of the Food, Drug, and Cosmetic Act. On the contrary, I am sure the subcommittee joins me in wishing to see the Food, Drug, and Cosmetic Act, 1938, brought up to date and made much more effective in protecting our lives and health and safety.

Nevertheless, I feel I must go on record here that I believe strongly that we should not enact as a separate piece of legislation H.R. 12437 by Chairman ROBERTS or H.R. 12420, the bill introduced by Congressman NELSEN, even though the language of these bills was taken out of one of the administration bills to amend and strengthen provisions of the Food, Drug, and Comestic Act. When I testified before the full Committee on Interstate and Foreign Commerce in June on H.R. 11581, the administration bill on drugs, and H.R. 11482, the bill dealing with cosmetics and therapeutic devices, containing together most of the major provisions of my own bill introduced 19 months ago—H.R. 1235—I raised some questions about the validity and the justification for this pafticular provision of H.R. 11582, the feed additives amendment, which has now been reintroduced as a separate bill. After mentioning approvingly some of the few provisions of H.R. 11581 and H.R. 11582 which are not in H.R. 1235 but which I would be willing to see added on to my bill, I turned to this particular provision on feed additives, relaxing the Delaney clause, and said:

"However, I have strong doubts, I must admit, over the retreat on the Delaney anticancer clause on feed additives, as contained in H.R. 11582, particularly in view of the Government's experience several years ago with the hormone-treated chickens. It cost us $10 million to remove from the market the fowl treated with a drug considered safe for the purpose—after it was learned that there were residues of the cancer-inducing substance in the skin of the chicken. Too often for complacency, new testing methods disclose the existence of harmful residues which had not shown up in earlier tests, but by then the damage is done."

NOT INCLUDED IN PRESIDENT'S CONSUMER MESSAGE

Mr. Chairman, it will be noted that my comments at the time on this particular provision of one of the administration bills were mild indeed. I thought I recognized why this provision had been included in the package of administration proposals making drastic changes to close loopholes and eliminate unsafe features in the 24-year-old Food, Drug, and Cosmetic Act. Most of the administration proposals, like nearly all of those in H.R. 1235, are tough changes in the law—necessarily so—to cope with increasing evidences of danger to the consumer. The President touched on some of these in his March 14 message to Congress on consumer protection, but there was not a single word in the President's message about relaxing or changing the Delaney anticancer clause in either the food additives or color additives sections of the law.

On the other hand, he strongly endorsed proposals—all of them in H.R. 1235—for requiring pretesting for safety of all cosmetics; for requiring proof of efficacy as well as safety of all new drugs; for requiring proof of safety and efficacy for all new therapeutic devices; for tightening up drastically our powers to cope with the illicit sale of pep pills and sleeping pills; for rewriting the factory inspection authorization to enable the Food and Drug Administration inspectors to ferret out dangerous conditions in the manufacture, distribution, warehousing and sale of foods, drugs, and cosmetics; for promoting the feasibility of having doctors prescribe by generic terms instead of trade names as a means of bringing down the cost of prescription drugs, and, for enabling the Government to move quickly—immediately—in taking off the market any previously approved drug about which serious doubts have developed after the drug has gone on sale.

These are the major provisions of H.R. 1235 and of those sections of H.R. 11581 and H.R.11582 which amend the Food, Drug, and Cosmetic Act. None of these purposes would be accomplished by passage of either of the two bills now before you this morning.

LEGISLATION BENEFITS ONLY SOME BUSINESS FIRMS

Instead, you propose in this legislation to take out of the administration package of proposals to strengthen the Food, Drug, and Cosmetic Act one obscure provision which does nothing whatsoever for the consumer, but puts profits into the pockets of some businesses making animal feeds.

Perhaps there are inequities in the feed additives "grandfather" clause which permit some feed manufacturers to continue to use cancer-inducing substances or coloring matter in their animal feed products if the particular firms were permitted to do so prior to the passage of the Food Additives Act of 1958 and the Color Additives Act of 1960, and as long as the Government cannot prove danger to the consumer on the other hand, a feed manufacturer not authorized before 1958 to use cancer-inducing chemical substances and not authorized before 1960 to use cancer-inducing coloring matter in animal feed cannot use them now, because of the Delaney clause, contained in both the 1958 and 1960 acts. So it is a competitive inequity.

But, gentlemen, let us look at it from the consumer standpoint. There is no value whatsoever to the consumer—none—in having our meat and poultry supply fattened for market with the aid of feed additives containing materials which could cause cancer. Some of the hormones are of economic value to the producer—fattening his livestock quicker with less feed.

I don't believe it means a single cent's difference in the consumer price of the meat, and it could endanger the consumer's health. That is why the stilbestrol-treated chickens had to be taken off the market several years ago at huge cost to the taxpayers. The Government had sanctioned the use of the stilbestrol pellets on the basis of evidence that no residue was found in the edible portions of the meat. Later—much later—with better testing methods, traces of this dangerous and cancer-inducing substance were found in the skins, and also in the livers and kidneys of the chickens. Who among us can guarantee that the further improvement of testing methods in the near future—or the distant future—will not demonstrate similar consequences from use of the cancer-inducing materials now permitted in some animal feeds under the "grandfather's" clause?

PROBLEM MUCH MORE SERIOUS IN NEW DRUGS

I did not come here to be obstructive. I know there is a competitive problem among feed manufacturers based on when a particular firm happened to begin marketing a particular feed additive which competitors later going into the field could not legally use. But the problem goes much deeper than the competitive situation in the animal feed industry.

Our present law on new drugs requires very stringent proof of the safety of a new drug before it can be marketed. Thalidomide could not be marketed in this country because the manufacturer was not able to convince Dr. Frances Kelsey of FDA that such beyond-a-doubt proof existed. She has testified that, for a long time, she could not put her finger on the exact danger.

If she had approved the drug, based on what appeared to be very convincing proof of safety as a result of widespread usage abroad, she would not have been the heroine she is now, but I am sure she would not have been criticized for accepting the scientific proof presented to her as sufficient. This is a terribly complex scientific problem in the clearing of new drugs, since, as we know, any new drug carries dangers with it and the question is whether the good it can do—under proper medical supervision—outdoes the potential danger. Think how long it took before researchers connected this drug to the sudden increase in the birth of malformed infants.

But here is my point: If Dr. Kelsey had approved the application for sale of this drug, the Food and Drug Administration would then have had to wait for legal and incontrovertible proof of its danger before it could then have removed it from the market. The "tingling sensation" Dr. Kelsey had read about in a letter to the editor of the British Medical Journal—a piece of information which alerted her suspicions—would hardly have been the proof necessary to stop sale of the drug if it had already been approved for sale in this country.

That is the big loophole in our new drug law. The bills you are considering this morning seek to meet this problem as it in-

volves feed additives by providing that the Secretary can quickly move to withdraw from sale any feed additive containing a chemical or color additive which he has once approved, if later he has substantial doubt of its safety. That part of the Roberts-Nelsen bill is all to the good.

OTHER CHANGES NEEDED IN DRUG LAW

But this problem is much more serious with drugs than it is with feed additives. We should not call forth a mouse when we need a massive solution to this problem of removing from the market drugs once approved but later found to be dangerous. Thus, if we are going to do anything on this, we should change all of the appropriate provisions of the food, drug, and cosmetic law to cover not only feed additives, but all drugs—in fact, I believe the feed additives involved in this matter are technically drugs under the act, and the safety feature of H.R. 12437 would be accomplished by H.R. 1235 or the administration bills.

Dr. Kelsey's experience points up the need for another important change in the drug laws: extending the period during which the Government has to act on a new drug application, as H.R. 1235 and H.R. 11581 both provide. Secretary Ribicoff and Commissioner Larrick testified on this during the full committee hearings in June. Dr. Kelsey herself has said that such a change in the law is needed to give her and other FDA scientists sufficient time for evaluating new drug applications. We don't need legislation to tighten up on experimental testing of drugs—FDA can now do that. But we need legislation to close other loopholes in the drug laws and it is urgent that we pass such legislation as I have proposed and the President has called for.

I know the present jurisdiction of the subcommittee is somewhat limited by the fact that H.R. 11581, H.R. 11582 and H.R. 1235 are pending before the full committee, and that this feed additives amendment alone, rather than any of the omnibus bills, is all that is before you right now.

But I think it would be most unfortunate if, out of all of the truly vital, urgent—changes needed in the Food, Drug, and Cosmetic Act right now, the Congress should rush to pass only a bill giving profits to feed manufacturers who happened to have run into a technicality in the law which prevents them from marketing feeds containing cancer-inducing substances, while other firms may still do so.

Furthermore, I refer you to the information I supplied this committee 2 years ago in connection with the color additives bill—information from experts at the NIH—that there is no such thing as a harmless portion of a cancer-inducing substance in food or in drugs or in anything which might be ingested. Tests so far have shown that small quantities of some cancer-inducing substances fed to or injected in some classifications of meat animals, notably beef cattle, in animal feed, to speed the fattening process or for similar economic purposes, do not show up in the edible meat and apparently also do not harm the animal. But please keep in mind that the same "proof" existed on the use of stilbestrol pellets in chickens. That "proof" was faulty, just as the "proof" of the safety of thalidomide was faulty.

GIVE THE CONSUMER "SOMETHING FOR SOMETHING"

I ask that you put this legislation aside as a separate bill. If the Food and Drug Administration can give you incontrovertible evidence that this proposed change in the law is important or necessary, then—even then—I would say, make it part of an omnibus bill which also does something for the consumer. This is one of the few sections of any of the omnibus bills which any indusrty will enthusiastically support. I say: If you're going to go out of your way to provide relief, as this bill would, to some feed manufacturing companies, make it, to use the Latin, a quid pro quo—something for something—in other words, as part of the price the consumer must pay for getting a whole lot more consumer protection in the law. Otherwise, the industry gets what it wants, and the consumer gets nothing.

Mr. Chairman, I have the whole story of what happened on the stilbestrol pellets case involving chickens several years ago. This consists of a statement by former HEW Secretary Flemming, at a news conference December 10, 1959, when HEW announced its agreement with Agriculture that stilbestrol would not be used in chickens and that the Government would then buy up all fowl which had been treated with this previously approved drug. Also, at the same time, Mr. Flemming released a chronological report on how the crisis had developed. This is my only copy. I believe it should be part of the hearing record on this legislation. I ask that you include this material—that you obtain copies from HEW and insert this information in your hearings. It shows what happened when it was discovered that this harmless use of stilbestrol in chickens was not harmless after all—and why the Government could not move quickly on its own authority when the evidence indicated substantial doubt as to safety. The lesson we should learn from it is this: We should be extremely wary about authorizing any cancer-inducing substance under any circumstances in food, drugs or cosmetics, as the Delaney clause provides. I do not believe the Delaney clause should now be weakened. We fought too hard to get it into law to see it weakened merely to help some animal feed manufacturers improve their competitive situation.

Mr. Chairman, I ask that my amendment be accepted to delete this section.

Mr. DELANEY. Mr. Chairman, I move to strike out the last word.

Mr. Chairman, I wish to associate myself with the amendment and the remarks of the gentlewoman from Missouri. The bill originally dealt with drugs for human consumption. That is the way the bill started originally in the Senate. I want to compliment both the Senate committee and the Committee on Interstate and Foreign Commerce for the fine work they have done on this bill insofar as drugs for human consumption are concerned.

But sandwiched in between is an animal feed clause that I feel has no place in this bill. That is a matter that should be treated in a separate bill when we have more time. It is a very deep subject. I know the committee has held hearings over an extended period of time and they have come, as far as I know, to no conclusion except to include it in this drug bill.

I say that the use of stilbestrol that has been proved to be dangerous and cancer inciting in poultry could possibly prove to be dangerous in animal feed. I feel we should go into this subject in great detail.

I do not agree with the interpretation on the grandfather clause aspect of this bill that permits in certain instances some companies that have been manufacturing to continue to manufacture. I recognize, too, that there is a slight loophole there, but I do not think in this bill on drugs for human consumption it belongs in here. It should be debated at great length. Therefore, I say I favor the amendment offered by the gentlewoman from Missouri. I feel that clause should be striken out of this otherwise fine bill.

Mr. ROBERTS of Alabama. Mr. Chairman, will the gentleman yield?

Mr. DELANEY. I yield to the gentleman from Alabama.

Mr. ROBERTS of Alabama. I have discussed this matter many times with the gentleman from New York who appeared before the subcommittee that held extensive hearings on this matter. As I understood the gentleman in his testimony before the subcommittee, and if I understood it correctly, he said that he opposed a widening of the grandfather clause. He would like to do away with all grandfather clauses. We come back to the proposition that the Food and Drug Administration in the final analysis is the agency upon which we must rely for decisions in these matters. Is that true?

Mr. DELANEY. I think the gentleman has stated my testimony before his committee correctly.

I still feel that this is a matter that should be treated separately. I for one feel that the use of stilbestrol in animal feed should be barred altogether until we are absolutely sure that it is not harmful for human consumption.

Mr. ROBERTS of Alabama. Mr. Chairman, I rise in opposition to the amendment.

Mr. Chairman, I am sure that I have the same respect for the gentlewoman from Missouri [Mrs. SULLIVAN], and the gentleman from New York [Mr. DELANEY], as other Members of the House with reference to their interest in this proposition. However, in legislating we have to legislate not in the area of suspicion, but we have to legislate as best we can according to what the scientists and what the experts tell us.

Mr. Chairman, the situation now existing that would be brought about by the amendment which has been offered by the gentlewoman from Missouri [Mrs. SULLIVAN], would not be improved one bit. There would be no less stilbestrol than is sold today. The only difference is that through the adoption of the gentlewoman's amendment we would simply perpetuate an inequity in the law whereby those manufacturers who qualify and who have been certificated under the 1958 act would continue to use it, and many manufacturers desiring to build new plants with new and better equipment would be denied it. It is used in about 80 to 85 percent of the cattle feed which is consumed. Both Secretary Flemming and Secretary Ribicoff asked that this change be made so as to permit its use, under two conditions: first, that there must be no residue in the meat. Second, that it must not be harmful to the animal.

Mr. Chairman, the safety of its use in animals—in beef, in lamb and in other large animals—has been the subject of various studies. I call the attention of the Members of the Committee to the fact that in 1957 a study was made by the American Medical Association, testing as to the safety of its use. Also, the National Institutes of Health made a statement to that effect, after studying and after reviewing very sensitive tests.

Dr. Harvey of the Food and Drug Administration testified before our subcommittee and testified in favor of this amendment. We did hear the bill separately from the other bill. It is rather peculiar to me that the gentlewoman from Missouri [Mrs. SULLIVAN], would introduce this amendment today, because I shall quote the words of the gentlewoman. We did exactly what the gentlewoman advised the subcommittee that she desired be done. The gentlewoman said, as follows:

I ask that you put this legislation aside as a separate bill if the Food and Drug Administration would give you incontrovertible evidence that this proposed change in the law is important or necessary. Then, even then, I would make it a part of an omnibus bill which also does something for the consumer.

What we have done in this omnibus bill is to give the Administrator the power of instant withdrawal from the market. We have also given him power whereby in case of imminent hazard to life, he can instantly and summarily, if you will, withdraw this drug.

Mr. Chairman, I say that I think my record is fairly good in the area of public health. I certainly would not come here sponsoring an amendment if I had any doubt as to its safety or to its efficacy. We have produced all of the proof which the scientists and doctors have been able to offer—the Food and Drug Administration, and others familiar with this particular drug—that it is safe and has been found safe in all instances in which it has been tested.

Mr. ROGERS of Florida. Mr. Chairman, will the gentleman yield?

Mr. ROBERTS of Alabama. I yield to the gentleman from Florida.

Mr. ROGERS of Florida. I agree with the gentleman from Alabama, the chairman of the subcommittee, and oppose this amendment.

The subcommittee has gone into this matter very thoroughly. It has been a subject of discussion for a long time. Even the Food and Drug Administration supports this strongly, and the gentleman from New York [Mr. DELANEY] so testified in his statement before the committee when he stated he had a letter from Deputy Commissioner Harvey wherein Mr. Harvey stated that the changes proposed in this legislation would fully protect the public health. He says, of course, that is the responsibility of the Food and Drug Administration, which it is.

I think, too, this amendment helps eliminate a ridiculous situation under the present interpretation.

If the company is now producing this drug, which is perfectly all right, and goes through all of the necessary procedures, and the Food and Drug Administration approves it, and if that company has one of its plants burn down and they rebuild the plant and improve the facilities and make them more sanitary than they were ever before, even though it was approvd before, under the present law they could never again produce this drug that was produced in that plant.

The CHAIRMAN. The time of the gentleman from Alabama [Mr. ROBERTS] has expired.

Mr. DELANEY. Mr. Chairman, I ask unanimous consent that the gentleman from Alabama [Mr. ROBERTS] may proceed for 1 additional minute.

The CHAIRMAN. Is there objection to the request of the gentleman from New York?

There was no objection.

Mr. DELANEY. Mr. Chairman, will the gentleman yield?

Mr. ROBERTS of Alabama. I yield to the gentleman.

Mr. DELANEY. I would like to ask this one question. Were we not assured by the Food and Drug Administration that stilbestrol, which it was said was safe for use in poultry, was later found upon more modern tests to be a carcinogenic agent, containing cancer-bearing effects?

Mr. ROBERTS of Alabama. That is correct. I will say this, if the Secretary had had the power that we give him under this bill, it would not have cost the Government $10 million to pay for all those chickens.

Mr. DELANEY. We opposed just as strenuously at this time the use of stilbestrol in poultry and other chicken-feeds.

Mr. HARRIS. Mr. Chairman, will the gentleman yield?

Mr. ROBERTS of Alabama. I yield.

Mr. HARRIS. Is it not true that when they found that there was a residue in the poultry, that the use of stilbestrol pellets in poultry was discontinued. And is it not true that we provide in this amendment the authority for the Secretary to see that no residue of the additive shall be found?

Mr. ROBERTS of Alabama. That is correct.

Mr. DELANEY. Mr. Chairman, will the gentleman yield further?

Mr. ROBERTS of Alabama. I yield.

Mr. DELANEY. Is it not true that in the heart, the kidney, the liver and the skin of these chickens, these poultry, that the cancer-inducing element was found?

Mr. ROBERTS of Alabama. I will admit that as to the poultry that is true. But we are not here talking about poultry. We are talking about large animals in this particular case.

Mr. NELSEN. Mr. Chairman, I move to strike out the last word.

Mr. Chairman, I wish to make a comment in opposition to the amendment. We find that manufacturer X may use a product, and manufacturer Y may not. As I interpret this debate, it is not a debate as to whether or not a certain drug should or should not be used. If a drug should not be used, it should be barred. But if one manufacturer may use it, it certainly seems unreasonable to say that another may not. That is my concern with this legislation. I would certainly be the last one to endorse the use of any kind of drug that was harmful to human beings. If the drug that has been mentioned is harmful, I think it is up to the Food and Drug Administration to bar its use completely. But to say that one may use it and another may not seems to me to create a ridiculous situation and one that it would be very difficult to administer by the Food and Drug Administration. I think it is an unfair situation and I hope this amendment will not be adopted.

If the Food and Drug Administration needs more power, let us give it to them.

Mr. SCHENCK. Mr. Chairman, will the gentleman yield?

Mr. NELSEN. I yield.

Mr. SCHENCK. I asked my colleague to yield for the purpose of asking the question of the chairman of our subcommittee, the gentleman from Alabama [Mr. ROBERTS]. Am I correct in my understanding at this time that under the present law the Food and Drug Administration may not withdraw the use of a drug that they find to be or feel will be harmful; but that the language you put in this bill is stronger because it permits the Food and Drug Administration immediately to withdraw?

Mr. ROBERTS of Alabama. That is correct. There is another place in the bill where they have it. They have immediate power of withdrawal. So we are giving them more power than they have ever had with reference to this situation or any other drug situation.

Mr. JENSEN. Mr. Chairman, will the gentleman yield?

Mr. NELSEN. I yield to the gentleman from Iowa.

Mr. JENSEN. The gentleman has addressed himself to the problem which feed dealers have experienced. I think the gentleman said, did he not, that that problem is being solved by this legislation?

Mr. NELSEN. My feeling is that the bill that is proposed would permit if X manufacturer may use the product then another manufacturer also may use it. This amendment would deny the extension of the grandfather clause to the other manufacturers. I feel the amendment that is proposed should be defeated because it keeps this operation so exclusively in the hands of just a few on this particular type of use.

Mr. JENSEN. The thing I am interested in, and I am sure is of interest to the gentleman from Minnesota also, will all feed dealers that mix feed for animals be in the same identical category if this bill is made the law of the land?

Mr. NELSEN. Right.

Mr. ROBERTS of Alabama. Mr. Chairman, will the gentleman yield?

Mr. NELSEN. I yield.

Mr. ROBERTS of Alabama. Is it not true that under the present procedures under the present law the burden of proof is on the Food and Drug Administration to prove that a drug is unsafe?

Mr. NELSEN. Right.

Mr. ROBERTS of Alabama. In this bill we shift the burden of proof to the manufacturer. He has to prove now that it is safe. Is not that a step forward in the power of the Food and Drug Administration to remove drugs if there is any question as to the safety of the drug? The Food and Drug Administration will have more power than it has ever had before in that respect.

Mr. HARRIS. Mr. Chairman, I move to strike out the last word.

Mr. JENSEN. Mr. Chairman, will the gentleman yield?

Mr. HARRIS. I yield to the gentleman from Iowa.

Mr. JENSEN. Under the provisions of this bill the people that administer this law will have about the same privilege and equal responsibility in the kind of drugs that are used in human medicine as well as in animal feeds?

Mr. HARRIS. If I understand what the gentleman means, the amendment here is an effort to correct the situation that exists with reference to the feed producers. There is a certain group of them that can use certain drugs; others that cannot use the same drugs. This amendment places the responsibility on the Secretary of Health, Education, and Welfare to make a positive finding that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, the feed additive will not, first, affect the animal; and, second, that no residue of the additive will be found in any edible portion of the animal after slaughter. All feed manufacturers would be put on the same and equal terms.

Mr. JENSEN. All right. I understand now. Now let me ask the gentleman, Did this bill come from his committee with unanimous approval?

Mr. HARRIS. It was reported by a unanimous vote of the committee.

Mr. JENSEN. After the original bill was considerably amended?

Mr. HARRIS. Yes; it was. We amended the original bill extensively. We took a good many of the amendments the Senate had made and made some of our own.

Mr. JENSEN. There was a bill whose number I think was H.R. 11582?

Mr. HARRIS. That bill has to do primarily with cosmetics and therapeutic devices. We did not deal with that subject in this bill.

Mr. JENSEN. The cosmetologists are not included in any way in this bill?

Mr. HARRIS. No.

Mr. JENSEN. I thank the gentleman.

Mr. BEERMANN. Mr. Chairman, will the gentleman yield?

Mr. HARRIS. I yield to the gentleman.

Mr. BEERMANN. If I, as a cattle feeder, want to buy cattle feed with stilbestrol in it by the language of this bill with this amendment in it, I will be able to buy stilbestrol feed from any feed manufacturer; is that correct?

Mr. HARRIS. Yes; after the manufacturer has obtained proper clearance under the new drug procedure.

Mr. BEERMANN. So it takes out the inequities that we have had heretofore?

Mr. HARRIS. Yes.

Mr. BEERMANN. I thank the gentleman.

The CHAIRMAN. The question is on the amendment offered by the gentlewoman from Missouri [Mrs. SULLIVAN].

The amendment was rejected.

Mr. O'BRIEN of New York. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. O'BRIEN of New York:

On page 55, on line 12, after the word "label" insert "(or on any labeling therefor)".

On page 55, on line 15, after the word "ingredient" insert the following: "(or, in the case of labeling, is so printed at the first place, and at the most conspicuous place if other than the first place, at which such proprietary name for such drug or ingredient, as the case may be, is used)".

Mr. O'BRIEN of New York. Mr. Chairman, I find myself in a position somewhat similar to that of the gentleman from Ohio, a few minutes ago, in that I am proposing an amendment to an amendment which I offered in the committee. The bill, as it now reads, requires that for any prescription drug, the established name of such drug or ingredient must be printed prominently on the label and so forth. Inadvertently, I failed to offer an amendment in the committee which would cover "labeling" and in the opinion of most people "labeling" is just as important as "label".

Mr. HARRIS. Mr. Chairman, will the gentleman yield?

Mr. O'BRIEN of New York. I yield to the gentleman.

Mr. HARRIS. Mr. Chairman, the gentleman talked to me about this previously. This is a conforming amendment and I see no objection to it.

Mr. SCHENCK. Mr. Chairman, we have no objection to the amendment.

The CHAIRMAN. The question is on the amendment offered by the gentleman from New York [Mr. O'BRIEN].

The amendment was agreed to.

Mr. COLLIER. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. COLLIER: On page 60, line 1, strike the period after the word "therein" and all thereafter through the period on line 24 and insert the following language: "pertinent sanitation methods, analytical reports on unfinished materials, quantitative formula data for inactive ingredients, facilities for weighing and measuring, packaging facilities, sterility controls, active ingredients assay controls, coding systems, facilities for maintaining separate identity for each drug, cleaning of equipment, methods for quarantine of drugs until after clearance with control laboratory and file of complaints from licensed medical practitioners and licensed medical institutions, shipping records, and data as to qualifications of technical and professional personnel performing functions subject to this act."

Mr. COLLIER. Mr. Chairman, as I said earlier in my remarks from this well, I thought this was a good, sound piece of legislation. However, like everything else that is not perfect, there is room for improvement and I sincerely believe that the adoption of this amendment will improve this bill. I say this because what in reality this does is to spell out, as I think it is the intent of this Congress and of our committee, the authority that we intend in the public interest for the Food and Drug Administration to have with regard to factory inspections. Let me ask anyone in this House listening to the reading of this amendment—what possible area beyond what is clearly and concisely defined in my amendment, the Food and Drug Administration would need to serve the public interest to see that any drugs are safe and to provide all of the protection that the public needs in this field?

On the other hand, considering the language of the bill before us, which is, in reality, the language adopted in the Senate, there are areas of vagueness. I do not think this House wants to enact legislation in a field that embraces the complexities, the technical problems, and their implications in an area of vagueness. Hence I feel that the adoption of this amendment which very specifically and very concisely spells out in detail factory inspection authority provided herein. Then we will not in the future run into any situation where we could not know from the language of the existing bill what the intent of Congress was or what its intent was not. Therefore, in the interest of improving this legislation I hope the House will adopt this improving language to that section of the bill.

Mr. HARRIS. Mr. Chairman, will the gentleman yield?

Mr. COLLIER. I yield.

Mr. HARRIS. I am very sorry I was not able to follow the reading of the gentleman's amendment. Is his amendment the same amendment that was offered in the committee, which the committee considered but did not approve?

Mr. COLLIER. It is not the same amendment. It is substantially the same amendment which did have substantial support in the committee, but perhaps insufficient support because, as the chairman will remember, we became involved in the substitution of the Senate amendment.

What I have done in addition is providing the very concise and defined language that I offered in the committee. I have added the only thing that I felt might have been the reason for objection on the part of any member of the committee. This addition includes "shipping records, data as to the qualifications of the technical and professional personnel performing functions subject to this act." What is spelled out in this amendment with reference to factory inspection is in the interest of the public and in the interest of the industry as a whole.

Mr. HARRIS. Mr. Chairman, will the gentleman yield further?

Mr. COLLIER. I yield.

Mr. HARRIS. Then do I understand that the part which your amendment inserts in the bill is item (D) referring to personnel data other than data as to the qualifications of technical and professional personnel?

Mr. COLLIER. I have covered in the amendment which was read by the Clerk that additional language because I felt that corrected what was objected to.

Mr. HARRIS. Can the gentleman then tell me what he has left out of the committee bill?

Mr. COLLIER. What I have left out of my amendment?

Mr. HARRIS. What is there in your amendment that you have left out of the bill that you undertook to do that we did not do?

Mr. COLLIER. I would not attempt to say, Mr. Chairman, what has been left out, because the purpose of the amendment is to clarify the intent and the purpose of this act; and, therefore, all my amendment does is to spell out in detail exactly what information shall be turned over to a factory inspector, item by item, and step by step. I can find

nothing in what is here that the inspector does not need to protect the public interest in every respect. As far as the committee language or the amendment that was adopted in the committee that embraced the Senate language is concerned, what this does is make clear in this legislation just what we intended.

Mr. HARRIS. Mr. Chairman, I ask unanimous consent that the amendment be reread.

The CHAIRMAN. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

The Clerk again read the amendment.

Mr. HEMPHILL. Mr. Chairman, I rise in opposition to the amendment, and the reason I rise in opposition to this amendment is, in the first place, I do not think the amendment fits into what the distinguished gentleman from Illinois meant for it to do. If I may direct his attention to me, and I want to be of help if I can, instead of striking out part of line 1 beginning with the word "in" on page 60 down to line 24, why not change the period to a semicolon and insert the language offered by the gentleman from Illinois and leave in the language which the gentleman from Illinois seeks to strike from the bill? If the gentleman will bear with me, there is a reason for that. One of the fears that people had about this legislation was that we would go in, or the Food and Drug people would go in, and inspect the records which were neither incidental or necessary to the safety or efficacy of the drug. In part of the language the gentleman from Illinois seeks to strike out, we find this protection which I think the industry deserves and which the industry itself recommended.

Down on page 60, line 12, it is stated:

No inspection authorized for prescription drugs by the preceding sentence shall extend to (a) financial data.

Which means you are not going into somebody's business and make them give up financial data that does not have anything to do with that situation.

The next is sales data, which again does not have anything to do with what we are trying to accomplish here. Pricing data. We are not going into that. This is not the OPA and there is no necessity for seeking pricing data at this time. Personnel data, other than data as to qualifications of technical personnel. We take care of this, as the chairman explained in his initial statement. Research data, and so on.

So if the gentleman's amendment prevails, and I hate to be in opposition to him, it would undo much of the good work that has been done in this legislation.

I wonder if the gentleman would consider a change, and I would like for my chairman to answer me on whether or not what I propose, adding the gentleman's language, which he says is all inclusive, and in striking the language, would not accomplish the purpose and preserve the protection.

Mr. COLLIER. Mr. Chairman, will the gentleman yield?

Mr. HEMPHILL. I yield to the gentleman from Illinois.

Mr. COLLIER. I agree with the gentleman 100 percent with regard to the foreclosure or requesting of information such as price data, financial data, and so on, but I take the position that good legislation or legislation at its best should say "Here is what you may do" instead of saying "This is what you may not do." So my approach in this amendment is to spell out what in fact the investigators may do and the information they are entitled to, whereas this language which says they shall not have access to financial data and so forth, if it is not provided in that which they can do, obviously you do not know and do not tell them what they cannot do.

Mr. HEMPHILL. I think if the gentleman will accept the compromise, what I am trying to do is to make sure everybody is served here. We not only spell out what you can do, we spell out what you cannot do. I do not know how anybody can improve on that kind of an approach to legislation. It says the intent of Congress is you shall have this authority but the intent of Congress is also expressed by the language that you cannot do certain things. If the gentleman would rephrase his amendment, we might be able to get together.

Mr. COLLIER. I would be willing to add this language. I think it leaves the portion here that is redundant in, but for the purpose of clarifying the intent of my amendment, I will be happy to accept it. But this is my personal feeling. I think it has to go beyond that.

Mr. HEMPHILL. Would the chairman of the committee agree to that? The gentleman says he is trying to spell out what the administration can or cannot do. The language, as I see it, that he seeks to strike out is that language which tells them what they can do. If we tell them what they can do and what they cannot do, we can correct it.

If the chairman will accept that, I will make the unanimous-consent request and correct the difficulty.

Mr. HARRIS. If the gentleman will yield, personally, I think the provision in the amendment that is in the bill includes just about all, if not all, of what the gentleman from Illinois has in his amendment. As a matter of fact, part of the gentleman's amendment, as I read it, contains identical language which is in the bill. I agree with the gentleman that if we accept his amendment to the provision in the bill there will be a lot of redundant material in it.

The CHAIRMAN. The time of the gentleman from South Carolina has expired.

Mr. HARRIS. Mr. Chairman, I move to strike out the last word, and then yield to the gentleman from South Carolina [Mr. HEMPHILL].

Mr. Chairman, it seems to me that it would be necessary if the gentleman feels that there is something in the language which he thinks ought to be included, I would have no objection to accepting the gentleman's language at the proper place, on line 24, where the period is placed, and taking it to conference and working out.

If the gentleman from Illinois [Mr. COLLIER] wants us to do that, why, I would have no objection to that.

Mr. COLLIER. Mr. Chairman, would the chairman of the full Committee on Interstate and Foreign Commerce please restate his remarks?

Mr. HARRIS. If the gentleman feels that there is something in his amendment that is not included in the language of the bill that should be included, I have no objection to taking his language at the place suggested by the gentleman from South Carolina, striking out the period and including that language, and then taking it over to conference and working it out. The redundant part could be worked out and left out.

Mr. COLLIER. Mr. Chairman, I would have no objection to that.

Mr. HEMPHILL. Mr. Chairman, I ask unanimous consent that the amendment at the desk be changed to read:

Strike out the period on line 1 of page 60, and then insert the language proposed by the gentleman from Illinois [Mr. COLLIER] in the original text of the gentleman's amendment.

The CHAIRMAN. Is there objection to the request of the gentleman from South Carolina?

Mr. HARRIS. Mr. Chairman, reserving the right to object, so I can definitely understand what is proposed, as I understand it the gentleman from South Carolina [Mr. HEMPHILL] has made a unanimous-consent request that the amendment of the gentleman from Illinois be modified by striking the language beginning after the period on line 1, page 60, down through the period on line 24, but in lieu thereof, he would strike out the period on line 24 and add the language that he read to the committee.

Mr. COLLIER. That is my understanding and hope. Of course, any redundancy which would exist by reason of this adoption would be clarified in the conference.

Mr. HARRIS. I would have no objection to that amendment.

The CHAIRMAN. Without objection, the first amendment is withdrawn, and the Clerk will now report the modified amendment as proposed by the gentleman from Illinois [Mr. COLLIER].

There was no objection.

The Clerk read as follows:

On page 60, line 24, strike the period and insert "pertinent sanitation methods, analytical reports on unfinished materials, quantative formula data for inactive ingredients, facilities for weighing and measuring, packaging facilities, sterility controls, active ingredents assay controls, coding systems, facilities for maintaining separate identity for each drug, cleaning of equipment, methods for quarantine of drugs until after clearance with control laboratory, and file of complaints from licensed medical practitioners and licensed medical institutions, shipping records, and data as to qualifications of technical and professional personnel performing functions subject to this Act."

The CHAIRMAN. The question is on the modified amendment of the gentleman from Illinois [Mr. COLLIER].

The modified amendment was agreed to.

Mr. SMITH of Virginia. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. SMITH of Virginia: On page 62, after line 21, insert the following:

"EFFECT ON STATE LAWS

"SEC. 203. Nothing in the Federal Food, Drug, and Cosmetic Act, as amended, shall be construed as invalidating any provision of State law which would be valid in the absence of such Act unless there is a direct and positive conflict between such Act and such provision of State law."

And renumber the following section accordingly.

Mr. SMITH of Virginia. Mr. Chairman, there are some confusing decisions of the Court which hold that whenever the Congress enacts a law it preempts jurisdiction over all matter contained in the act to the exclusion of all State laws. This results in some unnecessary reduction of State inspections, and so forth, on various and sundry matters, particularly with respect to food products. This would merely say that this Food and Drug Act shall not be construed as the intent of Congress to abolish all State laws on the same subject where they are not in conflict with the Federal law. That is the substance of the amendment.

Mr. HARRIS. Mr. Chairman, will the gentleman yield?

Mr. SMITH of Virginia. I yield to the gentleman.

Mr. HARRIS. Mr. Chairman, earlier in the debate today I was asked the question by one of our colleagues about the preemption of State laws and made the categorical statement that this legislation did not preempt any State laws and was not so intended. The gentleman was kind enough to call to my attention his amendment, prior to this time. I have had occasion to look it over and I have no objection to it. I think it is in line with the statement that I made previously on the floor of the House.

Mr. SCHENCK. Mr. Chairman, will the gentleman yield?

Mr. SMITH of Virginia. I yield to the gentleman from Ohio.

Mr. SCHENCK. Mr. Chairman, as the gentleman will recall in my statement on the floor I pointed out that there are many instances where State laws in the area of food and drugs and health are even stronger than some of the Federal laws. I pointed out also that the Federal law should not preempt in those fields. I would like to assure the gentleman from Virginia that I have no objection to his amendment.

Mr. RIVERS of South Carolina. Mr. Chairman, will the gentleman yield?

Mr. SMITH of Virginia. I yield to the gentleman.

Mr. RIVERS of South Carolina. Does this now include the Steve Nelson case?

Mr. SMITH of Virginia. This would not include anything other than food inspections.

The CHAIRMAN. The question is on the amendment offered by the gentleman from Virginia [Mr. SMITH].

The amendment was agreed to.

Mr. HARRIS. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. HARRIS: On page 42, line 15, strike out "335" and insert in lieu thereof "355".

On page 58, line 25, and on page 59, line 5, strike out "(o)" and insert in lieu thereof "(n)".

Mr. HARRIS. Mr. Chairman, these are just clarifying amendments.

The CHAIRMAN. The question is on the amendment offered by the gentleman from Arkansas.

The amendment was agreed to.

Mrs. SULLIVAN. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mrs. SULLIVAN: On page 46, line 4, strike out lines 4 through 19.

Mrs. SULLIVAN. Mr. Chairman, my previous amendment was directed at a proposal to allow more feed manufacturers to use a cancer-inducing substance in feed for meat animals. There is some economic justification for using stilbestrol in fattening cattle, if it can be proved completely safe—as it has not been so far. But farmers can fatten their livestock to market weight much faster and on less feed by using these additives, and therefore, in the absence of overwhelming proof of danger to the consumer from eating meat from such animals, the farm people believe they should have the right to use this additive in feeding livestock.

But, Mr. Chairman, there is no justification—economic or otherwise—for permitting the use of cancer-inducing coloring matter in this feed. The animals, I believe, cannot distinguish colors. But the farm hands apparently can. So the dangerous additive, which must not be fed to the cattle for at least several days before slaughter, to make sure there is no residue in the meat, is identified with coloring matter to differentiate one kind of feed from another.

Now just look what we are getting into here. The feed manufacturers say they have to use colors, which are now prohibited for this use because they can cause cancer. Are we allowing this very potent and very dangerous cancer-inducing substance, stilbestrol, to be handled by farmhands who are unable to read directions on the label or package, and must have special colors used to guide them—colors which are cancer inducing?

Before the color additives act was passed in 1960, I obtained and put in the CONGRESSIONAL RECORD evidence from National Institutes of Health scientists, cancer experts, that there is no such thing as a harmless amount of a cancer-inducing substance as far as humans are concerned.

In this bill—in the section to which I previously offered an amendment—we would let more feed manufacturers use a cancer-inducing substance in animal feed for economic reasons. Now, in this section, we would be saying: put a little more cancer in, for color, to help the farmhand know which sack to use in the final days before slaughter. Are we to believe our farmers are too dumb to handle this material otherwise?

If the man can't read or understand directions, how do we dare trust him with these potent, dangerous, substances, to use the right proportion or amount?

There is no justification for permitting cancer-inducing coloring matter in anything going into our food supply. The Delaney clause prohibits it. Let us uphold that principle. This provision of the bill must come out.

Mr. ROBERTS of Alabama. Mr. Chairman, I rise in opposition to the amendment.

Mr. Chairman, the same arguments that apply with reference to the gentlewoman's other amendment apply to this amendment. The only reason, I suppose, for offering this amendment is that veterinary drugs have been classified both as food additives and as color additives. I repeat that there was no proof before the subcommittee that the use of stilbestrol as presently used under the direction of the Food and Drug Administration has been shown to induce cancer in animals. No residue has been found, no harm to the animal.

The same proposition was before the House a few minutes ago on a similar amendment, and with the additional power of withdrawal contained in the omnibus bill those people who might have some suspicion of this stilbestrol are in a better position than they ever have been before. The Food and Drug Administration testified in favor of this amendment. It has been asked for by Secretary Ribicoff when he was head of the Department of Health, Education, and Welfare, also Secretary Flemming. It has been approved by studies made by the American Medical Association and by the National Institutes of Health. I would respectively ask that the House vote "no" on this amendment.

The CHAIRMAN. The question is on the amendment offered by the gentlewoman from Missouri [Mrs. SULLIVAN].

The amendment was rejected.

Mr. BLATNIK. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. BLATNIK: On page 58, strike out line 15 and all that follows down to, but not including, the quotation marks in line 23.

Mr. BLATNIK. Mr. Chairman, this amendment is a straightforward and simple amendment. It is simple in technique but important in meaning. What it does is to strike out the seven lines that were added to section 131 of this bill. This addition—lines 15 through 22 on page 58—nullifies the previous language of section 131 beginning on page 57, line 11 down to line 14 on page 58, the language in the committee bill that asks that in the advertisements to doctors, there also be included three points of information:

First, the established generic names as defined in section 502(e) of this bill.

Second, the formula showing the quantitative ingredients.

Third, and most important, the information relating to side effects, contraindications, and effectiveness of the drug.

The language which I am striking out makes unnecessary the listing of these

three points of information and merely states that, if you write to the manufacturer in response to an ad, he would be required to tell you the rest of the story.

Mr. Chairman, I am offering this amendment to section 131 of H.R. 11581 because I believe that an overwhelming record of evidence has demonstrated that many drug advertisements are misleading and that in some instances they are outright false. To allow advertisements of this nature to appear unpoliced can be highly detrimental and even dangerous to the health and safety of the people of this Nation. There is ample evidence to demonstrate that because of time limitations physicians rely on drug advertisements a great deal in deciding which they should prescribe for their patients. It is incumbent upon us to assure that no false or misleading information is inadvertently relied upon. Little more than a small notation on the advertisement indicating harmful side effects, effectiveness, or contraindications is needed to accomplish this purpose. Deletion of the lines added in committee will assure that this minimum amount, but essential information, will appear so that doctors will have all the facts, pro and con.

First. Lines 15 through 22 on page 58 divest the Federal Government of any regulatory authority over false and misleading advertising of prescription drugs. They leave the policing of this vitally important field to the industry itself. It goes counter to the whole concept of national policy settled long ago in both the Wheeler-Lee amendment to the Clayton Act and the Food and Drug Act itself.

Second. It is argued that these exceptions apply only to those ads where other information on side effects, and so forth, are available from the manufacturer. The implication is that some ads would, therefore, not be eliminated from Federal regulations. The fact is that under existing law—Food and Drug Act—the manufacturer of a prescription drug is required to provide full disclosures on any literature used in promoting the drug, especially medical journal ads. In other words, this part of section 131 is a waiver from the requirements of section 131 of the bill, the original purpose of which was to require a statement of side effects, contraindications, and effectiveness. I include at this point an explanation of why my amendment is necessary:

First. What does this proviso do? It nullifies all of section 131—starting on page 57 of H.R. 11581 down through line 14 of page 58 of the bill—by stating that the information required by the first part of section 131—lines 11, page 57 through lines 14, page 58—is unnecessary if there is a brief statement on the advertisement indicating further information can be obtained from the drug manufacturer, found on most advertisements already, and if this information is available from the manufacturer, already required by law.

Second. Effect of lines 15 through 22, page 58 of H.R. 11581. Waive in all instances the provisions of section 131 which require that a formula showing quantitatively each ingredient of the drug advertised and requiring information relating to side effects, contraindications and effectiveness through use of a completely noninformation phrase which directs the reader to write to the manufacturer for further information. The condition in the Younger amendment that the information be readily available upon request is redundant, since this is already required by statute.

A. Divest Federal Government of any regulatory authority over false and misleading advertising of prescription drugs.

Since the Federal Trade Commission's authority to take action against false and misleading advertising is transferred to FDA through section 131 of H.R. 11581—lines 8 through 14 of page 58—and the Food and Drug Administration cannot take action if there is a brief line stating information is available if reader writes to the manufacturer, the Federal Government cannot regulate false and misleading advertising. Medical journal advertisers are left free to "employ half-truths, part of the truth, or outright falsehoods."

B. It is inconsistent with the recommendation of the President made to the Senate Committee on the Judiciary, that drug ads "should be required to make fair disclosure of the information—good or bad—needed to do a better job of selecting drugs for use in their practice." The President stated that—in same letter—the language he recommended for this provision was "designed to eliminate misleading drug advertising directed to doctors."

C. Quote from Washington Post, page A20, Thursday, September 27, 1962:

> Chairman Paul Rand Dixon of the Federal Trade Commission, said the amendment "completely nullifies" the Government's existing, but admittedly clouded, authority over prescription-drug ads in medical journals.

I can cut my explanation down very briefly by just showing you two examples of how ads can mislead.

Here is the first one. Here is a three-page advertisement.

The headline says:

> For the first time, the drug that lowered this patient's blood pressure without side effects.

Obviously, they had quite a bit of space because you notice at the bottom one-third of the left-hand page is a picture of a scale. Now that does not provide any fundamental basic medical knowledge to a doctor because he knows what a weighing scale looks like, but it is in the picture.

On the right-hand side of the page is a little line which states as follows:

> It has infrequent side effects. The true advantage of Singoserp over other derivatives of Rauwolfia seems * * * to be the relative infrequency with which it produces disturbing side effects.

But here it implies that for the first time something was done without side effects.

But the Advertising Committee of the American Medical Association which is the clearing committee for advertisements intended to be printed in their own official organ, the Journal of the American Medical Association, looked at this ad and they rejected it and refused to carry it. Here is what they said. They felt this advertisement, and I quote, "carries a misleading implication of a broad, too all-inclusive nature."

Yet, 1 month later this three-page advertisement—"misleading" and "broad" and "all-inclusive" appeared in four widely used medical journals that do not have a screening committee.

Let me give you an even worse story. The situation to which I have just referred was merely a case of misleading advertisement.

Take a look at this advertisement of Tao, a new drug. It is an antibiotic. Notice that the left-hand page is all wasted except for the picture of a slide rule. Would you not think they would have used that space to tell what the bad effects, the side effects might be? In short, to tell the whole story. They do not need a slide rule to illustrate what the drug does. Listen to what it says: On the first page it is implied that Tao is a superior antibiotic. And on the other page it says:

> Tao encompasses even strains of common pathogens (notably straphylococci) resistant to penicillin and erythromycin.

They say it is superior to penicillin.

What does the American Medical Association say about it? They said that this was "altogether too strong and misleading" a statement. This is a quote about this particular advertisement. This particular advertisement claimed that the drug had a greater range of efficacy than penicillin. The American Medical Association committee reported to the advertising agency that this claim "seems completely false since clinically it is quite inferior to penicillin in the treatment of most infections."

The CHAIRMAN. The time of the gentleman from Minnesota has expired.

(By unanimous consent Mr. BLATNIK was allowed to proceed for 2 additional minutes.)

Mr. BLATNIK. The American Medical Association rejected this as being completely false and misleading, yet 6 months later the same ad appeared in four widely used medical journals which reached all of the doctors of America.

Now, on the left-hand page at the bottom of this ad in very small print appears the following statement—they do comply with the law—"Complete bibliography and product information available on request." If you write for a comprehensive brochure you get the whole story. This is what lines 15 to 22 on page 58 of the bill would continue despite these experiences.

What I am asking is to strike out lines 15 through 22 and leave the remaining language in. Under Federal law as it now stands manufacturers and pharmaceutical companies, manufacturers of drugs, must by Federal law send a brochure with all the information, good, bad, and all, to druggists. But druggists do not prescribe.

I want to see this bill so drawn as to make sure that doctors get all available information, because even they from time to time need reminders of the side effects, because some are very dangerous.

I do urge, and strongly urge the adoption of this amendment. It must be deleted.

We, as holders of the public trust, will be sadly remiss in our duty to the American people if we do not assure that honest and safe advertising is provided to physicians throughout the land. Acceptance of my amendment will provide the essential information without inconveniencing the drug advertisers.

Mr. YOUNGER. Mr. Chairman, I move to strike out the last word.

Mr. Chairman, in view of the fact that the gentleman has mentioned my name I think I have a right to speak. The amendment which I introduced was introduced in connection with the House bill. When the committee considered the bill they substituted the Senate section for the House section. The wording of this amendment is not mine. Therefore, I have no objection whatsoever to the amendment which the gentleman from Minnesota [Mr. BLATNIK] offers.

Mr. HARRIS. Mr. Chairman, I rise in opposition to the pro forma amendment.

Mr. Chairman, I think the membership should know what they are doing. We could very quickly find ourselves in a position where we will be in the middle of a situation difficult to explain.

The gentleman from Minnesota, author of the amendment, has given you examples of advertisements justifying why this language should be stricken. But let me remind you that he told you that these advertisements were misleading. Under section 15 of the Federal Trade Commission Act today the law deals with that subject. This section provides that no advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession and contains no false representation of a material fact, and so forth. So today there is in the law sufficient authority to deal with the misleading advertisements that the gentleman from Minnesota relies upon insofar as his amendment is concerned.

Let me point up to you what the problem is here. I do not say I like the amendment that is included in the bill which the gentleman from Minnesota seeks to strike out. However, if everything is stricken out, there will be no opportunity to work it out when we get to conference.

Are we going to take the position, shall we say, that a doctor is going to practice medicine and determine what drugs to prescribe for anyone by reading an advertisement in the Journal of the American Medical Association or a State medical journal or magazine? Is that what you are going to say to the people of this country? Are we going to say that we expect the physicians, the professional people in whose hands we place our lives, to practice medicine by an advertisement contained in a magazine somewhere? If that is what you are going to say, let me show you how difficult it would be to include everything about a drug in an advertisement in some medical journal somewhere.

When you try to say that everything with respect to side effects, contraindications, and effectiveness has to be put into an advertisement somewhere, I can say to you it is not possible to do it. You can get scientists and doctors, you can get pharmaceutical people and all those who work in laboratories and drug manufacturing companies to express different opinions all over the lot in many cases as to whether or not there is a side effect or this, that, or the other thing. As I say, I am not satisfied with the language.

From various sources the doctor marshals his facts relating to a particular drug and makes his own decision as to whether or not to prescribe it for a particular patient.

I think it is almost an insult to the medical profession to give the impression that they practice medicine from advertisements in medical journals. I think it is an indication that we do not trust the doctors in making up their minds as to what drug should be prescribed for a patient for a particular ailment. I would not want my doctor to prescribe by reading an advertisement somewhere, and I do not think anyone else would, either.

So I think we better be careful about tying this amendment down, and not giving us an opportunity to work it out. I know that there has been a lot of interest in it down in the Department of Health, Education and Welfare. I know a letter has been circulated by the Secretary. I am not sure that we can require every new drug that comes out to state all of these things in an ad somewhere.

There are two things to consider. You have received letters from doctors all over the country on this subject. They were worried and disturbed about this provision. When the amendment was adopted, it was a vehicle for working something out. State medical societies contacted every Member, and you had on your desk a statement as to the problem with which they would be faced. You had information from the advertising people saying that what you were going to do through this procedure was effectively to destroy the advertising that goes in medical journals which serve a very useful purpose to doctors all over the country.

Mr. Chairman, I am just telling the members of the committee what the facts are. I do not believe we ought to take hasty action here which would prevent us from working this matter out when we get into conference on it.

Mr. DINGELL. Mr. Chairman, I rise in support of the amendment.

Mr. Chairman, comment was made that this is going to require the publication of an ad in a medical journal to be voluminous. Permit me to read the language of the bill. The bill on line 1 says: "and such other information relating to side effects, contraindications, and effectiveness shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e)."

Mr. Chairman, this means after a hearing. It means an opportunity to be heard by the party concerned. That is what it means. It does not mean that there are going to be vast, voluminous statements in these ads. It does not mean that the people placing the ads are going to be denied an opportunity to put them into the medical journals.

Mr. Chairman, what this amendment says is this: That no longer will irresponsible manufacturers be able to put in medical documents, statements which are disproved by the Journal of the American Medical Association, which are disproved as irresponsible and unfactual statements with regard to effectiveness, and unfactual and irresponsible statements with regard to contraindications.

Mr. YOUNGER. Mr. Chairman, will the gentleman yield?

Mr. DINGELL. I would be glad to yield to the gentleman from California.

Mr. YOUNGER. Is the gentleman going to propose the other section up there which the gentleman said he was going to put in?

Mr. DINGELL. I shall be happy to do so. As a matter of fact, if the gentleman desires, I will ask unanimous consent to include that language in the amendment offered by the gentleman from Minnesota.

Mr. YOUNGER. If the gentleman will yield further, it was my understanding that the gentleman was going to put that in.

Mr. DINGELL. I was at the time our negotiations were going on. I would be happy to do so, if the gentleman desires.

Mr. YOUNGER. I think it ought to go in.

Mr. DINGELL. Mr. Chairman, in order to facilitate this, I ask unanimous consent that the amendment offered by the gentleman from Minnesota [Mr. BLATNIK] be amended to include a further amendment as follows:

On line 1, page 58, after the word "information" insert "in brief summary".

Mr. HARRIS. Mr. Chairman, reserving the right to object—and I do not like to object to the gentleman's request—I am afraid the gentleman is hastily doing something here which has not been given the fullest consideration. I have been talking with the gentleman from Minnesota, and I think we have language that we can include which is a little different from what the gentleman from Michigan has offered.

Mr. YATES. Mr. Chairman, a parliamentary inquiry.

The CHAIRMAN. The gentleman will state it.

Mr. YATES. Is it in order for the gentleman from Michigan to offer his language as an amendment to the amendment which has been offered by the gentleman from Minnesota?

The CHAIRMAN. If it is an amendment to the amendment. But that is not clear, of course. I may say to the gentleman that the unanimous consent request is now pending which has been requested by the gentleman from Michigan.

Mr. YATES. I understood the gentleman from Arkansas objected to it.

The CHAIRMAN. The gentleman from Arkansas has reserved the right to object.

Mr. YATES. Had the gentleman from Arkansas objected?

Mr. HARRIS. I will if necessary.

Mr. YATES. I ask that the distinguished chairman offer the language as

an amendment to the amendment of the gentleman from Minnesota.

Mr. HARRIS. I think we can probably work something out.

Mr. DINGELL. Mr. Chairman, I ask unanimous consent to withdraw my amendment in order that we may proceed.

The CHAIRMAN. The gentleman from Michigan [Mr. DINGELL] withdraws his request. Is there objection to the request?

There was no objection.

Mr. DINGELL. Mr. Chairman, with regard to the statement made about the attitude of doctors, permit me to read from a survey made for the American Medical Association as a service to the Ethical Pharmaceutical Industry:

The following was found to be the reaction of doctors to drug advertisements—

And listen to this. The most heinous and despicable practice that doctors found was this—

a company knowingly misleading the doctor through bad advertising.

According to the survey, this is accomplished in three ways. First, by "exaggerated product claims." Second, by "releasing news on a drug to the medical profession before it has been fully tested." And, third—the worst of all—"advertising the advantages of a drug without mentioning its side effects." On this last point, the survey found, 90 percent of the doctors consider it "the most heinous crime a pharmaceutical company can commit."

What we say is that the doctors should be protected as they desire to be according to their own survey from ads which fail to give a full statement as to contraindications, a full statement as to side effects.

You have all heard about norlutin. It was a substance which was marketed and made available to mothers. This substance created male hermaphroditism in female infants. Three months after this fact was found and was reported on in a circular to the medical profession, the manufacturers' ads were still proclaiming the safety of norlutin.

This is what we seek to stop. We seek to stop irresponsible advertising to the medical profession. We seek to see to it that insofar as is reasonably possible a doctor, when he prescribes, has the fullest information that is available and that the ads which he receives and which surveys by the medical profession have found to be the largest influencing factor on doctors in their prescription of medicine make available the full truth.

Mr. Chairman, I ask unanimous consent that the gentleman from New York [Mr. CELLER] may extend his remarks at this point in the RECORD and include extraneous matter.

The CHAIRMAN. Is there objection to the request of the gentleman from Michigan?

There was no objection.

Mr. CELLER. Mr. Chairman, the drug bill before the House today is sorely needed, and it has my wholehearted support.

This bill is the outgrowth of years of painstaking investigation and hearings by both Houses of the Congress. It is a response to a longfelt need to reform the abuses which have been found in the marketing and promotion of the new drugs.

As a result of the disclosures before the Antitrust and Monopoly Subcommittee of the other body under the distinguished and able chairmanship of Senator KEFAUVER, I joined with Senator KEFAUVER on April 12, 1961, in introducing H.R. 6245—the counterpart of S. 1552, the original Senate drug bill. The hearings held before the Antitrust Subcommittee of the Committee on the Judiciary on H.R. 6245 in May of this year, developed overwhelming evidence of the need for such legislation as we now have before us. At our hearings—where the tragic thalidomide story was told for the first time by Dr. Helen Taussig of Johns Hopkins—a number of distinguished members of the medical profession strongly supported a new drug-control law with most cogent reasons.

There is one provision in this bill, however, which gives me pause. The bill, as adopted unanimously by the other body, requires truth in drug advertising. It provides that a prescription drug shall be deemed misbranded "unless the manufacturer includes in all advertisements and other printed matter with respect to that drug a true statement of, first, the established name, second, the formula, and third, such other information relating to side effects, contraindications, and effectiveness as shall be required."

This provision is in full accord with the President's Consumer Message of March 15, 1962, wherein the President said:

The physician and consumer should have the assurance * * * that any drug or therapeutic device on the market today is safe and effective for its intended use; * * * and that the accompanying promotional material tells the full story—its bad effects as well as its good.

There has been added to this bill, however, a destructive qualification that the drug manufacturer is relieved of the responsibility for telling the truth, and the whole truth, and nothing but the truth about his drug, if the advertisement invites the doctor who reads it to write for a brochure which does tell the truth. It is to the last degree unlikely, I submit, that the busy doctor can find time in his crowded day to write the dimly remembered manufacturer to get the full story about a drug he has seen described in an alluring, but uninformative, advertisement.

Here, where health, indeed life itself, may be at stake—here above all is the outworn doctrine caveat emptor obsolete.

Our securities laws provide that stock may not be sold to the public against false or misleading information. I fail to see why we should not be equally stringent in the sale of lifesaving—but potentially dangerous—drugs.

While I am well aware of the many medical miracles wrought by our modern wonder drugs, and while the drug companies have many splendid accomplishments of which they may justly be proud, I am not convinced that false or misleading drug advertising is the price we must pay for pharmaceutical progress.

During the hearings of our Antitrust Subcommittee on H.R. 6245, a veritable parade of eminent doctors protested the excesses and abuses of drug advertising.

Dr. Leona Baumgartner, then the distinguished commissioner of the New York City Department of Health and now the newly appointed Deputy Administrator of AID, testified before the Antitrust Subcommittee—page 67:

In short, the physician is bombarded with seductive advertising which fails to tell the truth, the whole truth, and nothing but the truth.

This often misleads him into prescribing a new drug without adequate warning or information about its possible side effects and, indeed, without any solid clinical evidence that the drug is effective or is even as safe as the advertisers claim. It is not sufficient to say that some law in some book presently forbids some of these practices. Long before governmental authorities are in a position to prove the illegality of these practices and get the cumbersome legal machinery into motion and remove the drug from the market, grave harm has been done.

Dr. Baumgartner added—page 72:

I can say, however, from personal experience and from the experiences of literally hundreds of doctors with whom we are in close contact that the torrent of new drug advertising which cascades daily into the office of the practicing physician is at once confusing and often misleading.

The doctor is daily overwhelmed with more material than he can possibly read, to say nothing of remembering the vaguely worded warnings, if, indeed, there is any warning, in small print at the back of an advertising brochure. Even where warning is given in an initial brochure, it is frequently followed by a stream of literature which extols the claimed virtues of the drugs so glowingly as to take all attention away from any hazards in use of the drug.

Dr. Baumgartner described some 15 drugs—12 of them prescription drugs—which had to be recalled from the market after extensive advertising because of such side effects as "cataracts, baldness or thinning of the hair, serious skin changes such as severe skin peeling and hardening of the skin, reduction of white blood cells, impotence, diminishing libido, vomiting, and vaginal smear alterations."

Dr. Baumgartner was followed by Dr. M. Harold Book, assistant professor of neuropathology in the Graduate School of Medicine at the University of Pennsylvania. Dr. Book testified before the subcommittee—pages 105 and 106:

In doing an autopsy on a patient who has had a serious illness and has been treated by a number of different drugs, as is usually the case when the doctor is striving desperately to save the patient, I have the distinct impression that the patient has suffered from the treatment as well as from the disease. * * * Sometimes it is apparent that the treatment has shortened the life of the patient. This might be considered a sort of involuntary euthanasia.

From personal experience with such tragic cases, Dr. Book delivered this scathing indictment of drug advertising—pages 101 and 102:

The drug houses are noticeably coy in publicizing the exact number and seriousness of side effects attending the use of their new products. In their advertisements, their brochures, their detailmen's pitch, and so

forth, they speak rather diffidently in terms like "side effects are minimal," "with few significant side effects," "no serious side effects noticed," and so forth.

However, they are careful to refrain from giving the number of the side effects, both slight and serious, per hundred treated cases.

Dr. Book also pointed out that the revenues provided by drug advertising offers a strong temptation for the medical journals to indulge the exuberant advertising claims of the drug manufacturers. Dr. Book testified—page 108:

For example, the advertising by the drug manufacturers, much of it of questionable nature, as has been amply demonstrated in the Senate hearings, has increased to the point where it now finances roughly half of the activities of the American Medical Association.

The CHAIRMAN. Please explain in what way the American Pharmaceutical Association finances half of the activities of the American Medical Association.

Dr. BOOK. I say that the advertising in the journals of the American Medical Association now pays for roughly half of the operating expenses of the American Medical Association.

The CHAIRMAN. Because of this practice there may be something akin to a conflict of interest.

The American Medical Association is supposed to act as the judge of the clinical and therapeutic value of these drugs. Therefore, knowing on what side their bread is buttered, they might lean to the side of the drug manufacturers who have so materially helped them by placing their ads in the medical journals. Is that what you are trying to drive at?

Dr. BOOK. That is right. That is exactly the feeling I get.

There is a distinct dichotomy between the editorial pages in the journals and the advertising pages. The editorial pages are of a very high plane of excellence. I cannot say the same for the advertising.

Asked whether most doctors would prescribe drugs for their patients on the basis of drug advertising before engaging in further research as to possible side effects, Dr. Book testified—page 113:

I have the impression, which is based on no survey, that doctors simply do not have the time to go into all of these things.

One might say that they should take the time—that may be true—but I have the feeling that they do not, because there are just too many of these things for them to cope with.

Here is cogent evidence indeed of the devitalizing effect of an amendment which would dispense with truth in drug advertising, provided only that the doctor be able to write the manufacturer in order to obtain the true facts.

Further revealing testimony on the abuses of drug advertising was given by Dr. Martin Cherkasky, director of Montefiore Hospital in New York City. Dr. Cherkasky testified—page 201:

Many of us in the medical profession have known for years that there are grave defects in the whole system of the manufacture, promotion, and distribution of ethical drugs.

Dr. Cherkasky accurately summarized the purposes of this bill when he stated—page 202:

I would like to make certain that our harassed and overburdened physicians are not confounded and confused by the conflicting claims, the myriad of names, and the ever-present pressure of the pharmaceutical competition for the doctor's brain and prescription pad.

According to Dr. Cherkasky, a requirement of truth in drug advertising is urgently needed because present-day malpractices are endangering the ability of our doctors to care for their patients—the American people. Dr. Cherkasky testified—pages 211 and 212:

The quantity and quality of the promotion and advertising of pharmaceuticals by the drug industry is undoubtedly seriously interfering with the ability of the average physician to render the highest quality of medical care.

Even a large teaching hospital such as my own, with highly sophisticated professional control and supervision, must be ever on guard against the vigorous pressures of the drug salesmen. Up until 4 years ago, detailmen from the drug manufacturers were allowed on occasion to set up displays at the entrance to the hospital cafeteria. We have discontinued this practice since we found that our physicians, especially our young house staffmen, were being confused by the insistent pressures of the "educational" efforts of the detailmen.

I checked with several other leading hospitals in New York City and found that they, too, have taken this step. Should it not give us all some cause for thought that teaching institutions find it desirable to shield young doctors from the "educational" efforts of the drug companies?

Of course, we cannot do anything to protect the doctors from the promotional materials which come through the U.S. mails or as presented in the numerous medical journals.

Mr. JOHNSON. Mr. Chairman, may I interrupt here a moment?

Doctor, are not the detail men the people on whom the general practitioner is apt to rely for information on new drugs?

Dr. CHERKASKY. When you consider the fact that there were almost 6,000 new drugs introduced in a 10-year period from 1949 to 1959, you know, it is impossible for any doctor, from his own resources, to be able to pick out the good drugs from the bad ones.

Unfortunately, many doctors rely heavily, and sometimes almost exclusively, on detailmen for information with regard to drugs, and, of course, as you know, I use the term "education" in quotes. The detail man does not educate, he indoctrinates; and there is an enormous difference between "education" and "indoctrination."

Mr. JOHNSON. In other words, the detail men are, so to speak, the shock troops in the assault on the doctor's attention, is that not correct?

Dr. CHERKASKY. When you also think of the fact that there are approximately 150,000 practicing physicians in the United States and there are approximately 15,000 detail men, that is about 1 for every 10 physicians, so that you can see the troops are thick.

Think of it, one detail man, whose compensation must necessarily depend on his success in promoting his employer's products, for every 10 doctors. Of course the detail man "indoctrinates" and, as Dr. Cherkasky put it, "the troops are thick" indeed. Dr. Cherasky continued—pages 212 and 213:

But what of the average general practitioner being bombarded daily with what has been estimated as about $5,000 worth of drug promotional material a year for each doctor?

An article in Fortune magazine of May 1960 has this to say about doctors' response to drug advertising:

"Drug companies have learned that doctors respond to the same kinds of emotional appeals as laymen. They are influenced by the same advertising techniques that are used for mass consumer advertising. They accept new drugs with amazing rapidity * * * this is true in part because it would appear that a physician's own market position is strongly influenced by his reputation for using the latest drug."

Or, take the statement in the 1960 Drug Market Data published by the National Wholesale Druggists Association:

"One of the reasons for the success of the supermarket is that the consumer does not have to ask for what she wants. She sees and recognizes what she wants. The merchandise is right there to suggest its purchase and perhaps to remind her that she needs something she does not have on today's shopping list. This same principle produces results in medical journals carrying a large volume of advertising."

Is that not distressing? After all, we are not buying soapsuds.

As a response to this, I agree fully with Senator KEFAUVER, who said in his speech before the Senate introducing the Senate bill, that here "we are not dealing with gadgets, but products of health, life, and death."

Dr. Dixon, the new Chairman of the Federal Trade Commission, was quoted in the New York Times of June 1, 1961, as saying:

"Twenty-four cents of every dollar the drug manufacturer gets for a prescription is used to promote advertising and sell their products."

It has been reported that approximately $750 million a year is spent on advertising and sales promotion.

Is it not startling, when you think of this figure, to realize that in 1957 the total expenditure of all of the medical schools in the United States for education was about $200 million? And I would guess that today we could say all the expenditures of medical schools and all the expenditures in hospitals for the training of more than 40,000 interns and residents does not approximate the amount of money the drug companies spend on advertising of drugs.

Mr. RODINO. It is a very interesting observation.

Dr. CHERKASKY. It is a tough competition between education and indoctrination, as you can see.

These vast sums of money spent in this manner increase the costs of drugs to the consumer and to the hospital. Just as serious is the danger that the busy physician, so inundated, will be unable to discriminate intelligently between which drugs are valuable and safe, and those which are useless or even on occasion, harmful.

In short, these extravagant expenditures by the drug companies lavished on advertising not only result in higher prices to the consumer, and some of these prices are extortionate, they actually endanger the patient by confusing the doctor.

Dr. Cherkasky was asked about the pernicious effects of advertising which contains exaggerated therapeutic claims for the drug. This was his testimony—page 214:

Doctor, if you give a patient a drug which is ineffective when he is very sick, what you are really doing is delaying treatment with a drug that would be effective?

Dr. CHERKASKY. Of course you are. You are not treating him appropriately, and, as a matter of fact, there may be other drugs

which are a little older, which have been swept aside by the new ones, which may not be any better or not as good.

Mr. JOHNSON. So that could be equally as bad as giving him drugs with side effects?

Dr. CHERKASKY. It could be deadly.

The Senate committee at its hearings last year heard much testimony concerning the reliability of the printed advertising material which the practitioner receives. These are often misleading and slanted. The cases of Decadron and Diabinese immediately come to mind (pp. 202 and 210 in the report of the committee hearings).

In both instances these drugs had very serious side effects, which are virtually absent from the advertising. You read the advertising for these two drugs, and you would not have a clue that there are serious problems attending their use.

As a matter of fact, one of the things that is so distressing about it is that Diabinese came out after Orinase. They are both oral preparations used for the treatment of diabetes. Orinase is a fine drug, with very, very few side effects, and this other material was introduced as, presumably, being better because it was more powerful, when, in fact, it has considerable and significant side effects, and the general practitioner out in the community, reading the advertisements, would not have an idea about this at all.

Referring to an article by Dr. Charles May, professor of pediatrics at the College of Physicians and Surgeons of Columbia University, in the January 1961 issue of the Journal of Medical Education, Dr. Cherkasky testified—page 215:

Dr. May also refers in his article to an example of serious conflict between promotional material and scientific information appearing in the same issue of the Journal of the American Medical Association. A synthetic progesteroid compound called Norlutin was advertised in the March 5, 1960, Journal without any reference to side effects. In the same issue of the magazine, a Dr. Wilkins reports on 36 cases of female pseudohermaphroditism in infants born of mothers who during pregnancy had been given norlutin. Again quoting Mr. May:

"The same advertisement for norlutin has continued to appear regularly in the J.A.M.A. for the ensuing 3 months since the article by Wilkins appeared in that Journal; in spite of this. 'During the past year or two, norlutin has caused fetal masculination with sufficient frequency to preclude its use or advertisement as a safe hormone to be taken during pregnancy.' "

A drug which is advertised in the same issue of the Journal, without pointing out the dangerous side effects, and this advertisement is continued for 3 months, whereas there is an article in the same Journal which says this is not a safe drug to be used durin pregnancy.

Think of it. A drug which has been associated with male sex characteristics in female babies, and the manufacturer does not have the candor to warn the doctors of the possible danger.

Indeed, the manufacturer has now applied for a license to sell norlutin as an oral contraceptive. One can only hope that norlutin is 100-percent effective for this purpose, else we shall have another thalidomide disaster.

Dr. Cherkasky's testimony continues—page 215:

Potent drugs inevitably have dangers of one sort or another. You may further sales, but certainly not the public's health by disregarding, omitting, or minimizing hazards. • • • I would say that when you see in the same edition of the Journal a scientific article pointing out the dangers and you have almost side by side an advertisement which does not mention those dangers and those advertisements continue for 3 months, you must come to the conclusion that the advertising people and the doctor people are not talking to one another, or not reading one another.

Speaking of the contrast between the expenditures of the drug companies on advertising and the money they devote to research, Dr. Cherkasky testified—page 218:

I do not know exactly what they spend for research, but I would be perfectly willing to swap it and say that what they spend for promotion and advertising ought to be spent for research and what they spend for research ought to be spent for promotion and advertising.

Mr. RODINO. The figure that we have is 6.3 percent spent for research, and advertising, I think this is the area of some 24 or 25 percent.

Lastly, Dr. Cherkasky testified—page 222:

I would say that advertisements are a prime source of prescription or drug information for many of the practicing doctors.

He added—pages 222 and 223:

When you recognize that there are 400 or 500 drugs introduced each year, and when you think of the enormous amount of literature that a doctor might have to wade through, it is physically beyond the capacity of a general practicing doctor to really look up the source material. Some drugs are brought on the market where the material dealing with their danger or effectiveness is so skimpy that even experts could not find out.

In the light of all this testimony, it is not surprising that Dr. Helen Taussig of Johns Hopkins concluded her testimony before the Antitrust Subcommittee on the thalidomide tragedy with the specific recommendation that warnings as to side effects and contraindications—page 149—"be printed in type as least as large and as prominent as are used for any trade name or brand thereof."

Dr. Taussig added: Page 420:

This is to prevent the warnings being printed in such fine print that people will overlook reading.

It seems simple, but it is an important point to bring to the attention of the doctors.

I have reviewed so fully the testimony before the Antitrust Subcommittee on this subject, both because it might otherwise be overlooked, and more important, because it establishes beyond a peradventure, in my judgment, that the truth-in-drug-advertising provision in this bill will be a grisly joke unless the harassed and busy doctor is relieved of the burden of learning the truth from the manufacturer, as this bill now provides.

At the urging of the President, the Judiciary Committee of the other body inserted, and the Senate unanimously approved, a truth-in-drug-advertising provision which would not be hamstrung by any such self-defeating qualification.

We have it on the authority of the Secretary of HEW that there is "no justification" for any such provision watering down this central feature of the bill. To believe otherwise would be to fly in the face of experience, to say nothing of the unanimous testimony of the distinguished doctors before the Antitrust Subcommittee which I have canvassed above.

To sum up, therefore, I strongly endorse this much needed drug bill, but I earnestly hope the House will amend the bill to make effective its truth-in-advertising provisions.

Mr. DINGELL. Mr. Chairman, I ask unanimous consent that the gentleman from California [Mr. Moss] may extend his remarks at this point in the RECORD.

The CHAIRMAN. Is there objection to the request of the gentleman from Michigan?

There was no objection.

Mr. MOSS. Mr. Chairman, in my opinion the committee bill on H.R. 11581, the drug amendments of 1962, is an excellent bill in many respects, but it is my feeling that it does not meet all the problems. I support the amendment to correct one important deficiency, namely, the advertising of prescription drugs to physicians. This would require that drug advertisements contain information relating to side effects and efficacy. This is substantially the same requirement as is contained in the bill passed unanimously by the Senate. The requirement stems from the failure of most drug advertisements to provide adequate information, even on the critical matter of injurious side effects of new drugs. The committee heard testimony from leading physicians to the effect that it is impossible for them to keep currently informed of the state of medical knowledge to be found scattered in more than 400 medical journals on the approximately 300 new drugs introduced each year. If the bill, amended as proposed, does not meet all the problems, I believe it will be urgent that further consideration should be given the matter early in the next Congress.

Mr. HARRIS. Mr. Chairman, I move to strike out the last word.

Mr. Chairman, I have discussed the proposed amendment of the gentleman from Michigan, Mr. DINGELL, to the amendment of the gentleman from Minnesota, with them and with the staff. I think the gentleman from Minnesota is now in a position where he is willing to ask unanimous consent that his amendment be modified in line with the suggestion of the gentleman from Michigan, Mr. DINGELL, a moment ago; that is, on page 58, line 1, after the word "information" insert "in brief summary."

Mr. BLATNIK. Mr. Chairman, I ask unanimous consent that I be permitted to modify my amendment as suggested by the distinguished chairman, on page 58, line 1, following the word "information" insert "in brief summary".

The CHAIRMAN. Is there objection to the request of the gentleman from Minnesota [Mr. BLATNIK]?

Mrs. CHURCH. Mr. Chairman, reserving the right to object, I rise to protest against legislation of this importance being written in this manner on this floor. If the rest of the House is not confused as to what is going on, under these tactics, I confess that I certainly am. The gentleman from Michigan first mentioned that certain negotiations had been in being, of which the House cer-

tainly has not been informed; and furthermore I would like to ask how it could actually be expected that anyone could adequately express in "brief summary" the side effects of many drugs? Is this even a practical suggestion?

Mr. DINGELL. Mr. Chairman, if the gentlewoman is addressing that question to me, I should be very happy to answer it.

Mrs. CHURCH. No; I was directing the question to the chairman of the committee, the gentleman from Arkansas [Mr. HARRIS].

Mr. HARRIS. Mr. Chairman, will the gentlewoman yield?

Mrs. CHURCH. I yield to the gentleman.

Mr. HARRIS. As I understand it, after listening to the gentleman from Michigan [Mr. DINGELL] and talking to the gentleman from Minnesota [Mr. BLATNIK], who is the author of the amendment, what he has in mind is in line with the conclusion we have all come to that it would accomplish the purposes that were desired here and what was intended by the committee when the amendment was adopted.

We do not intend to have an ironclad policy that the advertisement should not contain all the information that the manufacturer has and that can be put in there, but we do contend that we should not, by legislation, require it to be something which it cannot be. We think that this language, which goes with the rest of the language in the bill, would accomplish the purposes which we intended.

Mrs. CHURCH. Further reserving the right to object, Mr. Chairman, may I ask the chairman of the committee if he feels that however impractical this amendment appears, he feels that he could go to conference with it and work out something that would be reasonable? Granting that we all wish to give adequate protection to the public, there is a responsibility also not to place impossible requirements upon members of the drug industry of proven integrity.

Mr. HARRIS. As I have told the gentleman from Minnesota, we could take this to conference and analyze it further and improve on it if necessary.

Mrs. CHURCH. Again pointing out that it might well be impossible, whatever the intent, to give total or adequate description of the side effects of a given drug in brief summary, I would urge the gentleman to give full consideration in conference to all the implications involved.

The CHAIRMAN. Is there objection to the request of the gentleman from Minnesota to modify his amendment?

There was no objection.

The CHAIRMAN. The Clerk will report the amendment as modified.

The Clerk read as follows:

Amendment offered by Mr. BLATNIK: On page 58, strike out line 15 and all that follows down to but not including the quotation marks in line 22, and on page 58, line 1, after "information" insert "in brief summary".

Mr. HOLIFIELD. Mr. Chairman, I move to strike out the last word.

Mr. Chairman, I have asked for this time for the purpose of clarification. I am a little bit confused at the position in which we stand at this time. I should like to ask the author of the amendment, the gentleman from Minnesota [Mr. BLATNIK], if his amendment as now presented to the House for action still retains the strikeout of lines 15 to 22.

Mr. BLATNIK. Yes.

Mr. HOLIFIELD. As to the addition of the words "in brief summary," I should like to ask just exactly what those words mean. The words "brief" and "summary" leave a loophole wide enough to drive a 10-ton Mack truck through. I do not know how brief it would be or how much of a summary it would be.

Mr. DINGELL. Mr. Chairman, will the gentleman yield?

Mr. HOLIFIELD. I yield to the gentleman from Michigan.

Mr. DINGELL. I am the individual who was responsible for drafting the original language. It is to see to it that information in capsule form goes to doctors in connection with the advertising. A situation arose about mycetin where it was permitted to go on the market, but it had severe side effects. It was permitted to go on the market but with the requirement that each and every advertisement set forth in brief form these side effects. These side effects were covered in about six lines, about six words across. I assure the gentleman this amendment will offer adequate protection to the American people and allow sufficient authority to the Food and Drug Administration to police closely bad advertising.

Mr. HOLIFIELD. I am glad to have that assurance from the gentleman.

Mr. FARBSTEIN. Mr. Chairman, will the gentleman yield?

Mr. HOLIFIELD. I yield to the gentleman from New York.

Mr. FARBSTEIN. Is there any objection to the inclusion in that phrase of the word "adequate"? This is "in brief summary." We should include the word "adequate" in the phrase.

Mr. DINGELL. I would be happy to go further in perfecting this, but I say a brief summary would be adequate to provide protection to the American people under the regulations which would be adopted by the Food and Drug Administration.

Mr. HOLIFIELD. With the assurance of the two gentleman who offered this amendment, I am prepared to support it. I just cannot see how we can write this legislation and in one instance require information to be furnished to the distributor and manufacturer and not require adequate information to be furnished to the doctors in these advertisements.

Now let us be realistic about this thing. These medical journals are looked at by doctors a lot more than they look at their textbooks once they get into their medical practice and I believe that this language that the gentleman from Minnesota has offered is certainly good language and I hope the committee supports it.

Mr. YOUNGER. Mr. Chairman, I ask unanimous consent that the gentleman from Minnesota [Mr. JUDD] may extend his remarks at this point in the RECORD.

The CHAIRMAN. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. JUDD. Mr. Chairman, not many Members of the Congress have had the opportunity to obtain more first-hand information regarding the American drug manufacturing industry than I. It is not possible to attain perfection in any field dealing with human beings, no two of whom react exactly the same way to a given drug or anesthesia or operation. Should we refuse our patients the blessings of anesthesia because, despite our study, and experience, and precautions, an occasional patient dies unpredictably under the very safest anesthetic?

It is with genuine concern that I hear attack by some upon the safety of our American medicines. In the agitation we have all experienced following upon the horrors of the thalidomide episode, I am afraid we have lost sight of the most important point of all.

We are forgetting that, as a matter of actual record and fact, American drugs are the safest in the world. We are overlooking the truly exemplary safety record of the American drug industry. Some have minimized—even assailed—the remarkable system we now have for bringing to our people lifesaving new medicines.

I ask you to bear in mind that thalidomide never came on the market in the United States. That is the heart of the matter. The drug was never marketed here precisely because the system we have for testing and appraising new drugs is an effective system.

As a nation, we have expressed our gratitude for the vigilance and dedication of Dr. Frances Kelsey of the Food and Drug Administration. Dr. Kelsey deserves this tribute. But we should never lose sight of the fact that Dr. Kelsey's action was taken as part of a system. It is a system of check and countercheck that has made possible an intelligent and productive partnership between private industry and Government.

Thalidomide is not an example of the failure of our system. On the contrary—it is proof of its effectiveness. In thalidomide, we have seen a dramatic demonstration that our existing laws are fashioned to protect the people, and at the same time to provide a climate of freedom in which research can be conducted.

It is also true, I believe, that progress is never made without some danger. The early history of aviation certainly bears out this point and the occasional tragedy despite all the safeguards known. You will remember that when Astronaut John Glenn appeared before us here, he also warned that lives may be lost as man pioneers in outer space; and he urged us not to let inevitable tragedies stand in the way of scientific progress.

I regret that the American drug industry is being criticized as a whole on the score of safety because the criticism

is not justified. There is no evidence to show that our drugs are to any significant degree unsafe. Quite the contrary. Let me give you some figures.

In the past 4 years, according to the Food and Drug Administration, only about 15 of some 780 new products have been withdrawn from the market because of a question of safety. And in the case of these 15 drugs, most were voluntarily withdrawn by the companies producing them. Moreover, in most of these situations, the drug companies themselves discovered the side effects that raised a question of safety, and voluntarily reported this information to the Food and Drug Administration.

This is a record of safety that would be hard to beat. In every profession or business there will be some who do not live up to the highest standards. That is why we pass laws designed to protect the good from the bad. But it is equally wrong to impute to an industry any practice which the industry itself fights to eliminate.

The Pharmaceutical Manufacturers Association recently issued a statement entitled "Safety of Prescription Drugs," which gives some idea of how this safety record has been achieved. I should like to quote from this statement:

> Testing of drugs in industry before they are marketed is extremely thorough. For example, the Pharmaceutical Manufacturers Association estimates that its member firms made use of nearly 9 million animals in 1961, including 5.7 million mice, 2.2 million rats, 739,000 chickens, 107,000 guinea pigs, 98,000 rabbits, 36,000 dogs, and 18,000 cats, and thousands of other birds and animals.
>
> Beyond a certain point the testing of a drug in animals may be of little help in determining its safety and effectiveness for man. Untoward effects in humans may appear only after several years of use, and adverse reactions in man may not be demonstrable in animals.
>
> But if research is to proceed, testing in humans must at some point be carried out. A new drug will be administered to humans only when, in the opinion of the responsible physician, animal studies have indicated that the drug may be used without undue hazard and that it has probable usefulness in the practice of medicine.
>
> When the drug seems safe and effective in a small number of humans, it must be tried on a wider scale under expert scientific supervision. Finally, a large enough sample of its use in man must be obtained to determine the safety and utility of the drug in actual clinical practice.
>
> At each of these clinical testing stages, many compounds obviously are eliminated. At the conclusion of the final stage, only one out of an estimated 3,000 compounds originally synthesized by the pharmaceutical manufacturer survives as a drug.

It is easy enough, using hindsight, to chastise a drug manufacturer because he sought to put thalidomide on the market. But remember that the manufacturer did so only after conducting exhaustive tests—tests that were at the time convincing to informed scientific judgment in the United States as well as abroad. Had thalidomide not been on the market in Europe, there would have been no evidence of its dangers. Had thalidomide not been on the market in Europe, there probably would have been no scientific reason to prohibit its sale here. Experience, and experience alone, gave the key to the drug's true nature.

I am not opposed to making drugs as safe as they can possibly be, quite the contrary. In considering the legislation before us, we must keep in mind three considerations.

First, we must have the best possible laws to prevent the marketing of unsafe drugs. Second, we must be certain beyond all reasonable doubt that those laws will not stand in the way of scientific research and medical progress. Third, we must not belittle the accomplishments of the American drug industry, which now takes and has in the past taken every step that is scientifically practical to see that safe drugs are produced.

I am asking that we keep a level head on this issue. No one—least of all the American people—is done a service by saying that our drugs are unsafe. Such statements are misleading, and are likely to undermine public confidence in the safety and quality of our medicines.

The fact is that a question of safety has been raised about only a tiny percentage of the many hundreds of new drugs put on the market in recent years. While we properly concern ourselves with safety, let us remind ourselves also of the great accomplishments of the drug manufacturing industry.

Since the introduction of potent new drugs in 1944, the death rate from influenza, tuberculosis, and rheumatic fever dropped dramatically. New drugs have made mastoiditis, once a common and painful ailment, so rare that medical schools now have difficulty in locating cases for teaching purposes. New medicines and health measures have lengthened our lifespan by up to 20 years and made it possible to live in better health than ever before.

Finally, let me remind you that the drug industry itself — through its Pharmaceutical Manufacturers Association—has appointed a learned commission to investigate the question of drug safety. This industry has a long and distinguished reputation for taking responsible action, and I am confident that this commission will do its utmost to find practical scientific solutions to the problems of drug safety.

I ask only that, in all fairness and in concern for the future well-being of our people, we do not damage with unjustified charges an industry that has done so much to make America the healthiest nation in the world.

The CHAIRMAN. The question is on the amendment offered by the gentleman from Minnesota [Mr. BLATNIK].

The amendment was agreed to.

Mr. WAGGONNER. Mr. Chairman, I ask unanimous consent that the gentleman from New York [Mr. MULTER] may extend his remarks at this point in the RECORD and include extraneous matter.

The CHAIRMAN. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

Mr. MULTER. Mr. Chairman, this is a good bill. Its enactment is long overdue. It will be a better bill with the adoption of the Blatnik amendment.

A few weeks ago Mr. Howard K. Smith presented in very dramatic fashion the important changes that have taken place in the advertisement of prescription drugs. He demonstrated quite clearly that the practices of the whole industry have changed in recent years and that physicians are being subjected to a veritable barrage of advertising gimmicks to persuade them to prescribe medicines for their patients.

As late as the 1940's, the advertising of prescription drugs was factual and was presented without the techniques of Madison Avenue. Today, advertising, using pictures of pretty girls and happy people, swell the journals of the American Medical Association and other scientific groups. Senator KEFAUVER's investigation established that promotion expenditures of 22 selected drug firms in the American Medical Association Journal alone had grown from approximately $2 million per year to $4 million per year. One advertiser grew from approximately $71,000 per year in 1955 to one-half million dollars in 1960. Plainly, expenditures of this magnitude do play a very important role in what the doctor prescribes. It should be remembered that the person who orders does not buy and the person who buys does not order prescription drugs. When the doctor is persuaded, the patient has no choice over the matter.

The impact of these advertisements is tremendous in persuading physicians to order medicines for their patients. In fairness, both to the physician and to his patient, the advertisement of a drug should not be allowed to express only the good points and to leave the bad to some promotional material that the physician may see at a later time or may never see. If the advertisement can give a brief description of the merits and advantages of using a particular prescription drug, space can be found for a fair summary of any relevant side effects, contraindications, cautions, and related information, to provide a rounded and fair story.

It does not seem to me that it would be asking too much to make the picture of the beautiful woman, or the happy child, or his relieved parents a little smaller in the interest of providing the physician who orders the medicine for his trusting patient a minimum word of caution about possible adverse effects.

The opposition to disclosing side effects, contraindications, warnings, and cautions in the advertising for prescription drugs is based on a false premise that this will destroy medical advertising and with it a number of medical journals.

This is a gross exaggeration of what the full disclosure requirements in advertising would entail. The Secretary is directed to prescribe by regulations the information relating to side effects, contraindications, and effectiveness that would be needed, and the bill provides that except in extraordinary circumstances no such regulation shall require prior approval of the exact content of the advertisement.

The Secretary's regulations necessarily would be limited to a fair summarization of side effects, contraindications as well as effectiveness so that a balanced story appropriate to an advertising page could be presented.

What has happened is that the drug firms and their advertising agencies are trying to scare the medical journals to take up the battle for them.

There can be no justification for half truths either in an advertising piece or in labeling copy. We are dealing with drugs that are lifesaving and which are used in serious, debilitating diseases. Fairness alone requires that the message to the physician be a balanced one giving both the good and the bad of the drug, within the limits of advertising copy, and that the patient's interest not be obscured by a glowing picture of the effectiveness of the drug with no mention at all of its possible side effects and contraindications.

Mr. JOELSON. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. JOELSON: After the semicolon on line 6, page 41, strike out the word "and", and add the following:

"The Secretary shall in consultation with professional organizations representing the medical profession and upon the recommendation of such organizations establish a list of physicians competent as clinical investigators to conduct such investigation; and".

Mr. JOELSON. Mr. Chairman, I think I speak for practically everybody in the House of Representatives when I say we owe a debt of gratitude to the chairman of the committee who has come up with a good bill protecting the American public from unsafe drugs and ineffective claims. However, I believe the bill can be tightened in this respect. The drug companies give drugs wholesale to the physicians for testing. Many of these physicians, although competent doctors, are not clinical investigators. Of course, we would not send a man needing brain surgery to a general practitioner. In medicine today there are specific techniques. All my amendment would do would be to require the clinical investigators to be certified as competent—not by the U.S. Government because we should have nothing to do with it, but I think we should encourage the American Medical Association and the various State societies representing doctors to see to it that the people who test these products are competent physicians trained in the skill of clinical investigation. I think my amendment would encourage the medical profession to stimulate this type of work.

Mr. HARRIS. Mr. Chairman, I rise in opposition to the amendment.

Mr. Chairman, I merely want to say, I think the gentleman has a good idea and there is some merit in what he proposes. But it certainly would not fit in here because it would follow these words which are now in the bill: "Such regulations may provide for conditioning such exemption upon—" and so forth and so on to enumerate subparagraphs 1, 2, and 3. Therefore, it would be completely out of order and the amendment should not be approved.

The CHAIRMAN. The question is on the amendment offered by the gentleman from New Jersey [Mr. JOELSON].

The amendment was rejected.

Mr. DINGELL. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. DINGELL: Page 57, immediately after line 8, and the following new section:

"SEC. 114. (a) Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following new section:

"'SEC. 510. The Secretary shall publish in convenient and readable form and shall distribute on a current basis to physicians, hospitals, medical and nurse training schools, depository libraries, and Federal, State, and local government offices concerned with the handling and utilization of drugs, true and correct copies of all printed matter which the Secretary has required to be included in any package in which any drug is distributed or sold or brochures approved by the Secretary available to practitioners on request.'

"(2) This subsection shall take effect on the first day of the seventh month following the month in which this Act is enacted."

Mr. DINGELL. Mr. Chairman, very briefly, this is the language of the Senate bill which in the consideration by the House committee in some strange and unknown way fell out.

There was no opposition whatsoever to this language in the Senate. The pharmaceutical industry has expressed no opposition whatsoever to the requirements of this provision.

The only thing this language would require of the Department of Health, Education, and Welfare is that as the new drug applications are approved pursuant to this act, a simple, brief, readable statement of efficacy, contraindications, side effects, and other highly pertinent medical knowledge go forth from the Secretary of Health, Education, and Welfare to each of the 170,000 doctors in the United States.

This will make available a regular service to the doctors so that they will have from an official source, without impeachment, thoroughly reliable information each time a new drug is approved.

The cost will run about $10,000 a week according to the highest estimates. This is based upon the number of doctors and the number of copies mailed out.

Mr. SCHENCK. Mr. Chairman, will the gentleman yield?

Mr. DINGELL. I yield.

Mr. SCHENCK. I was going to ask the gentleman to estimate the cost, and also whether or not this does not add an extra burden to the Secretary of Health, Education, and Welfare to become a publishing agent of material already developed and published by pharmaceutical manufacturers.

Mr. DINGELL. It really is not duplication because no really comparable service exists. One publishing house runs about 16,000 copies a year, and this is the information which is available from the American Medical Association only in the bound volumes of their publication.

The United States Pharmacopoeia is published only once every 5 years and gives mostly chemical information, not very much medical information.

The other services, like the Physicians Desk Reference, are services which are actually paid on a sold-space basis by sales from the publisher to the drug houses which put these drugs on the market and they put into these publications only such information as they desire.

These are the reasons why this is important: First of all, other services do not come out with a sufficient frequency. Second, packaged inserts do not meet the needs of the doctors. Third, the information put out by HEW would be authentic and come at such intervals as to be really useful to the doctors.

Mr. SCHENCK. May I ask the gentleman if there is any reason to believe that the information to be published by the Secretary of Health, Education, and Welfare will be any more authentic or reliable than that which is already published by pharmaceutical manufacturers, because you would have to get that information from that source, anyway.

Mr. DINGELL. I think it would be a little more reliable. It will be published not so much in the sense of advertising but in the sense of advising the doctors fully.

Let me say about cost. This was not objected to by anyone in the course of its consideration in the Senate. It had unanimous bipartisan support by Members on both sides of the aisle. The maximum cost would not run over a quarter of a million dollars a year for the cost of publishing, packaging, and mailing back to the doctors throughout the country. I feel it makes available to the doctors a service which will be valuable to them and which will enable them to vastly better serve and protect and to care for the health and welfare of the patients.

Mr. LAIRD. Mr. Chairman, will the gentleman yield?

Mr. DINGELL. I yield to the gentleman from Wisconsin.

Mr. LAIRD. Where does the gentleman get this estimate? There would be 170,000 copies. He stated $10,000 a week. That would not cover the postage.

Mr. DINGELL. This is the estimate that comes from the Senate committee staff which worked on this particular matter.

The CHAIRMAN. The time of the gentleman from Michigan has expired.

Mr. HARRIS. Mr. Chairman, I ask unanimous consent that all debate on the pending amendment close in 5 minutes.

The CHAIRMAN. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

Mr. HARRIS. Mr. Chairman, I rise in opposition to the amendment offered by the gentleman from Michigan. I do not believe the amendment is necessary. The committee considered the amendment and did not agree to it. I do not want to take the position that we are

putting the Department of Health, Education, and Welfare in the business of publishing and distributing a lot of material. We do not know what it would cost. I do not think the gentleman from Michigan knows what it would cost. Also Members of Congress would be called upon to get these publications, like many other things, and we would have to be sending literature all around the country. I do not believe the Congress wants to get into that kind of a situation that we do not know anything about.

Mr. Chairman, I ask that the amendment be defeated.

The CHAIRMAN. The question is on the amendment offered by the gentleman from Michigan [Mr. DINGELL].

The amendment was rejected.

The CHAIRMAN. The question now recurs on the substitute committee amendment as amended.

The substitute committee amendment as amended was agreed to.

Mr. HARRIS. Mr. Chairman, I ask unanimous consent that all Members may be permitted to extend their remarks in the RECORD on this bill.

The CHAIRMAN. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

The CHAIRMAN. Under the rule, the Committee rises.

Accordingly, the Committee rose; and the Speaker having resumed the chair, Mr. FLOOD, Chairman of the Committee of the Whole House on the State of the Union, reported that that Committee having had under consideration the bill (H.R. 11581) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws, pursuant to House Resolution 808, he reported the bill back to the House with an amendment adopted by the Committee of the Whole.

The SPEAKER. Under the rule, the previous question is ordered.

The question is on the amendment.

The amendment was agreed to.

The SPEAKER. The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed and read a third time, and was read the third time.

The SPEAKER. The question is on the passage of the bill.

The bill was passed.

A motion to reconsider was laid on the table.

Mr. HARRIS. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the Senate bill (S. 1552) to amend and supplement the laws with respect to the manufacture and distribution of drugs, and for other purposes, strike out all after the enacting clause, and insert in lieu thereof the provisions of H.R. 11581, to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws, just passed.

The Clerk read the title of the Senate bill.

The SPEAKER. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

The Clerk read as follows:

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Drug Industry Act of 1962".

INFORMATION OF PATENTS FOR DRUGS

SEC. 2. Section 702 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372) is amended by adding at the end thereof the following new subsection:

"(d) The Secretary is authorized and directed, upon request from the Commissioner of Patents, to furnish full and complete information with respect to such questions relating to drugs as the Commissioner may submit concerning any patent application. The Secretary is further authorized and directed, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required."

REGISTRATION

SEC. 3. (a)(1) Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end thereof the following section:

"REGISTRATION OF PRODUCERS OF DRUGS

"SEC. 508. (a) As used in this section—

"(1) the term 'manufacture, preparation, propagation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

"(2) the term 'name' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

"(b) On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register with the Secretary his name, places of business, and all such establishments.

"(c) Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of any drug in any establishment which he owns or operates shall immediately register with the Secretary his name, place of business, and such establishment.

"(d) Every person duly registered in accordance with this section shall immediately register with the Secretary any additional establishment which he owns or operates and in which he begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs.

"(e) The Secretary may assign a registration number to any person or any establishment registered in accordance with this section.

"(f) The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this section.

"(g) This section shall not apply to—

"(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs, or patients under the care of such practitioners in the course of their professional practice and which do not manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;

"(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice;

"(3) persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

"(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

"(h) Every establishment registered with the Secretary pursuant to this section shall be subject to inspection pursuant to section 704 and shall be so inspected by one or more officers or employees duly designated by the Secretary at least once in the two-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive two-year period thereafter."

(2) Any person who, on the day immediately preceding the date of enactment of this Act, owned or operated any establishment in any State (as defined in section 201(v) of the Federal Food, Drug, and Cosmetic Act as amended by this Act) engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, shall, if he first registers in accordance with subsection (b) of section 508 of that Act (as added thereto by paragraph (1) of this subsection) prior to the first day of the seventh calendar month following the month in which this Act is enacted, be deemed to have complied with that subsection for the calendar year 1962. Such registration, if made within such period and effected in 1963, shall also be deemed to be in compliance with such subsection for that calendar year.

(b) Section 301 of such Act (21 U.S.C. 331) is amended by adding at the end thereof the following new paragraph:

"(o) The failure to register as required by section 508."

(c) Section 502 of such Act (21 U.S.C. 352) is amended by adding at the end thereof the following new paragraph:

"(n) If it is a drug and was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 508."

FACTORY INSPECTION

SEC. 4. (a) Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended to read as follows:

"(a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect at reasonable times and within reasonable limits and in a reasonable manner, such factory, ware-

house, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 305 (i) or (j) or section 507 (d) or (g) of this Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the Act). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to—

"(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs, or patients under the care of such practitioners in the course of their professional practice and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;

"(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice;

"(3) persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

"(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health."

(b) Section 704(b) of such Act (21 U.S.C. 374(b)) is amended by inserting after "warehouse," the words "consulting laboratory,".

(c) Subsection (a) of section 302 of such Act (21 U.S.C. 332(a)) is amended by striking out "(f),".

(d) Nothing in the amendments made by subsections (a) and (b) of this section shall be construed to negate or derogate from any authority of the Secretary existing prior to the enactment of this Act.

QUALITY MANUFACTURING CONTROLS

SEC. 5. Section 501(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 351(a)(2)) is amended to read as follows:

"(2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packaging, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess."

NEW DRUG CLEARANCE PROCEDURE

SEC. 6. (a) Section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335 (a)), is amended to read as follows:

"(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug."

(b) Section 505(c) of such Act (21 U.S.C. 355(c)) is amended to read as follows:

"(c) Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

"(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

"(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted, and the Secretary's order thereon shall be issued, on an expedited basis."

(c)(1) The first four sentences of subsection (h) of such section 505 (21 U.S.C. 355 (h)) are amended to read as follows:

"(h) An appeal may be taken by the applicant from an order of the Secretary refusing to approve an application or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order."

(2) The ninth sentence of such subsection (h) is amended to read as follows: "The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code."

(3) The amendments made by this subsection shall not apply to any appeal taken prior to the date of enactment of this Act.

RECORDS AND REPORTS AS TO EXPERIENCE ON NEW DRUGS AND ANTIBIOTICS

SEC. 7. (a) Subsection (i) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended (1) by inserting "the foregoing subsections of" after "operation of"; (2) by inserting the words "and effectiveness" after the word "safety"; and (3) by adding at the end thereof the following new sentences: "Such regulations may provide for conditioning such exemption upon the establishment and maintenance of such records, and the making of such reports to the Secretary, of data obtained as the result of such investigational us of such drugs, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drugs in the event of the filing of an application pursuant to subsection (b): *Provided, however,* That regulations issued under this subsection and under subsection (j) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations are applicable, of similar information received or otherwise obtained by the Secretary. Such regulations may, within the discretion of the Secretary include among other conditions relating to the protection of the public health, provisions for adequate tests in animals and disclosure to the Secretary of the results of such tests before a new drug may be distributed by a manufacturer to scientific experts for testing and evaluation of its effects in human beings, and for revoking the exemption if the Secretary finds that it is not reasonably safe to make such tests in human beings, and may within the discretion of the Secretary, also include provisions requiring said experts to register with the Secretary, to keep records with respect to the tests performed, and to furnish to the Secretary simultaneous copies of their reports to the manufacturer and, upon request of the Secretary, reports at other times."

(b) Section 505 (21 U.S.C. 355) of such Act is further amended by adding at the end thereof the following new subsection:

"(j)(1) In the case of any drug for which approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section.

"(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records."

(c) Subsection (d) of section 507 of such Act (21 U.S.C. 357(d)) is amended by adding at the end thereof the following new sentence: "Such regulations may provide for conditioning the exemption under clause (3) upon the establishment and maintenance of such records, and the making of such reports to the Secretary, of data obtained as the result of such investigational use of such drugs within the purview of this section, as the Secretary finds will enable him to evaluate the safety and effectiveness for use of such drugs within the purview of this section in the event of an application for certification or release pursuant to subsection (a): *Provided, however,* That regulations issued under this subsection and under subsection (g) shall have due regard for the professional ethics of the medical profession and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom

such regulations are applicable, of similar information received or otherwise obtained by the Secretary."

(d) Section 507 of such Act (21 U.S.C. 357) is further amended by adding at the end of such section the following new subsection:

"(g) (1) Every person engaged in manufacturing, compounding, or processing any drug within the purview of this section with respect to which a certificate or release has been issued pursuant to this section shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such person with respect to such drug within the purview of this section, as the Secretary may by general regulation, or by order with respect to such certification or release, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to make, or to facilitate, a determination as to whether such certification or release should be rescinded or whether any regulation issued under this section should be amended or repealed.

"(2) Every person required under this section to maintain records, and every person having charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records."

(e) Section 301(e) of such Act (21 U.S.C. 331(e)) is amended by inserting before the period at the end thereof a semicolon and the following: "or the failure to establish or maintain any record, or make any report, required under section 505 (i) or (j) or 507 (d) or (g), or the refusal to permit access to or verification or copying of any such required record".

(f) Section 302(a) of such Act (21 U.S.C. 332(a)) is amended by striking out "(e),".

EFFECTIVENESS AND SAFETY OF NEW DRUGS

SEC. 8. (a) (1) Section 201(p)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)(1)), defining the term "new drug", is amended by (A) inserting therein, immediately after the words "to evaluate the safety", the words "and effectiveness", and (B) inserting therein, immediately after the words "as safe", the words "and effective".

(2) Section 201(p)(2) of that Act is amended by inserting therein, immediately after the word "safety", the words "and effectiveness".

(b) Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by inserting therein, immediately after the words "is safe for use", the words "and whether such drug is effective in use".

(c) Section 505(d) of such Act (21 U.S.C. 355(d)) is amended to read as follows:

"(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term 'substantial evidence' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

(d) Section 505(e) of such Act (21 U.S.C. 355(e)) is amended to read as follows:

"(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (j), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based."

(e) Section 505(f) of such Act (21 U.S.C. 355(f)) is amended to read as follows:

"(f) An order refusing to approve, or withdrawing or suspending approval of, an application with respect to any drug under this section shall be revoked whenever the Secretary finds that the facts so require."

(f)(1) Paragraph (1) of section 301 of such Act is amended by (1) inserting "approval of" before "an application", and (2) striking out "effective" and inserting in lieu thereof "in effect".

(2) Clause (C) of section 503(b)(1) of such Act is amended by striking out "effective" and inserting in lieu thereof "approved".

(g)(1) As used in this subsection, the term "enactment date" means the date of enactment of this Act; and the term "basic Act" means the Federal Food, Drug, and Cosmetic Act. Except as otherwise provided in this subsection, the amendments made by the foregoing provisions of this section shall take effect on the enactment date.

(2) An application filed pursuant to section 505(b) of the basic Act which was "effective" within the meaning of that Act on the day immediately preceding the enactment date shall be deemed, as of the enactment date, to be an application "approved" by the Secretary within the meaning of the basic Act as amended by this Act.

(3) In the case of any drug with respect to which an application filed under section 505(b) of the basic Act is deemed to be an approved application on the enactment date by virtue of paragraph (2) of this subsection—

(A) the amendments made by this section to section 201(p), and to subsections (b) and (d) of section 505, of the basic Act, insofar as such amendments relate to the effectiveness of drugs, shall not, so long as approval of such application is not withdrawn or suspended pursuant to section 505(e) of that Act, apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application, but shall apply to any changed use, or conditions of use, prescribed, recommended, or suggested in its labeling, including such conditions of use as are the subject of an amendment or supplement to such application pending on, or filed after, the enactment date; and

(B) clause (3) of the first sentence of section 505(e) of the basic Act, as amended by this Act, shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application (except with respect to such use, or conditions of use, as are the subject of an amendment or supplement to such approved application, which amendment or supplement has been approved after the enactment date under section 505 of the basic Act as amended by this Act) until whichever of the following first occurs: (i) the expiration of the two-year period beginning with the enactment date; (ii) the effective date of an order under section 505(e) of the basic Act, other than

clause (3) of the first sentence of such section 505(e), withdrawing or suspending the approval of such application.

(4) In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the amendments to section 201(p) made by this section shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day.

CONSPICUOUSNESS OF OFFICIAL NAMES

SEC. 9. (a) Section 502(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(e)) is amended by—

(1) inserting the subparagraph designation "(1)" after "(e)";

(2) striking out the words "If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient", and inserting in lieu thereof "If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii) in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient";

(3) striking out the words "the name" and inserting in lieu thereof the words "the established name";

(4) inserting therein, immediately after the colon following the words "contained therein", the following: *"Provided,* That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs; and (B) the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient:";

(5) striking out the words "clause (2) of this paragraph" in the proviso to such paragraph and inserting in lieu thereof "clause (A)(ii) or clause (B) of this subparagraph"; and

(6) adding at the end of such paragraph the following new subparagraph:

"(2) As used in this paragraph (e), the term 'established name', with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 509, or (B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient: *Provided,* That where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homoeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homoeopathic Pharmacopoeia shall apply."

(b) Section 502(g) of such Act is amended by inserting immediately before the period at the end thereof a colon and the following proviso: *"Provided further,* That in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail."

(c) This section shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted.

REVIEW AND DESIGNATION OF OFFICIAL NAMES

SEC. 10. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as amended by this Act, is further amended by adding after section 508 the following new section:

"SEC. 509. (a) The Secretary may designate an official name for any drug if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Any official name designated under this section for any drug shall be the only official name of that drug used in any official compendium published after such name has been prescribed or for any other purpose of this Act.

"(b) Within a reasonable time after the effective date of this section, and at such other times as he may deem necessary, the Secretary shall cause a review to be made of the official names by which drugs are identified in the official United States Pharmacopoeia, the official Homoeopathic Pharmacopoeia of the United States, and the official National Formulary, and all supplements thereto, to determine whether revision of any of those names is necessary or desirable in the interest of usefulness and simplicity.

"(c) Whenever he determines after any such review that (1) any such official name is unduly complex or is not useful for any other reason, (2) two or more official names have been applied to a single drug, or to two or more drugs which are identical in chemical structure and pharmacological action and which are substantially identical in strength, quality, and purity, or (3) no official name has been applied to a medically useful drug, he shall transmit in writing to the compiler of each official compendium in which that drug or drugs are identified and recognized his request for the recommendation of a single official name for such drug or drugs which will have usefulness and simplicity. Whenever such a single official name has not been recommended within one hundred and eighty days after such request, or the Secretary determines that any name so recommended is not useful for any reason, he shall designate a single official name for such drug or drugs. Whenever he determines that the name so recommended is useful, he shall designate that name as the official name of such drug or drugs. Such designation shall be made as a regulation upon public notice and in accordance with the procedure set forth in section 4 of the Administrative Procedure Act (5 U.S.C. 1003).

"(d) After each such review, and at such other times as the Secretary may determine to be necessary or desirable, the Secretary shall cause to be compiled, published, and publicly distributed a list which shall list all revised official names of drugs designated under this section and shall contain such descriptive and explanatory matter as the Secretary may determine to be required for the effective use of those names.

"(e) Upon a request in writing by any compiler of an official compendium that the Secretary exercise the authority granted to him under section 509(a), he shall upon public notice and in accordance with the procedure set forth in section 4 of the Administrative Procedure Act (5 U.S.C. 1003) designate the official name of the drug for which the request is made."

INFORMATION TO PHYSICIANS AND OTHERS

SEC. 11. (a)(1) Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), as amended by this Act, is further amended by adding at the end thereof the following new paragraphs:

"(o) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof maintains for transmittal and transmits, to any practitioner licensed by law of that State to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter approved by the Secretary available to practitioners on written request. Nothing in this paragraph shall be construed to exempt any person from any labeling requirements imposed by or under other provisions of this Act.

"(p) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributors thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor, with respect to that drug a true statement of (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug, and (3) such other information relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) of this Act: *Provided,* That no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52–57)."

(2) No drug which was being commercially distributed prior to the date of enactment of this Act shall be deemed to be misbranded under paragraph (p) of section 502 of the Federal Food, Drug, and Cosmetic Act, as added to that section by this subsection, until the earlier of the following dates: (1) the first day of the seventh month following the month in which this Act is enacted; (2) the effective date of regulations first issued under clause (3) of such paragraph (p) in accordance with the procedure specified in section 701(e) of the Federal Food, Drug, and Cosmetic Act.

(b)(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as amended by this Act, is further amended by adding after section 509 the following new section:

"SEC. 510. The Secretary shall publish in convenient and readable form and shall distribute on a current basis to physicians, hospitals, medical and nurse training schools, depository libraries, and Federal, State, and local government offices concerned with the handling and utilization of drugs, true and correct copies of all printed matter which the Secretary has required to be included in any package in which any drug is distributed or sold or brochures approved by the Secretary available to practitioners on request."

(2) This subsection shall take effect on the first day of the seventh month following the month in which this Act is enacted.

CERTIFICATION OF ANTIBIOTICS

SEC. 12. (a) Section 507(a) of such Act (21 U.S.C. 357(a)) is amended by adding at the end thereof the following new sentence: "For purposes of this section and of section 502(l), the term 'antibiotic drug' means any

drug containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including the chemically synthesized equivalent of any such substance)."

(b) Section 507(a) of such Act (21 U.S.C. 357(a)) is further amended by striking the word "or" preceding the word "bacitracin" and adding after the word "bacitracin" a comma and the following: "or any other antibiotic drug,".

(c) Section 502(l) of such Act (21 U.S.C. 352(l)) is amended by striking the word "or" preceding the word "bacitracin" and adding after the word "bacitracin" a comma and the following: "or any other antibiotic drug,".

(d) Section 507(c) of such Act (21 U.S.C. 357(c)) is amended by adding at the end thereof the following: "In deciding whether an antibiotic drug, or class of antibiotic drugs, is to be exempted from the requirement of certification the Secretary shall give consideration, among other relevant factors, to:

"(1) Whether such drug or class of drugs is manufactured by a person who has, or hereafter shall have, produced fifty consecutive batches of such drug or class of drugs in compliance with the regulations for the certification thereof within a period of not more than eighteen calendar months, upon the application by such persons to the Secretary; or

"(2) Whether such drug or class of drugs is manufactured by any person who has otherwise demonstrated such consistency in the production of such drug or class of drugs, in compliance with the regulations for the certification thereof, as in the judgment of the Secretary, is adequate to insure the safety and efficacy of use thereof.

When an antibiotic drug or a drug manufacturer has been exempted from the requirement of certification, the manufacturer may still obtain certification of a batch or batches of that drug if he applies for and meets the requirements for certification. Nothing in this Act shall be deemed to prevent a manufacturer or distributor of an antibiotic drug from making a truthful statement in labeling or advertising of the product as to whether it has been certified or exempted from the requirement of certification."

(e) The first sentence of section 507(e) of such Act (21 U.S.C. 357(e)) is amended to read as follows: "No drug which is subject to section 507 shall be deemed to be subject to any provision of section 505 except a new drug exempted from the requirements of this section and of section 502(l) pursuant to regulations promulgated by the Secretary: Provided, That, for purposes of section 505, the initial request for certification, as thereafter duly amended, pursuant to section 507, of a new drug so exempted shall be considered a part of the application filed pursuant to section 505(b) with respect to the person filing such request and to such drug as of the date of the exemption."

(f) This section shall take effect on the first day of the seventh month following the month in which this Act is enacted.

DEFINITION

SEC. 13. Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end thereof the following new subsection:

"(v) The term 'State' means any State or possession of the United States, the District of Columbia, and the Commonwealth of Puerto Rico."

The SPEAKER. The Clerk will report the amendment.

The Clerk read as follows:

Amendment offered by Mr. HARRIS: Strike out all after the enacting clause and insert the following: "That this Act, divided into titles and sections according to the following table of contents, may be cited as the 'Drug Amendments of 1962'.

"TABLE OF CONTENTS

"Title I—Drugs

"Part A—Amendments to Assure Safety, Effectiveness, and Reliability
"Sec. 101. Requirement of adequate controls in manufacture.
"Sec. 102. Effectiveness and safety of new drugs.
"Sec. 103. Records and reports as to experience on new drugs.
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"Sec. 111. Authority to standardize names.
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"Sec. 201. Factory inspection.
"Sec. 202. Confidentiality of information obtained by inspection.
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"TITLE I—DRUGS

"Part A—Amendments to assure safety, effectiveness, and reliability

"Requirement of Adequate Controls in Manufacture

"SEC. 101. Clause (2) of paragraph (a) of section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended to read as follows: '(2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;'.

"Effectiveness and Safety of New Drugs

"SEC. 102. (a)(1) Section 201(p)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)(1)), defining the term 'new drug', is amended by (A) inserting therein, immediately after the words 'to evaluate the safety', the words 'and effectiveness', and (B) inserting therein, immediately after the words 'as safe', the words 'and effective'.

"(2) Section 201(p)(2) of such Act (21 U.S.C. 321(p)(2)) is amended by inserting therein, immediately after the word 'safety', the words 'and effectiveness'.

"(b) Section 505(b) of such Act (21 U.S.C. 355(b)) is amended by inserting therein, immediately after the words 'is safe for use', the words 'and whether such drug is effective in use'.

"(c) Section 505(d) of such Act (21 U.S.C. 355(d)) is amended to read as follows:

"'(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.'

"(d) Section 505(e) of such Act (21 U.S.C. 355(e)) is amended to read as follows:

"'(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application with respect to any drug under this section if the

Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (j), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.'

"Records and Reports as to Experience on New Drugs

"SEC. 103. (a) Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end thereof the following new subsection:

"(j)(1) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section.

"'(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.'

"(b) Section 505(i) of such Act (21 U.S.C. 355(i)) is amended (1) by inserting 'the foregoing subsections of' immediately after 'operation of'; (2) by inserting 'and effectiveness' immediately after 'safety'; and (3) by adding at the end thereof the following new sentences: 'Such regulations may provide for conditioning such exemption upon—

"'(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests of such drug adequate to justify the proposed clinical testing;

"'(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

"'(3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that (1) experts using such drugs for investigational purposes inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and obtain the consent of such human beings or their representatives, and (2) such experts certify to such manufacturer or sponsor that such consent will be obtained. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.'

"(c) Section 301(e) of such Act (21 U.S.C. 331(e)) is amended to read as follows:

"'(e) The refusal to permit access to or copying of any record as required by section 703; or the failure to establish or maintain any record, or make any report, required under section 505 (i) or (j), or the refusal to permit access to or verification or copying of any such required record.'

"(d) Subsection (a) of section 302 of such Act is amended by striking out '(e),'.

"New Drug Clearance Procedure

"SEC. 104. (a) Section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a)), is amended to read as follows:

"'(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug.'

"(b) Section 505(c) of such Act (21 U.S.C. 355(c)) is amended to read as follows:

"'(c) Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

"'(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

"'(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after such hearing is completed.'

"(c) Section 505(f) of such Act (21 U.S.C. 355(f)) is amended to read as follows:

"'(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.'

"(d)(1) The first four sentences of section 505(h) of such Act (21 U.S.C. 355(h)) are amended to read as follows:

"'(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order.'

"(2) The ninth sentence of such section 505(h) is amended to read as follows: 'The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code.'

"(3) The amendments made by this subsection shall not apply to any appeal taken prior to the date of enactment of this Act.

"(e)(1) Section 301(l) of such Act (21 U.S.C. 331(l)) is amended by (1) inserting 'approval of' before 'an application', and (2) striking out 'effective' and inserting in lieu thereof 'in effect'.

"(2) Clause (C) of section 503(b)(1) of such Act (21 U.S.C. 353(b)(1)) is amended by striking out 'effective' and inserting in lieu thereof 'approved'.

"(f)(1) Clause (A) of paragraph (3) of section 409(c) of such Act (21 U.S.C. 348(c)) is amended by inserting before the semicolon at the end thereof the following: ', except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal'.

"(2) Subparagraph (B) of paragraph (5) of section 706(b) of such Act (21 U.S.C. 376(b)) is amended by inserting before the period at the end of the subparagraph a colon and the following proviso: *'Provided,* That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal'.

"Certification of All Antibiotics

"SEC. 105. (a) The heading of section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) is further amended to read 'CERTIFICATION OF DRUGS CONTAINING ANTIBIOTICS', and the first sentence of subsection (a) of such section 507 is amended to read as follows: 'The Secretary of Health, Education, and Welfare, pursuant to regulations

promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin or any derivative thereof, and of drugs intended for use by man and composed wholly or partly of any other kind of antibiotic substance (including the chemically synthesized equivalent of any such substance).'

"(b) Such section 507 is further amended by adding at the end of such section the following new subsection:

"'(h) In the case of a drug for which, on the day immediately preceding the effective date of this subsection, a prior approval of an application under section 505 had not been withdrawn under section 505(e), the initial issuance of regulations providing for certification or exemption of such drug under this section 507 shall, with respect to the conditions of use prescribed, recommended, or suggested in the labeling covered by such application, not be conditioned upon an affirmative finding of the efficacy of such drug. Any subsequent amendment or repeal of such regulations so as no longer to provide for such certification or exemption on the ground of a lack of efficacy of such drug for use under such conditions of use may be effected only if (1) such amendment or repeal is made in accordance with the procedure specified in subsection (f) of this section and (2) the Secretary finds, on the basis of new information with respect to such drug evaluated together with the information before him when the application under section 505 became effective or was approved, that there is a lack of substantial evidence (as defined in section 505(d)) that the drug has the effect it purports or is represented to have under such conditions of use.'

"(c) Section 502(l) of such Act (21 U.S.C. 352(l)) is amended to read as follows:

"'(l) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, or a drug intended for use by man and composed wholly or partly of any other kind of substance within the purview of section 507, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507, and (2) such certificate or release is in effect with respect to such drug: *Provided,* That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507 (c) or (d).'

"Records and Reports as to Experience on Antibiotics

"SEC. 106. (a) Section 507 of such Act (21 U.S.C. 357) is amended by adding at the end thereof the following new subsection:

"'(g)(1) Every person engaged in manufacturing, compounding, or processing any drug within the purview of this section with respect to which a certificate or release has been issued pursuant to this section shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such person with respect to such drug, as the Secretary may by general regulation, or by order with respect to such certification or release, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to make, or to facilitate, a determination as to whether such certification or release should be rescinded or whether any regulation issued under this section should be amended or repealed.

"'(2) Every person required under this section to maintain records, and every person having charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.'

"(b) Section 507(d) of such Act (21 U.S.C. 357(d)) is amended by adding at the end thereof the following new sentences: 'Such regulations may provide for conditioning the exemption under clause (3) upon—

"'(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests of such drug adequate to justify the proposed clinical testing;

"'(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

"'(3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application for certification or release pursuant to subsection (a).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that (1) experts using such drugs for investigational purposes inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and obtain the consent of such human beings or their representatives, and (2) such experts certify to such manufacturer or sponsor that such consent will be obtained. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.'

"(c) Section 301(e) of such Act (21 U.S.C. 331(e)), as amended by section 103(c) of this Act, is further amended by striking out '505 (i) or (j)' and inserting in lieu thereof '505 (i) or (j), or 507 (d) or (g)'.

"Effective Dates and Application of Part A

"SEC. 107. (a) Except as otherwise provided in this section, the amendments made by the foregoing sections of this part A shall take effect on the date of enactment.

"(b) The amendments made by sections 101, 103, 105, and 106 of this part A shall, with respect to any drug, take effect on the first day of the seventh calendar month following the month in which this Act is enacted.

"(c) The amendments made by this Act to the Federal Food, Drug, and Cosmetic Act, insofar as such amendments relate to the effectiveness of drugs (except clause (3) of the first sentence of section 505(e) of such Act), shall not apply to any drug with respect to which an application under section 505 of the Federal Food, Drug, and Cosmetic Act was effective on the day immediately preceding the date of enactment of this Act, so long as amendment of such application is not proposed and approval of such application has not been suspended or withdrawn under section 505 of such Act, as amended by this Act. An application filed pursuant to section 505(b) of such Act which was effective on the day immediately preceding the date of enactment of this Act shall, upon the date of enactment of this Act, be deemed to be an application approved by the Secretary. If an application filed with respect to a new drug pursuant to such section 505(b) prior to the date of enactment of this Act is still pending before the Secretary on such date, the running of the period within which the Secretary must act on such application pursuant to section 505(c) of such Act, as amended by this Act, shall be deemed to have commenced on the day immediately following the date on which such application was in fact filed.

"(d) The amendments made by this Act to section 201(p) of the Federal Food, Drug, and Cosmetic Act shall not apply to any drug which, on the day immediately preceding the date of enactment of this Act, (1) was commercially used or sold in the United States, (2) was not a new drug as defined by section 201(p) of the Federal Food, Drug, and Cosmetic Act as then in force, and (3) was not covered by an effective application under section 505 of that Act, when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day.

"*Part B—Standardization of drug names*

"Authority to Standardize Names

"SEC. 111. (a) The Federal Food, Drug, and Cosmetic Act, as amended by this Act, is further amended by adding at the end of chapter V the following new section:

"'Authority to standardize names

"'SEC. 508. Whenever in the judgment of the Secretary such action is necessary or desirable in the interest of achieving usefulness or simplicity of drug nomenclature, or because of the existence of two or more nonproprietary names (other than the systematic chemical name) for the same drug (or two or more drugs which are identical in their active ingredients and substantially identical in their pharmacological action, strength, quality, and purity), or because the common or usual name of a drug is misleading, confusing, or not sufficiently informative, or because there exists no common or usual name for a drug, he may promulgate regulations establishing a single standard name for such drug (or for such identical drugs), together with any related or additional information which in the judgment of the Secretary is desirable to facilitate the correct and effective use of such standard name. In no event, however, shall the Secretary establish a standard name so as to infringe a valid trademark.'

"(b) This section shall take effect on the date of its enactment.

"Name To Be Used on Drug Label

"SEC. 112. (a) Section 502(e) of such Act (21 U.S.C. 352(e)) is amended by—

"(1) inserting the subparagraph designation '(1)' after '(e)';

"(2) striking out the words 'If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient', and inserting in lieu thereof 'If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient';

"(3) striking out the words 'the name' and inserting in lieu thereof the words 'the established name';

"(4) inserting therein, immediately after the colon following the words 'contained therein', the following: *'Provided,* That the

requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs; and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (or on any labeling therefor) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient (or, in the case of labeling, is so printed at the first place, and at the most conspicuous place if other than the first place, at which such proprietary name for such drug or ingredient, as the case may be, is used):';

"(5) striking out the words 'clause (2) of this paragraph in the proviso to such paragraph and inserting in lieu thereof 'clause (A)(ii) or clause (B) of this subparagraph'; and

"(6) adding at the end of such paragraph the following new subparagraph:

"'(2) As used in this paragraph (e), the term "established name", with respect to a drug or ingredient thereof means (A) the applicable standard name established pursuant to section 508, or (B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient: *Provided further*, That where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homoeopathic Pharmacopolia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homoeopathic drug, in which case the official title used in the Homoeopathic Pharmacopoeia shall apply.'

"(b) Section 502(g) of such Act (21 U.S.C. 352(g)) is amended by inserting immediately before the period at the end thereof a colon and the following proviso: '*Provided further*, That, in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail'.

"(c) This section shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted.

"Nonapplicability to Cosmetics

"SEC. 113. Chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 111 of this Act, is further amended by adding at the end thereof the following:

"'Nonapplicability to cosmetics

"'SEC. 509. This chapter, as amended by the Drug Amendments of 1962, shall not apply to any cosmetic unless such cosmetic is also a drug or device or component thereof.'

"Part D—Amendments as to advertising

"Prescription Drug Advertisements

"SEC. 131. (a) Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is further amended by adding at the end thereof the following new paragraph:

"'(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor, with respect to that drug a true statement of (1) the established name as defined in section 502 (e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) of this Act: *Provided*, That (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52–57).'

"(b) No drug which was being commercially distributed prior to the date of enactment of this Act shall be deemed to be misbranded under paragraph (n) of section 502 of the Federal Food, Drug, and Cosmetic Act, as added by this section, until the earlier of the following dates: (1) the first day of the seventh month following the month in which this Act is enacted; or (2) the effective date of regulations first issued under clause (3) of such paragraph (n) in accordance with the procedure specified in section 701(e) of the Federal Food, Drug, and Cosmetic Act.

"TITLE II—FACTORY INSPECTION AUTHORITY

"Factory Inspection

"SEC. 201. (a) Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended to read as follows:

"'(a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, or establishment in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j) or section 507 (d) or (g) of this Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the Act) pertinent sanitation methods, analytical reports on unfinished materials, quantitative formula data for active ingredients, qualitative formula data for inactive ingredients, facilities for weighing and measuring, packaging facilities, sterility controls, active ingredient assay controls, coding systems, facilities for maintaining separate identity for each drug, cleaning of equipment, methods for quarantine of drugs until after clearance with control laboratory and file of complaints from licensed medical practitioners and licensed medical institutions, shipping records, and data as to qualifications of technical and professional personnel performing functions subject to this Act. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to—

"'(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs, or patients under the care of such practitioners in the course of their professional practice and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;

"'(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice;

"'(3) persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

"'(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.'

"(b) Section 302(a) of such Act (21 U.S.C. 332(a)) is amended by striking out '(f),'.

"(c) Nothing in the amendments made by subsection (a) of this section shall be construed to negate or derogate from any authority of the Secretary existing prior to the enactment of this Act.

"Confidentiality of Information Obtained by Inspection

"SEC. 202. Section 301(j) of such Act (21 U.S.C. 331 (j)) is amended by—

"(1) inserting 'or as authorized by law,' after 'Act,';

"(2) striking out the following: 'concerning any method or process which as a trade secret is entitled to protection'; and

"(3) inserting immediately before the period at the end thereof the following: ': *Provided*, That nothing in this Act shall authorize the withholding of information from the duly authorized committees of the Congress'.

"Effect on State Laws

"SEC. 203. Nothing in the Federal Food, Drug, and Cosmetic Act, as amended, shall be construed as invalidating any provision of State law which would be valid in the absence of such Act unless there is a direct and positive conflict between such Act and such provision of State law.

"Effective Date

"SEC. 204. The amendments made by this title shall take effect on the date of enactment of this Act."

The amendment was agreed to.

The Senate bill was ordered to be read a third time, was read the third time and passed.

A motion to reconsider was laid on the table.

The title was amended so as to read: "An Act to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, effectiveness, and reliability of drugs, authorize standardization of drug names, and clarify and strengthen existing inspection authority, and for other purposes."

Mr. HARRIS. Mr. Speaker, I move that the House insist upon the provisions of the bill passed by the House and request a conference with the Senate.

The motion was agreed to.

The SPEAKER. The Chair appoints the following conferees: Messrs. HARRIS, ROBERTS of Alabama, O'BRIEN of New York, ROGERS of Florida, BENNETT of Michigan, SCHENCK, and NELSEN.

FURTHER MESSAGE FROM THE SENATE

A further message from the Senate by Mr. McGown, one of its clerks, announced that the Senate had passed, with an amendment in which the concurrence of the House is requested, a bill of the House of the following title:

H.R. 7927. An act to adjust postal rates, and for other purposes.

PROGRAM FOR THE BALANCE OF THE WEEK

Mr. ARENDS. Mr. Speaker, I ask unanimous consent to address the House for 1 minute and to revise and extend my remarks.

The SPEAKER. Is there objection to the request of the gentleman from Illinois?

There was no objection.

Mr. ARENDS. Mr. Speaker, I take this time in order to ask the majority leader if he can tell us anything about the program for tomorrow and anything about the program for next week, which the gentleman might have in mind.

Mr. ALBERT. Mr. Speaker, will the gentleman yield?

Mr. ARENDS. I yield to the gentleman from Oklahoma.

Mr. ALBERT. The only business in order, at least, the only major legislative business in order tomorrow will be the continuing appropriation resolution.

I am not in a position as yet to discuss with the gentlemen of the House the program for next week. However, I shall be ready to announce the program tomorrow.

Mr. ARENDS. The one other bill which was scheduled on the calendar for this week is off?

Mr. ALBERT. It will go over until next week.

Mr. ARENDS. I thank the gentleman.

GENERAL LEAVE TO EXTEND

Mr. HARRIS. Mr. Speaker, I ask unanimous consent that all Members desiring to do so have 5 legislative days in which to extend their remarks on the bill H.R. 11581 which was under consideration today.

The SPEAKER. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

THE NATIONAL MOTTO "IN GOD WE TRUST"

Mr. JONES of Missouri. Mr. Speaker, I ask unanimous consent for the immediate consideration of the resolution (H. Res. 740) to replace the 11 stars above the Speaker's desk in the Hall of the House with the national motto, "In God We Trust."

The SPEAKER. Is there objection to the request of the gentleman from Missouri?

Mr. SCHENCK. Mr. Speaker, reserving the right to object, I ask my colleague from Missouri whether or not the language in this resolution was changed to indicate some of the letters would be replaced?

Mr. JONES of Missouri. There is a committee amendment which I shall offer at the proper time.

Mr. SCHENCK. Mr. Speaker, I withdraw my reservation of objection.

Mr. GROSS. Mr. Speaker, reserving the right to object, I should like to ask the gentleman if there remains enough gold in this country to install this lettering?

Mr. JONES of Missouri. I think so. I think I can assure the gentleman there is. This resolution was considered in the Committee on House Administration. It was introduced by the gentleman from Minnesota [Mr. MARSHALL] and, as far as I have been able to find out, there is unanimous approval of it. I hope the House will adopt it immediately.

Mr. GROSS. Mr. Speaker, I withdraw my reservation of objection.

The SPEAKER. Is there objection to the request of the gentleman from Missouri?

There was no objection.

The Clerk read as follows:

Resolved, That the Architect of the Capitol shall provide for replacing the eleven stars located above the Speaker's desk in the Hall of the House with the national motto of the United States, "In God We Trust", in gold lettering.

Mr. JONES of Missouri. Mr. Speaker, I offer an amendment.

The Clerk read as follows:

Committee amendment offered by Mr. JONES of Missouri: On page 1, line 2, strike out "the eleven" and insert "some or all of the".

The committee amendment was agreed to.

Mr. MARSHALL. Mr. Speaker, I ask unanimous consent to extend my remarks at this point in the RECORD and include extraneous matter.

The SPEAKER. Is there objection to the request of the gentleman from Minnesota?

There was no objection.

Mr. MARSHALL. Mr. Speaker, one day our late colleague, Louis Rabaut, and I were admiring the appearance of the House Chamber. I am sure that all of us who have served and are serving in the House of Representatives appreciate the great traditions surrounding our Chamber. It so happened that both of us commented about the 15 stars above the Speaker's chair. We both had been questioned as to why there were 15 stars. We, at the time, felt that there was some significance to 15 stars but did not know what it was. Later we found that it was purely for decorative purposes.

We both commented what a fine place it would be for something of significance to our great Chamber. We both discussed some wording or a motto which might be placed there. I suggested that the words "In God We Trust" would be a remainder to all of us and would reaffirm our faith in God. Louis Rabaut expressed his satisfaction to me concerning the wording and suggested that I might proceed to draw up a resolution accordingly.

In reading past historical documents, our forefathers repeatedly expressed their feeling toward Almighty God, realizing the need of His bountiful blessings if the new Republic was to survive. It is fitting that some reminder be made at this time since 100 years ago this country was torn in conflict and during those dark days our great President, Abraham Lincoln, repeatedly expressed his faith in Almighty God.

During the times when our country is facing great crises, it is well that we remind ourselves of our reliance upon God and reaffirm our faith in Him. I hope that the House will unanimously adopt this resolution and when Members read the wording they will be inspired to greater faith. It will be a constant reminder to visitors in the Chamber of this country's faith in the words "In God We Trust."

Our distinguished Speaker has taken a personal interest in this matter and I am pleased to include herewith a letter signed by him, addressed to the Honorable OMAR BURLESON, chairman, Committee on House Administration, which is self-explanatory, as well as certain other appropriate correspondence:

THE SPEAKER'S ROOMS,
U.S. HOUSE OF REPRESENTATIVES,
Washington, D.C., September 4, 1962.

Hon. OMAR BURLESON,
Chairman, Committee on House Administration, U.S. House of Representatives, Washington, D.C.

DEAR OMAR: I have had called to my attention your letter of August 9 to the Honorable J. George Stewart, Architect of the Capitol, in relation to House Resolution 740, introduced by Congressman FRED MARSHALL, of Minnesota. As a result of your letter to Mr. Stewart, he contacted Mr. John Harbeson who was architectural consultant on the restoration of the House Chamber in 1949 and 1950. I enclose, for your information, the letter which Mr. Stewart received from Mr. Harbeson.

I have been informed that the 15 stars located about the Speaker's rostrum are decorative and have no symbolic significance. For example, 13 stars might. I personally feel that the suggestion of Congressman MARSHALL, if it can be worked out, would be one that would be desirable.

I have no opposition to House Resolution 740, in fact, I have an affirmative state of mind favorable to the same. The words "In God We Trust" symbolizes the journey that

our country has always taken since its origin and, pray God, will always take.

With kind personal regards, I am,

Sincerely yours,

JOHN W. MCCORMACK.

HOUSE OF REPRESENTATIVES, U.S.,
COMMITTEE ON HOUSE ADMINISTRATION,
Washington, D.C., August 9, 1962.

Hon. J. GEORGE STEWART,
Architect of the Capitol,
Washington, D.C.

DEAR MR. STEWART: Attached are two copies of House Resolution 740 which directs the Architect of the Capitol to replace the 11 stars located above the Speaker's desk in the Hall of the House with the national motto of the United States, "In God We Trust," in gold lettering.

Your views and recommendations would be most helpful to the committee in its consideration of the resolution.

With best wishes, I am,

Sincerely yours,

OMAR BURLESON, *Chairman.*

AUGUST 24, 1962.

Mr. JOHN F. HARBESON,
Philadelphia, Pa.

DEAR JOHN: I am enclosing herewith copy of letter of August 9, 1962, from Hon. OMAR BURLESON, chairman, Committee on House Administration, enclosing copy of House Resolution 740, 87th Congress, introduced by Congressman MARSHALL of Minnesota, relating to a change in the House Chamber.

Since you were the architectural consultant on the House Chamber remodeling project, I would appreciate your views and recommendations on changes proposed in the resolution.

Sincerely yours,

J. GEORGE STEWART,
Architect of the Capitol.

PHILADELPHIA, PA., *August 30, 1962.*

Hon. J. GEORGE STEWART,
Architect of the Capitol,
U.S. Capitol, Washington, D.C.

DEAR GEORGE: On returning from a short vacation in Maine, I find your letter of August 24, 1962, enclosing copy of one from Congressman OMAR BURLESON discussing a resolution introduced by Congressman MARSHALL suggesting a change in the House Chamber.

1. I have studied the drawings and photographs showing the location where the proposed change would take place, above the Speaker's desk in the Hall of the House.

2. The replacing of some of the stars located on the frieze of the central motive by the words "In God We Trust" in gold lettering is entirely feasible from the standpoint of construction, would result in an appearance completely satisfactory esthetically, and would entail a minimum cost, as the letters used could be made from patterns already existing.

3. Both the stars and the words "In God We Trust" occur on our national coinage and, therefore, would be appropriate in the House Chamber. We recommend that the letter forms used be of the classic type used elsewhere in the House Chamber.

If you wish us to make a layout showing what the resulting appearance would be we shall be glad to do so.

Sincerely,

JOHN HARBESON.

THE SPEAKER'S ROOMS,
U.S. HOUSE OF REPRESENTATIVES,
Washington, D.C., September 4, 1962.

Hon. FRED MARSHALL,
U.S. House of Representatives,
Washington, D.C.

DEAR FRED: For your information, I enclose a copy of a letter that I have sent to Chairman BURLESON, together with a copy of the letter that Mr. Stewart received from Mr. John Harbeson.

With kind regards, I am,

Sincerely yours,

JOHN W. MCCORMACK.

SEPTEMBER 7, 1962.

Mr. JOHN F. HARBESON,
Philadelphia, Pa.

DEAR JOHN: Thank you for your letter of August 30, 1962, relating to the installation of the lettering "In God We Trust" in place of the 11 stars located above the Speaker's desk in the House Chamber at the Capitol.

I have shown your letter to the Speaker of the House, Hon. JOHN W. MCCORMACK, and he is pleased with the suggestion and has so advised Chairman BURLESON.

I would be glad to have you prepare and present to me a layout showing the resulting appearance, as suggested in the final paragraph of your letter.

With best wishes, I am,

Sincerely yours,

J. GEORGE STEWART,
Architect of the Capitol.

SEPTEMBER 10, 1962.

Hon. OMAR BURLESON,
Chairman, Committee on House Administration, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Reference is made to your letter of August 9, 1962, requesting my views and recommendations on House Resolution 740, directing the Architect of the Capitol to replace the 11 stars located above the Speaker's desk in the Hall of the House with the words "In God We Trust" in gold lettering.

By letter of August 24, 1962, I brought the resolution and your letter to the attention of Mr. John F. Harbeson, architect, of Philadelphia, who served as the architectural consultant for the remodeling of the House Chamber in 1949–50.

After receiving Mr. Harbeson's affirmative reply, I took the matter up with Hon. JOHN W. MCCORMACK, Speaker of the House.

The Speaker was favorably impressed with the suggestion and, as a result, wrote letter to you of September 4, 1962, with which he sent letter from Mr. Harbeson.

I have asked Mr. Harbeson to prepare a layout showing the resulting appearance after the proposed change. As soon as the layout is received, I will be pleased to bring it to the attention of both your committee and the Speaker.

With best wishes, I am,

Sincerely yours,

J. GEORGE STEWART,
Architect of the Capitol.

Mr. RANDALL. Mr. Speaker, when the House adopted House Resolution 740 it wrote a page of history which causes wonderment as to why all of us so long neglected to do the thing that has been done today. But better now than even later there is to be permanently inscribed before the eyes of all the Representatives of the people of these United States whenever they sit in the House Chamber, our national motto.

The resolution adopted today was first introduced on August 1, 1962, by Congressman FRED MARSHALL, of Minnesota, our good friend and a fellow Member loved and respected by all of his colleagues. He recently announced his retirement at the conclusion of the current session but his thoughtfulness in causing to be introduced this resolution will provide him a secure place in the hearts and thoughts of the membership of this House for years and years after he has departed the Chamber.

The resolution is simple in its content. It simply directs the Architect to remove some of the gold stars that appear over and back of the Speaker's chair. There are 11 stars in the center panel and 2 on each side for a total of 15, and the resolution calls for removal of as many as may be necessary and to be put in their place our national motto, "In God We Trust." The gold stars were quite decorative but they had no particular significance or meaning, being there purely as a decoration. Hereafter, we are to have continuously before our eyes our recognition of Almighty God and that our faith, trust, and hope are reposed in His goodness.

"In God We Trust" has appeared on most issues of our coins since about the beginning of the Civil War. For some reason there was an increase of religious sentiment engendered by the outbreak of the war between the States and the Reverend M. R. Watkinson, of Ridleyville, Pa., along with many devout persons throughout the country wrote to the Secretary of the Treasury, Salmon P. Chase and urged that the Diety be recognized on our coins. On November 13, 1861, after the Union forces had been shaken by a series of battlefield defeats and suffered a great loss of morale the Reverend Watkinson wrote, "from my heart I have felt our national shame in disowning God as not the least of our present national disasters." It was letters such as these that led to the recognition of Almighty God on our coins, and accordingly, Secretary Chase ordered the director of the mint at Philadelphia to commence work to prepare a desirable motto and backed coinage legislation which authorized use of this slogan. Several forms were proposed, among them being, "God Our Trust," and "God and Our Country," and finally the inscription we have all learned to love so well, "In God We Trust."

The first appearance of our national motto was upon coins struck off in 1864 and then it disappeared in 1866 and continued to disappear and reappear on various coins until 1955 when the Congress of the United States at long last got around to the much neglected legislation and ordered it placed on paper money and all coins.

There is something of a parallel here because just as it took the Congress from 1864 to 1955 to provide that our paper money and coins should be so inscribed, so it has taken the House of Representatives all the years and through the many changes, renovations and doing over of the House Chamber to finally correct an omission that now seems difficult to believe had not been proposed long ago. Things of this kind must slip the mind of us lawmakers because it was not until 1955 that Congress got around to set apart a room for prayer, when by concurrent resolution, the Capitol prayer room was authorized.

All of us in the House owe a debt of gratitude to the author of the resolution and to the Committee on House Administration for its conclusion that no hearings were necessary and for the favorable report from the Architect and the good letter from our beloved Speaker. We are

likewise indebted to the member of the House Administration Committee who handled the resolution on the floor, our colleague the gentleman from Missouri [Mr. JONES].

We sincerely believe the House by its historic action today calling for this inscription to be placed constantly before the eyes of every Member emphasized anew that we are not only a God-fearing people but that we all realize that only by faith and trust in God can there be any hope for the solution of what seems to be the endless problems facing the Congress in world affairs and within our country. The House in providing for the inscription put our great national motto in the most prominent place in the greatest legislative hall in the world. By this we speak out to the entire world that we are not an atheistic country or a godless Nation like our enemies behind the Iron Curtain; that we cast our lot on the side of the Almighty and reposing faith in His guidance we will ultimately win all of our struggles.

We suppose that the actual work will be accomplished during the fall recess of the House and when the 88th Congress assembles in January there will be among that group many new Members who will see this national motto and little realize it had not been a part of the House Chamber since the beginning. For those who return and know how this inscription came to be there will be the good feeling that something has been done which should have been accomplished years ago.

One of the byproducts of our act today is that we have given perhaps not directly but yet in a not so subtle way our answer to the recent decision of the U.S. Supreme Court order banning the regents prayer from the New York State schools. At the conclusion of the session some Members were heard to say that we had just reversed the decision of the Supreme Court. They may be right but this we know that our action of today will go a long way to reaffirm the faith of every Member in our Heavenly Father by the constant reminder of our national motto, "In God We Trust."

The SPEAKER. The question is on the resolution.

The resolution was agreed to.

A motion to reconsider was laid on the table.

GENERAL LEAVE TO EXTEND

Mr. JONES of Missouri. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days in which to extend their remarks on the resolution just passed.

The SPEAKER. Is there objection to the request of the gentleman from Missouri?

There was no objection.

OCEANOGRAPHIC ACT OF 1962

Mr. DINGELL submitted a conference report and statement on the bill (S. 901) to advance the marine sciences, to establish a comprehensive 10-year program of oceanographic research and surveys, to promote commerce and navigation, to secure the national defense, to expand ocean, coastal, and Great Lakes resources, to authorize the construction of research and survey ships and laboratory facilities, to expedite oceanographic instrumentation, to assure systematic studies of effects of radioactive materials in marine environments, to enhance the public health and general welfare, and for other purposes.

WHITE HOUSE CONFERENCE ON NARCOTICS

Mr. RYAN of New York. Mr. Speaker, I ask unanimous consent to extend my remarks at this point in the RECORD and include a speech of the President today at the White House Conference on Narcotics.

The SPEAKER. Is there objection to the request of the gentleman from New York?

There was no objection.

Mr. RYAN of New York. Mr. Speaker, today President Kennedy opened the White House Conference on Narcotic and Drug Abuse, a milestone in attacking the complex problem of drug addiction. The President and the Attorney General have seized the initiative and shown the continuing interest of the administration in seeking and finding solutions. I am sure that my colleagues will be interested in the President's remarks welcoming the participants. I include them at this point in the RECORD:

REMARKS OF PRESIDENT JOHN F. KENNEDY BEFORE THE WHITE HOUSE CONFERENCE ON NARCOTIC AND DRUG ABUSE

Mr. Chairman, participants in this Conference on Narcotic and Drug Abuse, and guests, for more than half a century this Nation has faced persistent and vexatious problems arising out of the abuse of narcotic and nonnarcotic drugs. It is especially tragic and upsetting that this great loss to our society in the form of human suffering and misery and lost productivity flows directly from agents which possess the capacity to relieve pain and suffering. Properly and expertly used, they contribute significantly to the improvement and betterment of our lives, a fact to which millions of us can give personal testimony—improperly used, their fruits can be degradation, incapacitation, and crime.

This national problem merits national concern. I am confident that this White House Conference—the first ever held in this field—will help focus attention on the various aspects of the problem and most importantly, will permit a pooling of our information and experiences to the end that an orderly, vigorous, and direct attack can be undertaken on all levels: local, State, Federal, and international. Assembled here today are representatives from cities, States, and 12 different Federal agencies, including many of the Nation's most distinguished men and women in the fields of medicine, law, sociology, education, and law enforcement.

There is universal agreement that the two key objectives of an effective program are the elimination of illicit traffic in drugs and secondly, the rehabilitation and restoration to society of the drug addict.

In recent years we have seen a drastic and dramatic reduction in the volume of illegal narcotics and drugs brought into this country. This is a result of the cooperative effort of numerous Federal, State, and local agencies, but I must single out the Federal Bureau of Narcotics for special note. Under the forceful and purposeful leadership of Commissioner Anslinger the Bureau reduced this misery-producing traffic so effectively that where 35 years ago addicts could purchase 100 percent, or pure, heroin, the sharply curtailed amount entering the United States today requires traffickers to dilute their product to the point that the addict obtains only 3 to 5 percent heroin in the packet he purchases.

This morning I presented a special citation to Commissioner Anslinger expressing the appreciation and gratitude owed him by the people of the United States and the world community for the enormous contribution he has made to the control of illicit drug traffic.

This vital aspect of the attack on the drug abuse problem must continue—surely the conference panel devoted to this subject will bring together our Nation's most experienced and skilled personnel.

Although there is admittedly some divergence of view regarding the remedial action which is most appropriate for the addict who peddles illicit narcotics, there is no divergence of opinion on the need for vastly improved techniques and programs aimed at rehabilitating all addicts. The discouragingly high degree of relapse among addicts who leave our medical institutions free of any physical dependence on drugs is clear evidence that more must be done. It comes as no surprise to learn that a great majority of those who leave our institutions to return to the same physical environment, to the same friends and to the same pressures which initially compelled them to addiction will soon succumb again and repeat the cycle. Positive efforts to break the cycle will obviously be more successful—and indeed much less costly—than a system which treats the symptoms and disregards the causes.

A group of eight eminent scientists has, at my request, spent the past 3 months preparing a report on drug abuse to serve as a working paper for this conference. The document, circulated to all participants, suggests many areas of inquiry. One meriting special attention deals with the growing abuse of nonnarcotic drugs, including barbiturates and amphetamines. Society's gain will be illusory if we have reduced the incidence of one kind of drug addiction only to have new kinds of drugs substituted. Abuse of these drugs is increasingly creating problems of abnormal and antisocial behavior, highway accidents, juvenile delinquency, broken homes. An especially disturbing aspect of the alarming increase in the illegal traffic in these drugs is their particular attraction to juveniles because of the ease with which they can be obtained and their extremely low cost in comparison with narcotic drugs. The Congress is now considering legislation which I have requested to strengthen Federal authority to control the manufacture and distribution of barbiturates and stimulant drugs. This key area should be the subject of continuous intensive scrutiny. The sooner effective devices for preventing abuse of these drugs are implemented, the less severe the problem will be.

Our focus on national issues must not obscure the international aspects of our drug abuse problem. Criminals responsible for international traffic in illicit narcotics have no respect for national boundaries. Many nations have a real concern in controlling illicit traffic, and toward this end, the United States, through our representation on the United Nations Commission on Narcotic Drugs, has sought international cooperation in dealing with this evil trade. In addition, the U.S. Government will continue to work directly with other nations to secure adequate international controls.

In my recent conversations with President Mateos, of Mexico, we discussed the eradica-

tion of illegal drug traffic, and agreed to redouble our efforts and our cooperation to achieve it.

The Bureau of Narcotics has cooperated with narcotic enforcement officers in Europe and the Near and Middle East to strike at the foreign sources of illicit narcotic drugs intended for U.S. consumption. These efforts have been so successful that the activity of the Bureau of Narcotics is being expanded to other parts of the world, a program which will be implemented before the end of this year.

It is unfortunate that in this area of drug abuse there have been conflicting approaches, a dearth of hard factual data, and only partial cooperation between Federal, State and local governmental levels. It is our hope and expectation that the convening of this conference will provide a forum where this frequently tragic and dangerous social problem of drug addiction can be systematically explored and a unified approach developed. As you begin your humane task, let me assure you of the full cooperation of the Federal Government and of our earnest intention to insure that drugs not be employed to debase mankind, but to serve it.

FISHING PORT IN CUBA

Mr. ADAIR. Mr. Speaker, I ask unanimous consent to address the House for 1 minute and to revise and extend my remarks.

The SPEAKER. Is there objection to the request of the gentleman from Indiana?

There was no objection.

Mr. ADAIR. Mr. Speaker, I note in today's papers that the State Department is aware of the announcement by the Soviets and Castro that a fishing port will be built in Cuba. Officials of the Department of State will watch the development closely. Will that watching be as "sidewalk superintendents"? Or will they face up to the fact that this port—and radio station—with facilities for handling more than 100 ships, submarines, or what have you, without a doubt will become a hostile naval base just 90 miles off our shores.

In a column adjacent to the news story about the State Department's watchful waiting for developments in the construction of the naval base was another story. It relates the concern of Americans over the Communist military buildup in Cuba and its threat to the peace and security of this Nation and the Western Hemisphere. The article I refer to was headlined "Pickets Halt Loading of Red Ship." Patriotic Americans at Houston, Tex., including housewives, children, and a group of Cuban refugees, picketed a Yugoslav freighter thereby halting the loading of U.S. surplus flour aboard a vessel which has just carried Russian grain to Cuba.

When are responsible officials going to awaken? Communism with great military potential as a threat to America's security is now within easy missile distance of the United States.

HITTING THE BEACHES

Mr. ALGER. Mr. Speaker, I ask unanimous consent to address the House for 1 minute and to revise and extend my remarks.

The SPEAKER. Is there objection to the request of the gentleman from Texas?

There was no objection.

Mr. ALGER. Mr. Speaker, I am happy to report to the House that the statement made yesterday by the gentleman from Ohio [Mr. HAYS] in which the gentleman from Texas now addressing the House and the gentleman from New York [Mr. PILLION], were mentioned, I have been assured privately, in no sense was intended to be derogatory, that we would be slow to hit the beaches with the gentleman from Ohio in case we ever, God forbid, became engaged in combat. I understand that no such implication was intended either in that part that was added under permission to revise, which we did not hear on the floor.

CHELSEA RIVER-BOSTON HARBOR PROJECT

Mr. LANE. Mr. Speaker, I ask unanimous consent to extend my remarks at this point in the RECORD.

The SPEAKER. Is there objection to the request of the gentleman from Massachusetts?

There was no objection.

Mr. LANE. Mr. Speaker, for many years I have been interested in securing the assistance of the Federal Government to improve navigation on the Chelsea River, which is a coastal stream emptying into Boston Harbor.

Boston is the major port that serves all the six New England States. Chelsea River, bordered by East Boston and the cities of Chelsea and Revere, is vital to the Port of Boston. This river is used primarily for the receipt of petroleum products, which are distributed by truck and rail over a large area. It accounts for over 39 percent of the petroleum receipts in Boston Harbor. Annual waterborne commerce is more than 5 million tons. Commercial vessels, with drafts ranging up to 34 feet, make thousands of trips in and out of this river each year.

Chelsea River is the heart of the petroleum supply line upon which the military installations and the concentration of defense industries depend, in addition to the growing needs of the New England economy.

The original authority for this project dates back to a resolution of the Public Works Committee, U.S. House of Representatives, adopted February 1, 1946. Improvements under the original project have proved to be inadequate.

After a thorough survey, the Corps of Engineers, U.S. Army, has recommended that prospective commerce in petroleum and petroleum products is sufficient to justify deepening the channel to 35 feet from the Boston Harbor main ship channel to the Chelsea Street Bridge generally 225 to 250 feet in width, a channel 35 feet deep varying in width from 250 to 430 feet above the Chelsea Street Bridge; and a maneuvering basin 35 feet deep with 800 feet average width and 1,000 feet average length.

Because of the larger sized tankers now in use for the waterborne transportation of petroleum, present shallow depths make navigation hazardous and results in delays to deep-draft commercial traffic using the harbor.

The estimated cost for these improvements, based on the price level of July 1960, would be:

Federal	$2,843,000
Non-Federal	2,140,000
Total	4,983,000

The annual benefits would be:

Transportation savings	$531,350
Towboat savings	66,900
Reduction in tidal delays	184,000
Total	782,250
Benefit-cost ratio	4.0

In addition to the recommendations of the U.S. Army Engineers, the U.S. Department of the Interior and the Commonwealth of Massachusetts favor this project, and the U.S. Bureau of the Budget offers no objections.

All the evidence points to the need for an early start on these improvements—House Document No. 350, 87th Congress—because they are essential to the economy of Massachusetts and New England.

OPERATION 85

The SPEAKER. Under previous order of the House, the gentleman from Nebraska [Mr. CUNNINGHAM] is recognized for 60 minutes.

Mr. CUNNINGHAM. Mr. Speaker, I am a member of what is called on our side of the aisle the 85th Club. This club is composed of Members who entered this Chamber 6 years ago.

Early this year in conference with each other and jointly we felt that we would want to offer something constructive as our contribution as a project to the improvement of the various maneuvers and programs of the Congress.

I do not know what to call this particular special order. It might be called "Operation 85." It might be called "A Program to Modernize Procedures." It might be called "A Program for a 'Do Something Congress.'"

This certainly is no reflection upon our distinguished Speaker and our distinguished majority and minority leaders because now as we are drawing to the close of this session I think we have accomplished a great deal. Our concern was that not enough attention was focused upon some of the procedures in the Congress that many of us felt, if improved and revised, might allow the proceedings in the Congress to be a little smoother and perhaps allow it to accomplish just as much as we accomplish now, only with less time spent upon it.

The members of the 85th Club who, as I said, are Members on our side of the aisle, are the gentleman from Michigan [Mr. BROOMFIELD], the gentleman from Michigan [Mr. CHAMBERLAIN], the gentleman from Illinois [Mr. COLLIER], the gentleman from Pennsylvania [Mr. CURTIN], the gentleman from New York [Mr. DOOLEY], the gentlewoman from New Jersey [Mrs. DWYER], the gentleman from New Jersey [Mr. GLENN], the

gentleman from Michigan [Mr. GRIFFIN], the gentleman from Illinois [Mr. MICHEL], the gentleman from West Virginia [Mr. MOORE], the gentleman from Minnesota [Mr. QUIE], the gentleman from New York [Mr. ROBISON], the gentleman from California [Mr. SMITH], and myself.

As I mentioned, about a year ago we sat down collectively to go over some of the various proposals that have been made by Members on both sides of the aisle and also to think among ourselves about some of the things that we think might be adopted or at least considered to improve the operation of this great and distinguished body.

There are many things that have come to our minds. Some of these proposals have been introduced before—some are of our own thinking. I would like briefly to recite some of the things we have in mind. Again may I emphasize that this is in no way a reflection either on the majority party or the minority party, but it is a sincere effort to give some attention to procedure which would increase the efficiency of this great body. For example, we thought of a proposition having to do with a more effective valuation of fiscal requirements of the executive agencies. We gave consideration to the item veto. We gave consideration to the joint sponsorship of bills as they do in the other body rather than individual bills as prevails in this body. We gave consideration to clerk hire allowances on a gross basis or population basis. This system now is so complicated that it almost takes a mathematician to figure out what the salaries of our employees should be.

We gave consideration to provisions for appointment of Representatives in case of disaster that might affect our country so that this great deliberative body could carry on. We gave consideration to back-door spending; to prefiling of bills during recess to allow earlier starts on departmental reports as is now being done in the New York State Legislature.

Also to give committee and subcommittee chairmen authority to allow broadcasting and telecasting of hearings and provide automatic rollcalls on all appropriation bills.

To confine extension and revision of remarks in the RECORD to grammatical and typographical corrections.

To amend the Reorganization Act of 1946 to provide that Congress will adjourn by the last day of August.

And following June 1, only the committee chairmen, subcommittee chairmen, and ranking minority Members may introduce bills with the understanding that such bills in each case will be limited to those which will be expected to be referred to the committee or subcommittee involved. This is done in many legislatures including that of my own State.

To limit each Member to include articles for extension in the RECORD only when such material pertains to matters of legislation.

To provide that appropriation bills will be laid on the table following House consideration until all have received tentative approval and the latest budget estimates are available and then fiscal action can be taken on the entire budget.

For seniority purposes in determining committee chairmen, all Members with 20 years' experience are considered equals. This would allow selection of committee chairmen who are representative of the majority of the Members of the committee.

For full reports in the CONGRESSIONAL RECORD of expenditures by committees, Members, and employees on official trips.

For an increase in the minority staff members of the committees.

For a summer recess which would allow all of us to have a couple of weeks with our families whom we are so often apart from to go back to our districts together or to go for some relaxation and come back refreshed so that tempers having gone through the hot summer months and for many months of the session would not be so short.

For a congressional student intern program where it would be provided that each congressional office might employ for a 3-month period a legitimate college student to be an intern in a Congressman's office. We also would provide more time for the study of appropriation bills.

Mr. Speaker, most of the proposals have been introduced in the last few days or earlier and others will be as the Members are able to have them framed.

Mr. Speaker, one of the bills that I have dropped into the hopper provides for more study of appropriation bills. At the present time after the filing of the committee report 3 calendar days elapse before a vote is taken. My proposal would provide that 5 legislative days should elapse, because these are very technical and very intricate measures, and it would give us all an opportunity to study them in greater detail.

Mr. Speaker, I am pleased to join my colleagues from the 85th Club in sponsoring a portion of this program for constructive action to improve the procedures of the Congress.

We do not seek to place blame on either party, nor do we criticize leadership or Members of this body. We are offering constructive and concrete suggestions—in one place and in one time—which we sincerely believe will increase the efficiency of the House of Representatives.

We are interested in doing the best possible job for the people we represent. We are interested in seeing that we are able to do the best possible job and that we and our colleagues are not hindered by antique rules which have outlived their usefulness.

The suggestions we are offering are not new or radical. Instead, we studied the many legislative ideas advanced by Members of this body and selected those we felt had the most merit. We agreed to divide those up among our number but to seek action on them jointly in hopes that through this means we would succeed where individuals have not had the time to push their separate proposals, as meritorious as they may be.

I believe the gentleman from California [Mr. SMITH] will in due time mention the other Members of this body who have already sponsored these ideas we endorse or ideas very similar to them. We appreciate the work these colleagues have done and heartily congratulate them for their efforts. We hope we can be of assistance.

The legislation I have introduced, House Resolution 809, will provide additional time for study by all Members of this body of hearings and reports on general appropriation bills before they are brought to the floor for debate and action next year. At present, there is only a necessity for 3 calendar days to pass following the formal filing of the Appropriations Committee report on a general appropriation bill before that bill is called up for decision.

I subscribe to the belief that if we are to represent, we must be informed on the bills before us. Without for one moment inferring that the Appropriations Committee of this body is not diligent and most effective, I believe that we can all use more time to study the record of hearings and the Appropriations Committee's written report prior to action on appropriations bills.

Accordingly, the resolution which I sponsor will provide that at least 5 legislative days shall pass after the filing of the Appropriations Committee's report before the general appropriation bill covered by the report may be brought to the floor for action.

This should not delay the work of the House for 1 minute. But it will allow all of us to be even more familiar with the details of multibillion-dollar appropriations bills which we vote on. We are responsible to our constituents for the spending of these billions of dollars. Certainly we must have time to be aware of just what these bills provide.

I appreciate the opportunity to be a part of this program. I urge my colleagues on both sides of the aisle to join in this program and to give every possible support to these bills as they move into the committees.

Mr. COLLIER. Mr. Speaker, will the gentleman yield?

Mr. CUNNINGHAM. I yield to the gentleman from Illinois.

Mr. COLLIER. Mr. Speaker, I would like to compliment and commend the gentleman from Nebraska for what I know to be a very sincere effort on his part to provide some means by which we, as Members of Congress, can make a constructive reappraisal of the legislative processes and many of those things with which we deal.

Mr. Speaker, the frightening public indebtedness and the critically low condition of our gold reserves should shake every fiscally responsible Member of Congress into taking positive action to curb the practice of back-door spending.

First, may I call to the attention of the Members of the House that section 9 of article I of the U.S. Constitution specifically states:

> No money shall be drawn from the Treasury but in the consequence of appropriations made by law; and a regular statement and account of receipts and expenditures of all public money shall be published from time to time.

There is grave doubt in my mind as to whether the Congress has not repeatedly

in the past exceeded its constitutional authority in committing the Treasury to obligations on a long-term basis and beyond the current fiscal year during which such commitments were made by law.

Under the Boggs decision rendered in 1949, language contained in measures calling for expenditures from debt receipts was declared "not to come under the definition of appropriations." Since that decision was rendered there has been a vacuum in the area of any positive definition of what actually constitutes a commitment upon the Treasury by the Congress.

Aside from the constitutional concept of commitments voted on a long-term basis, we are today facing critical problems which we must not continue to sidestep. My colleagues, just as sure as the sun will rise tomorrow, the people of this country will have to face up to the fact that we cannot go on spending and spending indefinitely with only verbal concern for our present astronomical Federal indebtedness.

In President Kennedy's inaugural address of January 20, 1961, he pledged to do whatever might be needed to insure the soundness of the dollar. In fact, the Chief Executive reiterated to Congress that it was not his intention to advocate any program of expenditures that would of and by itself unbalance the budget. This, however, has certainly not been the pursued policy of the administration.

The sad fact is that Congress not only continues to consistently appropriate funds in excess of revenues, but, in fact, pledges the good faith of the U.S. Government in commitments that stretch far beyond each fiscal year.

The fact of the matter is that we, as responsible representatives of the people of this Nation, have a solemn obligation to preserve the fiscal integrity of the country—and this most certainly embraces an obligation to the next generation which will be saddled with the great indebtedness which now obviously will become the sad heritage of your children and mine, and even our grandchildren. It would seem that our experiences of the past and the present state of the Treasury finances would shake more elected representatives into realizing that we cannot roll merrily on, ignoring the simple facts of addition, subtraction, and multiplication, as they apply to our national income, pattern of expenditures, and excessive interest rates on refinancing.

It is all well and good to say that the answer lies in an expanded economy which will bring increased revenues, but is this not wishful thinking in the face of our experience?

Although it may not always be politically expedient to forgo the appropriation and commitment of Federal funds, we will have to either do it voluntarily or we will ultimately be forced to embark upon a program of Government control in our economy. This would be a sad plight for a nation that has built its strength upon a free economy. It seems to me that we are heading for a new era of inflation which can only retard prosperity and create new serious problems for all of our citizens. It is about time that we put into practice some degree of the sacrifices which President Kennedy promised would be forthcoming. It is about time we start looking about for ways in which we can do something for our country rather than constantly seeking that which the Government can do for us. We spend billions each year for national defense and to maintain our strength in a world which is plagued with an ideology and philosophy that would destroy our way of life. And yet we have displayed no honest effort to make any sacrifice to keep the foundation of our fiscal house solid.

Early action on House Resolution 321 will be the first step toward doing that which is our responsibility to do. It will prescribe a course that will stem any new inflation. Our economy depends upon it and our position of strength in the world today depends upon the fiscal stability of this Nation.

Mr. CUNNINGHAM. I thank the distinguished gentleman from Illinois, who has, with the rest of us, worked very hard on this project, which, as I say, is certainly in no sense a political matter, but there are things that should be done and we hope everyone will help in this project.

Mr. QUIE. Mr. Speaker, will the gentleman yield?

Mr. CUNNINGHAM. I yield to the gentleman from Minnesota.

Mr. QUIE. Mr. Speaker, at this late date I think everyone will agree that the House needs some reorganization, not only because of the late date but in order that we may do our duty more responsibly. The gentleman should be commended for the work he has done, as the gentleman from New York [Mr. ROBISON] who has worked with him on this matter of developing ways that the Congress can work more responsibly.

I notice as we consider appropriation bills we consider them in different packages, never realizing until the end of the session whether we have appropriated money within or without the budget. The experience of the past year shows that we have been appropriating more money and spending more money than we have taken in. I believe a plan can be devised by which we can operate more efficiently and responsibly and take in the whole picture of our Federal spending before the appropriation bills are finally passed.

When the mailman brings you a bill from the department store or drugstore, when he brings renewal notices from insurance companies or magazines, or when you have other financial obligations, do you sit right down and write a check? Or do you first find out how many bills you will receive this month and whether they must be paid in full or in installments?

Most of us have a budget of some kind or at least an idea of what we will have to pay each month in bills. We base our spending on this budget. We do not buy everything we want right now, but we keep our eyes on the total we have available and spend as we feel we can each month.

Do you realize that the Congress does just the opposite? The Congress blindly appropriates money more than a dozen times each year without having any clear idea of how much the total will be, or how much tax money will be available to pay the bills. That is, in my opinion, why we have had so many deficits in recent years.

We still operate in Congress as they did in Civil War days. We have no clear idea of how much we will spend each year, despite the close scrutiny given each separate appropriation bill by the Appropriations Committees of the House and Senate.

This is because each major Government department is provided for in a separate bill. Each department's appropriation bill comes up at a different time during the year. Each bill is passed without any clear idea of what the total of all these bills will be. It is a foolish and dangerous procedure.

We need a more responsible procedure. I am proposing one. Basically—it works like this:

When the appropriation bill for the Agriculture Department comes to the House, the House will consider it and make a judgment on it. But then, instead of passing the bill, we will hold it until we have considered appropriation bills for all the other departments and agencies.

After all of the bills have been considered, we will know how much the total is and how it compares to the amount of anticipated tax revenue. We will know pretty well whether we are going to spend less than the Government receives—or spend $1 billion, $2 billion, or $10 billion more than we expect to receive. If it turns out that we are way over expected revenues, the House can go over all these bills again and cut out some of the new programs and reduce others until we have a balanced budget.

And at this time, the forgotten Americans—the taxpayers—can let everyone here know just how they feel about big Federal spending programs.

The way things are done now, the taxpayers have to be on the alert every week to watch for the many separate appropriation bills, and I know it is a hard job to keep up with all the goings-on in Congress when your interests are naturally concentrated on earning a living and raising a family. Yet the lobbyists and special interest people are here every week, plugging away for their special projects and programs, pleading for a few more million dollars for this department and that agency. They have a lot of success, for their arguments are persuasive and they claim to represent a lot of people interested in these special programs.

As I say, the taxpayers of the country have to counteract every one of the hundreds of lobbyists all through the year. Now, if my suggestion is adopted, the lobbyists will find it harder to operate. The taxpayers will find out the total amount Congress expects to appropriate and can easily see whether this is any time for expanding old programs and starting new ones, or whether the state of the Nation's finances make it desirable to cut

back, pull in our belts a notch, and hold off on these special interest projects until there is money available, if that day ever comes.

We have a national debt of over $300 billion. In addition, this Government is obligated to pay about $750 billion more for other programs and activities already started. It is time we brought some order out of our chaotic appropriation methods. I sincerely believe it is time Uncle Sam took a lesson from all his nephews and nieces on how to run a budget.

Mr. CUNNINGHAM. I thank the gentleman from Minnesota, because he has also worked diligently on this project.

Mr. CURTIN. Mr. Speaker, will the gentleman yield?

Mr. CUNNINGHAM. I yield to the gentleman from Pennsylvania.

Mr. CURTIN. Mr. Speaker, I wish to commend the gentleman from Nebraska for his leadership in this matter and, as a participant in the program just outlined by Mr. CUNNINGHAM, I wish to take a few minutes of the time of this body to speak on a resolution which would require a vote of the House, by the yeas and nays, on all appropriation bills. I speak of House Resolution 813, which I introduced yesterday, and all similar resolutions previously introduced.

This is a matter which Members have discussed over the years but which has never reached the point of affirmative action.

As we look back over the action of the House during this Congress and consider the various appropriation and supplemental appropriation bills which have been brought before us, there would seem to be no real reason why our individual votes should not have been recorded by the yeas and nays in each instance.

We very frequently appropriate billions of dollars in a single appropriation bill and this, by any standard, is a lot of the taxpayers' money. The taxpayers of this country at large, and particularly the taxpayers who are our constituents, should have no doubt as to how each of us voted on each of these bills which so affect their individual pocketbooks.

I have heard no valid arguments against this position except the statement that it is always done on certain appropriation bills. This is correct and I am glad of it, but we should extend the practice to all such bills.

As we approach the closing day of this 87th Congress, let us firmly resolve to give this matter very serious consideration in the next Congress.

I thank the gentleman for yielding.

Mr. CUNNINGHAM. I thank the distinguished gentleman, our colleague from Pennsylvania, who, as a member of the 85th Club which I have mentioned, has worked diligently on this project. I certainly hope that some serious consideration can be given to his particular proposal.

Mr. NELSEN. Mr. Speaker, will the gentleman yield?

Mr. CUNNINGHAM. I yield to the gentleman from Minnesota.

Mr. NELSEN. Mr. Speaker, while I am not a member of the 85th Club, I am a member of the 86th Club.

Mr. Speaker, I feel that we owe to the 85th Club a vote of thanks and commendation for their efforts which they have so well discussed here today in bringing about various circumstances relative to our Government and to the welfare of our country.

Mr. Speaker, many of us who adopt a rather conservative line are sometimes criticized for that. But I think it must be remembered that if our country is to be strong militarily, if we are to protect our balance of trade, if we are to protect our gold reserve and our fiscal integrity, a part of it is because of the fact that one of the contributing factors to that end is careful administration of our governmental affairs.

Mr. Speaker, I note in the discussion today those factors have been highlighted. I wish to endorse that feeling, and I wish to compliment the gentleman in the well of the House, the gentleman from Nebraska [Mr. CUNNINGHAM], for the gentleman's leadership and for the gentleman's work in that direction.

Mr. BEERMANN. Mr. Speaker, will the gentleman yield?

Mr. CUNNINGHAM. I yield to the gentleman from Nebraska.

Mr. BEERMANN. Mr. Speaker, I too am not a member of the 85th club nor the 86th club. But as a member of the 87th club and a fellow colleague of my distinguished friend, the gentleman from the Second Congressional District of Nebraska, I would like to compliment the gentleman for the gentleman's work performed in all fields about which I know since I have been here. I want to take this time to thank the gentleman personally and publicly for the help and assistance which the gentleman gave to me when I first came to Congress with reference to procedures and the various workings of the House of Representatives in order that I could do my job more effectively.

Mr. Speaker, I would like to close by saying that I hope the gentleman continues in this work. I know we shall see some results from the fruits of his efforts.

Mr. CUNNINGHAM. I thank the gentleman.

Mr. Speaker, I ask unanimous consent at this point to insert, following the remarks of the gentleman from Nebraska, the remarks of the gentleman from New York [Mr. ROBISON].

The SPEAKER pro tempore (Mr. LIBONATI). Is there objection to the request of the gentleman from Nebraska?

There was no objection.

The remarks referred to follow:

Mr. ROBISON. Mr. Speaker, I am pleased to join with my colleagues on this side of the aisle who entered their congressional service in the 85th Congress, in introducing legislation to bring about desirable reforms in the procedures and housekeeping aspects of the House of Representatives.

All of us are aware of the complicated and faintly ridiculous formula by which the salaries of employees of the House are computed. Beginning with the Federal Employees' Pay Act of 1945, cost-of-living and percentage increases made in the salaries of staff personnel of the House of Representatives, including the staffs of Members of Congress, have been made by adding such increases to a basic sum which was the annual salary prior to the 1945 act. This has now reached such an extreme that, to compute the salary of any employee of the House, it is necessary to take the basic salary and go through such additional steps involving nine separate increases, in order to arrive at the actual gross salary which the employee receives.

There have been regular outcries against this archaic procedure, and these protests have generally been made at the time pay raises have been enacted by the House. There have always, in answer to these protests, been assurances by various members of the leadership and by the Committee on House Administration that studies would be made and consideration given to modernizing and reforming these procedures. The net result has been nothing except the further confusion of additional steps added to the formula.

With the possibility of a further Federal pay increase being considered by the House in a few days, we face the distinct probability that a tenth step will be added to the salary formula.

Various reasons are given for the inaction in modernizing this system. But, regardless of the true reason, editorial criticism is often made that the basic reason for inaction is the desire on the part of the Congress to cloud and obfuscate the actual salaries being paid its employees, by stating such salaries according to a basic figure. I do not believe this. The gross salaries of all Members of the House are available to anyone who wishes to visit the Disbursing Office and study the payroll. This is as it should be, and surely there is no logical reason for continuing the archaic system of salary computation now used which, among other things, poses a huge and needless workload on the personnel of the House Disbursing Office.

Accordingly, I have introduced H.R. 13236 to simplify the payroll administration in the House of Representatives by providing that the salaries of employees of the House and the clerk hire allowance of Members which consist of aggregate annual amounts rather than basic annual amounts plus the nine additional amounts now used. I strongly urge that this body take steps to modernize itself. The legislative subjects with which we deal bring home forceably that we are living in the second half of the 20th century. Yet, the House continues to function under rules and regulations which are decades out of date.

Mr. CUNNINGHAM. Mr. Speaker, I now ask unanimous consent to insert an article which appeared in the U.S. News & World Report of September 12, 1960, entitled "What's Wrong With Congress—118 Members Answer."

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Nebraska?

There was no objection.

The material referred to follows:

WHAT'S WRONG WITH CONGRESS—118 MEMBERS ANSWER

(One more Congress has just ended its work—and once again, as always, there are complaints about what it did or did not do.

(Is there something really wrong with the way Congress operates? Has it failed to keep pace with the growth of the Nation and its problems?

(Is it time for changes to be made?

(To find out what Members themselves think, U.S. News & World Report asked them 12 questions. Answers came back from 28 Senators and 90 House Members, providing a cross-section of opinion in both Houses.

(Generally, the survey shows, the lawmakers are more proud than alarmed about their performance. Yet they find many things that they think wrong, and feel that they could do better.

(Presented here are their criticisms, and their suggestions for improvement.)

The big complaints:

Tuesday-to-Thursday Club—3-day workweek.

Nineteenth-century methods.

Not enough staff to handle work.

Mounting, incessant demands on Members.

Too many problems from States and cities.

Gradual destroying of Senate as deliberative body.

Short, overcrowded sessions.

Too much power for committee chairmen.

Lobbyists and pressure groups increasing.

Too busy to study legislation.

For 172 years, the Congress of the United States has charted this Nation's course. It has shaped policies, voted appropriations, levied taxes to pay ever-growing bills.

In all of that time, Congress has been under fire.

There are complaints that Congress does not do enough, or that it does too much. Its acts are attacked as either too radical or not radical enough.

Yet, in war and in peace, in time of prosperity and of depression, under the rule of one party and then of another, Congress has gone along its way.

The First Congress legislated for a nation of 4 million people, the 86th Congress for a nation of 180 million. The first Senate had 26 Members, the first House 65 Members. The 87th Congress, to be elected November 8, will have 100 Senators and 437 House Members.

Always, as its size and responsibilities have grown, there has been a feeling that something is wrong with Congress.

Is there really something wrong? To get an answer, U.S. News & World Report went directly to the men and women who serve in Congress. Each individual Senator and Representative was asked 12 questions, all related to this overall question: "What is wrong with Congress?"

Answers were received from 28 Members of the Senate and 90 Members of the House, giving an appraisal of Congress and its work by 118 of its Members. An additional 40 Members replied that lack of time alone prevented them from giving their appraisals.

From their answers, you learn that Members of Congress find much that they regard as wrong.

Much criticism is directed at what has become a Tuesday-to-Thursday workweek for most of a legislative session. Procedures and rules under which work is carried out in both Houses are widely regarded by Members as faulty and needing change.

There is a strong feeling in the House that its Members should be elected for 4-year terms instead of 2-year terms. Both Representatives and Senators are convinced of the need for larger staffs to deal with multiplying problems that arise in a growing nation.

Some criticism is made of the way committees operate, although the choice of committee chairmen by seniority is almost unanimously approved.

While finding much that is wrong, Congress' Members also find much of which to be proud. Overall, there is an evident feeling that the system, whatever its flaws, works surprisingly well.

What follows are the questions put to Members of Congress by U.S. News & World Report, and the answers they gave.

QUESTION: WHAT, IN YOUR OPINION, IS WRONG WITH THE WAY CONGRESS FUNCTIONS?

This opening, shotgun-type question produced a spirited defense of Congress by many Members. At the same time, there were many sharp criticisms. Such as these:

Representative CHARLES B. HOEVEN, Republican, of Iowa: Congress "wastes too much time in accomplishing its work."

Representative William E. Hess, Republican, of Ohio: "All necessary legislation could be enacted over a shorter period of time."

Representative FRED MARSHALL, Democrat, of Minnesota: "The dilatory tactics on the part of the Senate ought to be curtailed."

A Republican Senator, who preferred to remain anonymous: "Congress is too much motivated by fears and anxieties concerning pressure groups and the 'next election.' Best recent example: The pay-raise bill of 1960."

Representative Wint Smith, Republican, of Kansas: "Congress has become subservient to labor bosses and international pressure groups."

Representative HARLAN HAGEN, Democrat, of California: "There is too much control over individual legislation residing in too few hands."

"Tuesday-through-Thursday club"

Much of the timewasting was blamed on Members themselves. Most common criticism, in this respect was directed at something that has come to be known in congressional circles as the "Tuesday-through-Thursday Club." This club, as Members describe it, is made up of lawmakers who leave Washington on Thursday night and don't come back until Tuesday morning.

Representative W. R. POAGE, Democrat, of Texas, tells about the "Tuesday-through-Thursday Club" in these words:

"So many Members of Congress go home to meet their constituents, to perform their legitimate duties and, in some cases, to practice law or operate a business that it becomes, for practical purposes, impossible to have any sessions Friday, Saturday, or Sunday, and nothing vital is done on Monday.

"There are about 250 Members of what we know as the TTT club (Tuesday through Thursday). They all live in the Northeast and as far west as Chicago. Other Members are no better, but a man in my area simply cannot afford either the time or the money to go home each weekend. * * * Very few of the TTT club Members will bother to attend a committee meeting if it is inconvenient. The result is we do not get the work done. I think that any Member of Congress should be dropped by a committee unless he attends, or offers a legitimate excuse such as sickness, at least half of the committee meetings."

Senator KARL E. MUNDT, Republican, of South Dakota, commented:

"The major difficulty with the way Congress functions is our failure to set and maintain a definite adjournment for each session. Consequently, the leadership in both Houses tends to adjust congressional schedules to the 'Tuesday through Thursday' routine, which best fits the convenience of Members on the east coast, and tends to delay the completion of business much longer than would be true if full schedules of activities were followed from Monday through Friday."

Representative FRANK CHELF, Democrat, of Kentucky, said:

"In my opinion, a considerable amount of our inability to operate early in the session is because of the powerful influence of the T. & T. club—in Tuesday and out Thursday."

Representative W. J. BRYAN DORN, Democrat, of South Carolina, observed:

"A lot of lawyers in the East want to go home and practice law every weekend."

Representative JOHN TABER, Republican, of New York, who has been in Congress 38 years, concluded:

"We should get back to work on the old basis, where we were there 6 days a week while the House was in session."

Out-of-date rules

Congressional rules of procedure drew much criticism.

Representative BURR P. HARRISON, Democrat, of Virginia, called it "operation in the 20th century century on 19th century procedures."

Representative ROBERT J. CORBETT, Republican, of Pennsylvania, said: "Rules need modernizing. Unnecessary delay is too easy."

Representative JAMES A. HALEY, Democrat, of Florida, commented: "The Congress has become too big and too unwieldy. Its duties and its procedures need to be streamlined."

Representative LeRoy H. Anderson, Democrat, of Montana, complained: "Under the present system, the committee frequently does not function as a committee but as a tool of the chairman. Legislation not having the support of committee, or subcommittee, chairmen usually has little chance. This is not representative government with 437 coequal Representatives."

Senator JOSEPH S. CLARK, Democrat, of Pennsylvania, singled out the Senate rules for special attack, saying:

"There is no other legislative body in the free world as incapable of action, when action is desired by a large majority but strongly resisted by a minority, as the Senate of the United States.

"It is my contention that the present rules of the Senate are obsolete, unworkable in the modern world, and a real danger to our American form of government at the Federal level. The political lag in reforming these rules which we have permitted ourselves should promptly be brought to an end."

Rules Committee a target

A favorite target for criticism by lawmakers was the House Rules Committee, which sets the schedules for consideration of measures on the floor after they have cleared other committees. The charge was made repeatedly that the Rules Committee often blocks a vote on a bill which it does not favor.

Representative Byron L. Johnson, Democrat, of Colorado, said there is "too much power in the Rules Committee."

An east coast Representative suggested:

"I believe there should be a limit on the time the Rules Committee can block action on any measure unanimously reported from another committee."

A Democratic Representative who asked not to be identified by name said:

"The Rules Committee as presently constituted is the most obvious and most serious example of the No. 1 problem—the great difficulty encountered by the majority of Members of the House in expressing their will. At the present writing (in August), for example, the House is effectively blocked from even voting on some major items of legislation affecting millions of Americans—education, health insurance for the elderly, and housing, to cite but three.

"Few Americans, even well-informed ones, know that the majority-minority ratio of membership on the three most powerful committees of the House—Rules, Ways and Means, and Appropriations—did not change at all following the large increase in Democratic margins in the 1958 elections.

"The majority-minority ratio on all other committees changed roughly reflecting the majority-minority ratio in the full House. But on the big three, the change in public opinion was in not the slightest degree reflected in the popular body of Congress.

"At a time of the greatest challenge to democratic government from a highly centralized totalitarian dictatorship in history,

we can no longer afford the luxury of seeing the Nation's highest legislative body paralyzed by a small group of men who come in some instances from thinly populated or gerrymandered districts and who therefore need pay little attention to the views of the majority of the millions of their fellow citizens.

"The present system tends to give undue power to the smaller towns and rural areas of the country, not only in the Senate, where population is, of course, not intended to count, but in the House as well."

Too many distractions

There was one complaint that was voiced by almost everyone replying to the U.S. News & World Report survey.

Representative RALPH J. SCOTT, Democrat, of North Carolina, summed it up like this:

"Too much of the Members' time is consumed in attending to matters that have no relation whatever to legislation."

Representative BURR P. HARRISON, Democrat, of Virginia, described the harried life of a Congressman in these words:

"A major fault is an intolerably vexatious, inefficient management of the time of its Members, which time has been purchased by the taxpayers. Congressional duties have increased enormously in the past quarter century.

"Social demands arise from the practice of annual congressional banquets held in Washington by business, agricultural, labor, veteran, fraternal, and other groups. The absence of a Member often is resented. Particularly in the spring, invitations of this kind can account for three or four evenings a week, and attendance upon the functions becomes work.

"Finally, for the majority of Members who now view their congressional service as a career rather than a short-term experience [there is] the task of maintaining contact with the home area through attendance on community functions, acceptance of speaking invitations and sampling of trends in public opinion by personal tours and correspondence. For a House Member, faced with biennial campaigns, this activity makes a constant demand on his time."

Senator JOHN STENNIS, Democrat, of Mississippi, said:

"I seem to thrive on the work. But after 13 years of service here, I frankly believe that the Senate as a deliberative body is gradually being destroyed, due to the mounting and incessant personal demands made on the time and attention of a Senator to so many personal requests and matters which are really outside and beyond the legislative field.

"Frankly, I do not know what, if anything, can be done about this situation. But, with the increased means of easy transportation and with the highly developed means of communication, combined with the fact that the people are financially able and are willing to come to Washington, the total effect is that through these personal demands a Senator is being made, in effect, a Congressman-at-large. It is impossible to serve such a large area and so many people on a personal basis."

Too much asked of Congress

Another complaint voiced by many Congressmen is that Congress is being forced to deal with problems that used to be handled at State or local levels.

A veteran Senator, who declined to be named, said:

"I have little criticism to offer as to the way Congress functions. The trouble, if any there be, stems from the fact that the legislative branch has embarked on too many programs that should be left to the individual States. Our Government is becoming more and more centralized. The States are becoming increasingly dependent upon the Federal Government for support in many fields in which, in the past, they assumed responsibility.

"Uncle Sam is becoming paternalistic to a very high degree, and my fear is that this trend will continue. Thus, the trouble lies, not in the manner in which Congress operates, but in the scope of its activities."

Senator STROM THURMOND, Democrat, of South Carolina, expressed a similar view:

"The constitutional design was for Congress to perform the legislative function of a central government whose powers were strictly limited in scope. Most of those isues which now require a preponderance of the time of Senators and Representatives are those which under the original conception of our Government would have been handled in each State by the State legislature."

More pride than alarm

In spite of all this growth and all these criticisms of certain details in congressional procedure, the majority of Members seemed to feel more pride than alarm about the accomplishments of Congress.

Representative Byron L. Johnson, Democrat, of Colorado, expressed the sentiment of many Members in this way:

"I cannot conclude my answer to your questions without observing that the Congress has run for 172 years with amateurs. No one can possibly be adequately trained, regardless of his background, for the complex demands the job involves. I think it is a remarkable tribute to the democratic process that the practices we have hammered out in this great Anglo-Saxon tradition have worked so well."

Senator FRANK J. LAUSCHE, Democrat, of Ohio, said:

"In my opinion, there is nothing wrong with the procedure under which Congress functions. It may be slow functioning, but under the circumstances, it is practically inescapable. However, in the slowness of the process, the Senators are able to accumulate extensive information on the many diverse bills that are pending. Discussions on the same subjects may seem repetitious, but, in the course of time, they begin to have their impact, acquainting Senators with the negative and affirmative aspects of an issue."

Representative CLARK W. THOMPSON, Democrat, of Texas, comments: "The function of the Congress, like any other body of human beings, occasionally merits criticism with deficiencies due more to the frailties of men than to any inherent defects in the system. Over the years, I have sometimes contemplated changes, but I always come up with the conclusion that, cumbersome as it may be sometimes, Congress does a good job."

QUESTION: DOES A SENATOR OR REPRESENTATIVE HAVE TIME TO STUDY FULLY THE ISSUES UPON WHICH HE MUST CAST A VOTE?

Agreement was almost unanimous on this question.

The answer was: "No."

Following are some typical comments:

Senator JOHN STENNIS, Democrat, of Mississippi: "A Senator does not have time even for a sketchy study, much less a full study, of all the issues upon which he must cast a vote."

Senator FRANK J. LAUSCHE, Democrat, of Ohio: "The time available to make an adequate study of all the bills that are pending is too meager. A Member can acquaint himself with the merits and demerits of the major bills. Frequently, however, there are bills which pass through the Senate unobserved, on the basis that they are of minor significance and noncontroversial when, in fact, involved in them is some basic principle of importance."

Senator THOMAS J. DODD, Democrat, of Connecticut: "No individual could hope to become fully informed on the hundreds of complex questions upon which Senators must vote each year. Members of the committees concerned with these questions can become thoroughly informed, and a Senator must frequently rely upon the judgment of the committees, unless his special interest in a particular problem or his basic political philosophy leads him to the contrary position."

Representative GEORGE H. MAHON, Democrat, of Texas, answered the question with: "No, but this is typical of most people in positions of responsibility in or out of Government. There is just not enough time in this modern age for citizens to do all the reading, studying and working that should be done. The problem is not peculiar to Congress."

Committee system helps

Senator JOHN MARSHALL BUTLER, Republican, of Maryland, said:

"No Senator or Representative has the time to study fully all the issues coming before him. This situation, however, is overcome to a large degree by the committee system and its areas of responsibility. But even with the committee system, the demands upon the time of a Senator or Congressman are such as to require concentration upon those items of particular importance to his State or the Nation."

Representative CARL ALBERT, Democrat, of Oklahoma, made this comment:

"No system could be devised, in my opinion, which would enable a Senator or Representative to study fully every issue upon which he must cast a vote. Congress, like most large organizations, functions through a division-of-labor method known in this case as the committee system. Members must trust their colleagues to specialize and to do the necessary research and conduct the necessary investigations in the various fields."

A few members took the view that, despite the shortage of time, a lawmaker could usually learn enough about pending measures to vote intelligently. Their comments follow:

Representative LeRoy H. Anderson, Democrat, of Montana: "Normally, no Member can be fully informed on every matter coming before the House; if, however, he studies the committee reports, he can know the issues involved in each question. On that basis, he will either know what his position should be or know that he needs to dig a little further and get more information about the subject. In general, then, the answer is 'Yes.' "

Representative CLARK W. THOMPSON, Democrat, of Texas: "Personally, I have time to study the issues on which I vote. I don't pretend to know the details of every bill, but I know men on each committee in whom I have great confidence. I consult with them and listen to their advice. Also I listen to the debate in cases where I do not feel adequately informed."

Representative B. Carroll Reece, Republican, of Tennessee: "A Representative or Senator does have time to study legislation, and I think a review of the discussion on important legislation indicates a thorough understanding of the legislation by the Members. Of course, each Member is not a specialist in every area, but those who are supposed to be specialists in a particular area do a thorough job as a rule."

Representative MELVIN R. LAIRD, Republican, of Wisconsin: "It depends upon the individual Congressman—his ability, his homework, and how well his party leadership and committee leadership keep him informed. To be effective, a Congressman must be able to organize his own time and his personal staff."

QUESTION: WHAT TAKES UP MOST OF THE TIME OF A MEMBER OF CONGRESS?

Nearly all Members complained about the time they are compelled to spend "running

errands" for constituents. Following are some sample criticisms:

Representative ABRAHAM J. MULTER, Democrat, of New York: "In my district, one half of my time is taken up running errands."

A southern Congressman, who did not want to be quoted by name, said: "I would say that answering correspondence (we average more than 100 letters a day from our district) and doing favors for constituents, totally unrelated to the business of legislating (arguing veterans' cases, handling social security matters and the like), take up the greater part of my time."

Representative FRANCIS E. WALTER, Democrat, of Pennsylvania: "Most of my time, as well as that of my staff, is consumed in receiving and servicing the innumerable telephone calls, telegrams, letters and visits from the constituents whom I represent."

Senator JOHN STENNIS, Democrat, of Mississippi: "A great deal of a Senator's time is taken up with visitors at the office, and with what are almost mandatory social and semisocial engagements with people from his home State, and with what I shall term 'extralegislative' matters. Legislative matters which should be given priority and a great deal of time do receive attention, all right, but all too frequently are pushed to the last or relegated to second place."

Mostly: Just plain hard work

By and large, however, the picture painted of a lawmaker's day is one of hard work: attending committee hearings and floor sessions, answering letters, doing research and reading bills and committee reports.

Representative JOHN J. RHODES, Republican, of Arizona, gave this as a typical working schedule:

"Time of the Member is taken up about as follows:

"(a) Committee work—30 percent.

"(b) Attendance on the floor of the House—20 percent.

"(c) Preparation for legislative matters—20 percent.

"(d) Answering correspondence—15 percent.

"(e) Activities on behalf of one's district—10 percent.

"(f) Entertainment of constituents and miscellaneous—5 percent."

Representative JAMIE L. WHITTEN, Democrat, of Mississippi, was one of many who listed committee hearings as the one activity taking most of a Member's time. He said: "This, of course, varies considerably, dependent upon the individual Member's committee assignment. In my own case, I attend committee hearings from 10 a.m. until 5 p.m., with an hour off for lunch, probably 4 days out of every 5 of a session."

Representative Louis C. Rabaut, Democrat, of Michigan, agreed: "If I had to select one as most time consuming, I believe I would point to committee duties."

Representative BURR P. HARRISON, Democrat, of Virginia, gave this description of a hectic day in the life of a Congressman:

"The various activities of the Congress are in progress at the same time, like a three-ring circus. If one duty is to be done properly, it is likely another must be content with a lick and a promise. Committees sit as the floor debate proceeds, and constituents wait in the offices.

"A Member busy in committee will be summoned by the bells to vote on the floor on a measure as to the merits of which he has heard no debate. A Member occupied on the floor, or in his office, will hurry to committee to propound a series of questions to a witness on points which the witness had discussed fully in testimony prior to this Member's arrival.

"During the course of an average day, a Member will spend a great deal of time in the Capitol Hill tunnel system, moving from committee, to floor, to office."

QUESTION: WHY HAS THE INSTITUTION OF CONGRESS HAD TO GROW TO ITS PRESENT SIZE?

To get an idea of just how big Congress has become, look at these figures: It costs $92 million a year to operate. It has 7,500 employees. The value of its land and buildings will soon reach $235 million.

Congress not large enough?

Yet many Members of Congress answering the survey made it clear they regard Congress as still too small and bound to grow even larger in the future. Their statements explain why.

Representative BASIL L. WHITENER, Democrat, of North Carolina:

"Your question indicates that you feel that Congress is inordinately large in its membership. I do not concur in that thought.

"It is my opinion that one of the big problems that this country is now facing, and will face in the future, is the increasing number of constituents to be represented by individual Members of Congress.

"It seems to me that, with a greatly expanded Government with correspondingly increasing demands upon the time of the individual Member of Congress, that we should have a fixed number of people to be represented by a Member of the House and that in the future the House of Representatives would increase in number as the population increased. This would not be inconsistent with good government, but would in fact, preserve a more representative form of government in our country."

Representative JOHN M. SLACK, JR., Democrat, of West Virginia:

"I believe the Congress is not large enough to properly reflect the interests of a nation with 180 million people.

"With the growth of population and the continuing expansion of Federal activities, there is a continuing increase in the purely service activities of a congressional seat. A House Member who represents a district containing perhaps 500,000 persons or more has literally no time off the job, especially when he must campaign for reelection every second year."

Senator JOHN STENNIS, Democrat, of Mississippi:

"The Congress has grown to an institution of its present size because we have continued to add layer on top of layer of additional programs and departments of the Federal Government. The chairman of the Appropriations Subcommittee handling the appropriations bill for the Department of Agriculture, a subcommittee of which I am a member, recently told me that, of the 765 items in the bill for this year, every program, with the exception of 3 or 4, has been added since he first became a Member of the Senate a little more than 30 years ago."

Senator FRANK J. LAUSCHE, Democrat, of Ohio:

"Within the body of every political institution, there seems to be a natural power that motivates growth whether the work required to be done justifies it or not. My experience as a mayor of Cleveland for 3 years, Governor of Ohio for 10 years, and presently, Senator for 3½ years, has convinced me that political institutions grow in the number of employees even though the business and work of the agency do not require it, and also reach out to take in operations whether they do or do not properly belong to that particular agency, solely to conform to this seeming demand for growth."

Friend of the public

Representative CRAIG HOSMER, Republican, of California, said that "it has been very necessary that Congress grow to its present size. Millions of Americans have no place to turn except to their elected representatives when they have a problem or even just want to get a complaint of a general nature off their chests. To my mind, the availability of Members of Congress to the public has been the safety valve which has prevented accumulations of public dissatisfactions, which in some other countries have led eventually to revolutions."

Representative DON L. SHORT, Republican, of North Dakota, said: "I'm not sure the institution of Congress had to grow to its present size. Committee staffs are overloaded in some instances, and there are a great many unnecessary congressional employees."

A House Member: "The institution of Congress has grown to its present size largely because Members of Congress themselves do not have the courage to say 'No' to the many asinine requests they get from their constituents."

QUESTION: DOES TOO MUCH POWER LIE IN THE HANDS OF COMMITTEE CHAIRMEN? IS SENIORITY THE BEST WAY TO DETERMINE WHO WILL BE COMMITTEE CHAIRMEN?

On these two points—the power of committee chairmen and the seniority system—Congress is often criticized by outsiders and sometimes by its own Members. Yet, in the U.S. News & World Report survey, a large majority of the Members responding said that committee chairmen do not have too much power. And there was almost unanimous agreement that the seniority system is the only practical way to pick committee chairmen.

Powerful chairmen or chaos

Following are typical comments of lawmakers who hold that committee chairmen are not too powerful.

A Senator, not desiring to be named, who heads an important committee:

"Speaking as chairman of a committee, I would say that I do not have too much power. Under the rules, any action I take as chairman can be overruled by a majority of the committee, and this quite often happens."

Representative WILLIAM S. BROOMFIELD, Republican, of Michigan:

"In the House at least, a strong chairman is a necessity, or else the legislative process would hopelessly bog down. There are simply too many members on most committees and too many divergent opinions on very controversial subjects."

Representative JAMES B. UTT, Republican, of California:

"Without this power there would be chaos."

Representative JOHN R. PILLION, Republican, of New York:

"The committee chairmen do not have too much power. The members can readily voice their will and take necessary legislative steps under the rules to obtain action desired by the majority."

Senator HOWARD W. CANNON, Democrat, of Nevada:

"The majority can always work its will in Congress, regardless of the power of one man or one group."

Some Members, however, took the opposite view, as in the following comments:

Representative LeRoy H. Anderson, Democrat, of Montana:

"Too much power, particularly to kill legislation they don't like, does lie in the committee chairmen's hands. The rules of Congress should make it easier to get legislation before the House in spite of the personal opposition of the chairman of the Rules Committee or the chairmen of other committees."

Representative DANTE B. FASCELL, Democrat, of Florida:

"Too much power lies in the hands of committee chairmen if they are able to keep a committee from considering legislation, either by refusing to call a committee meeting or by refusing to take up a bill. Perhaps provision should be made to make it possible for a committee to meet either on the call of its chairman or on the call of a majority of the committee with notice to the chairman."

A Senator who prefers not to be quoted by name said: "The rules of Senate committees are sometimes ignored" by their chairmen.

Senator JOHN STENNIS, Democrat, of Mississippi, after 13 years in the Senate, believes this: "The question of how much power rests in the hands of a committee chairman depends entirely upon the attitude of the chairman and the personnel and membership of the committee."

Seniority: How else?

Senator WARREN G. MAGNUSON, Democrat, of Washington, chairman of the Interstate and Foreign Commerce Committee, summed up what appears to be the majority view on the seniority system:

"I believe seniority is the best way to determine who will be committee chairmen. I know of no other system that would work in a legislative body. If the selection were by a majority vote of the committee, there would be contests, which in turn would leave scars and hard feelings that, in my judgment, would seriously impair the work of the committee. Occasionally the seniority system brings to the top men of inferior quality, but in the main, the system works very, very well."

Representative FRANCIS E. WALTER, Democrat, of Pennsylvania, head of the House Un-American Activities Committee, said:

"I am firmly convinced that seniority is the best method to select chairmen of the various congressional committees. Experience has taught us that there is no better substitute for this system.

"If selection of a chairmanship were based on any other system, I believe that politics would be the overriding factor in the selection of a chairman, and in this I do not believe the public good would be served. There is no substitute for experience and, as the record indicates, men who become chairmen of congressional committees have, on the whole, proved wise and able."

Representative CARL ALBERT, Democrat, of Oklahoma:

"Committee chairmen are generally men who have served for a long time. They are acquainted with the background of the legislation with which their committee is concerned. They know the rules of Congress and are familiar with the legislative process. While it may not always be true, I think it is generally true that the senior Members of the House are usually among the abler Members."

Representative BURR P. HARRISON, Democrat, of Virginia, brought up a point that many Members made: "The difficulty is in selecting a better system. Prior to the inauguration of the seniority system, the power was in the Speaker and the party leadership, who exercised the power so arbitrarily and capriciously that seniority was substituted."

A Representative from a Southern State said: "If the chairmen were selected by any other method there would be too many opportunities for pressure groups to operate as opposed to the national interest. The longer a person remains in Congress, the greater his respect for it and for the Government."

Urged: Overhaul of system

Senator WILLIAM PROXMIRE, Democrat, of Wisconsin, spoke for opponents of seniority as follows:

"I think that election by members of a committee of their committee chairmen would generally result in more competence and broader representation of the interests of the whole Nation. At the same time I recognize that it is very difficult and perhaps impossible to eliminate the seniority system without the vigorous cooperation of a very strong President—as in the first Wilson administration.

"I have suggested as a compromise that the seniority system might be continued as the basic method of selecting committee chairmen, but that it be modified so that no one section of the country be permitted to receive more than one-half of the 15 important committee chairmanships in the Senate. At the present time, the 11 Southern States of the old Confederacy enjoy 10 of the 15 important committee chairmanships. Under my proposal, a senior nonsoutherner would succeed the three most recently appointed southern committee chairmen."

Senator THOMAS J. DODD, Democrat, of Connecticut:

"The real objection is that the seniority system concentrates in the positions of power representatives of those sections of the country where there is little real competition between rival parties or rival political philosophies.

"Incumbent Senators who face no such clashes have a tremendous advantage in staying in office and thus in building up seniority, an advantage that is not enjoyed by representatives from other sections, who are subjected to the shifting tides of public opinion and party dominance. As the two-party system extends into these one-party areas, this artificial advantage which has distorted the seniority picture will tend to disappear."

Changes were recommended in the seniority system by a number of Congressmen.

A Representative from the South wants "a provision added to the House rules requiring committee chairmen to step down between the ages of 65 and 70. Such a provision would, in my opinion, serve to infuse the committee system with new ideas, perhaps, and provide a fresh approach to legislative matters."

Representative CHARLES E. BENNETT, Democrat, of Florida, suggested:

"In the case of ill health or extreme age involving a degree of disability it would be sound judgment for the chairman to defer to the next in line in the event that health seems to dictate this policy. This has been in fact done at least one time to my knowledge, and perhaps has been done more often in the past."

Representative HARLAN HAGEN, Democrat, of California:

"My recommendation would be that there be a limit on the number of years that any one man could serve as chairman—for example, 6 years."

QUESTION: WHY DOES CONGRESS DRIFT ALONG FOR 6 OR 7 MONTHS AND THEN RUSH THROUGH LEGISLATION IN CLOSING DAYS OF THE SESSION? DOES THIS METHOD RESULT IN THE BEST TYPE OF LEGISLATION?

More than a few Congressmen felt it was "unfair" to say that Congress "drifts" in the first few months of a session.

Senator James E. Murray, Democrat, of Montana, stated:

"It is far better for Congress to consider measures carefully and act upon them after hearings and consideration than to attempt to start passing bills the day after Members get here, without information, to give a public impression of activity. Is this question fair? Are we 'drifting along' in the perod when the hearings and study is under way, and then rushing through legislation because, at the end of the study period, there is expeditious action on the floor?

"The Interior Committee recently considered 20 bills in a day-long executive session. In the preceding months, each and every one of these bills had been subjected to departmental reports, hearings, and careful study. I do not think the committee can properly be charged with drifting for taking the time to study them, or 'rushing through legislation' because, when study had been completed, we acted on the bills expeditiously. The description of congressional conduct in this question represents your conclusion, which, I respectfully contend, is not entirely accurate or fair."

Representative JOSEPH E. KARTH, Democrat, of Minnesota: "I think it is erroneous for one to assume that Congress drifts along for 6 or 7 months and then puts on the rush act in the closing days of the session. The first 6 or 7 months of a congressional session are put to very good use. Most of the committees of the House are extremely busy holding hearings in an endeavor to get the public reaction, whether it be favorable or unfavorable to legislation in their committee. I firmly believe it is extremely important to have exhaustive hearings on all legislative matters of any consequence * * *. To do anything less would be a serious abridgment of our democratic process of government. Although this democratic procedure is lengthy, it is this very basic fundamental that makes our country one of the people, by the people, and for the people."

One session: 17,850 bills

Senator OREN E. LONG, Democrat, of Hawaii, calling attention to the workload on Congress, said:

"The number of bills that Congress has to deal with runs into several thousand—about 17,850 during the 86th Congress, for example. Individual Members cannot study all of them. Furthermore, the merits of a bill cannot be studied on the floor. The result is that they are divided up among a number of major committees. Each committee may have before it several hundred bills for its consideration. Obviously, this requires a long period of study. Extensive hearings in many instances must be held. The result is that, during the first months, very few bills are disposed of, while information concerning the bill accumulates. There comes a time when the loose ends are tied up, and specific recommendations made to the entire body. Naturally this development tends to come during the end of the session. When a great many bills are passed during the closing weeks or even days of a session, it does not mean that snap judgment is being taken. It is just the opposite."

Some Members said they believed the end-of-session logjam of laws was deliberate, at least in part.

A Republican Senator put it this way: "This tendency is partly due to procrastination in facing up to thorny and controversial measures, but in my opinion, the real reason is a studied and intentional policy on the part of the leadership to hold up consideration of difficult and controversial measures and then shoot them through in the hurly-burly of the closing days when there is little time to examine and weigh them."

"Exhaustion and confusion"

Representative SAMUEL L. DEVINE, Republican, of Ohio, voiced the same opinion: "The leadership is entirely responsible for permitting Congress to drift along for 6 or 7 months and then legislate by exhaustion and confusion. Obviously, this does not result in the best type of legislation."

Representative THOMAS B. CURTIS, Republican, of Missouri, had a similar comment, with some additional points: "The leadership of the House, on both sides, has found that legislation can be killed or gotten through during the period of adjournment rush more as they wish it.

"Furthermore, the Congressmen from 'safe' political districts are those with greatest seniority and therefore have the greatest control over the House machinery. They no longer live in their districts. They live in Washington, D.C. As long as Congress is in session they have an answer to their constituents back home of why they aren't home.

"I opposed the congressional pay increase a few years back on the grounds that a

Congressman's job was part time, not full time, and needs to remain part time if the theory of representative government was to work.

"In my judgment this [pay raise] did more to seal the doom of representative government in the United States than any single thing I can think of. By implication, it made Representatives full-time employees and encouraged them to be Washington residents, instead of people living in, and part of, the communities they were elected to represent."

Representative CLARK W. THOMPSON, Democrat, of Texas, by contrast, thinks most of the delay is due to "human nature." His comment:

"Human nature being what it is, we are inclined to take it a little bit easy in the early phases of the Congress, and then, in order to meet the required deadlines, burn the midnight oil in the later weeks."

Federal agencies blamed

Some of the slowdowns in the legislative process are blamed on executive agencies.

Senator DENNIS CHAVEZ, Democrat, of New Mexico, and chairman of the Senate Public Works Committee, noted that factor:

"The committees of Congress have grown exceedingly dependent upon the reports of the Federal agencies on bills and upon the attitude of the Bureau of the Budget. It requires 2 months or more for the agencies to report on a bill, generally speaking, and thus legislation introduced in January of each year is not acted upon earlier than March.

"As the hour of adjournment draws near, Members tend to push committees to act on their bills rather than exerting these efforts during the time of March to June, when committees could handle the bills if they had the supporting evidence to act."

Senator WARREN G. MAGNUSON, Democrat, of Washington, chairman of the Senate Interstate and Foreign Commerce Committee, brought up this suggestion to help speed the work of committees:

"The necessity of hearing witnesses is the chief cause of the pile-up of legislation toward the end of the session. It has been suggested that more of the responsibility for hearing witnesses be delegated to competent staff members. Staff performing a part of the 'hearing function' would operate under such tested procedures as are employed by regulatory commissions and the courts. For example, the staff in the category of referee or examiner might be appointed to take testimony, to wade through the hearings and to report objectively to the committees themselves."

QUESTION: DO SECTIONAL PROBLEMS AND DEMANDS OF CONSTITUENTS BECOME A MATTER OF MAJOR CONCERN? DOES THE NATIONAL INTEREST, AS A RESULT, TEND TO GET OVERLOOKED IN MANY CASES?

There is candid agreement by Members of both Houses of Congress that much of their time and effort is devoted to local matters, rather than broad issues that affect the whole Nation.

"Wheels that squeak"

A western Senator with long experience replied flatly:

"Sectional matters do sometimes become a matter of major concern—to the detriment of the national interest."

Representative THOMAS M. PELLY, Republican, of Washington, explained it in this way:

"Sectional problems and constituents' demands are the wheels that squeak, and as a result invite a Member's major concern. A careful analysis of the pattern of voting would show that the majority of Members do not vote on record against the interests of their constituents even when the overriding national interest could lie in the other direction."

Senator WILLIAM PROXMIRE, Democrat, of Wisconsin, cited examples:

"On the basis of my limited time—3 years—in the Senate, I feel there are few basic and serious contradictions between sectional interest and national interest. Civil rights may be one. Tax advantages of certain producers, such as oil and gas producers, may be another. The regulation of certain industries may be a third.

"At the same time, it seems to me that the frank and open championing of a section's interests by its Senators has strong merit."

Senator WALLACE F. BENNETT, Republican, of Utah, put the problem this way:

"A Senator has four areas of responsibility and loyalty: (1) the national interest, (2) the interest of his State, (3) the interest of his party, (4) the interests of individual constituents. The emphasis as between these also shifts constantly. People involved in each of the last three always tend to associate their interest with the national interest."

In the view of many Members of Congress, this tug of interests actually works out to produce legislation that benefits the entire Nation.

Senator HARRISON A. WILLIAMS, JR., Democrat, of New Jersey, reached this conclusion:

"I would say that the national interest is often served when representatives of varying regions, speaking eloquently for the interests of those regions, work together and finally compromise on a program that serves the entire Nation."

Conflicts—and compromise

Representative CLIFFORD G. MCINTIRE, Republican, of Maine, said:

"Sectional and constituent demands cannot very well operate to thwart the national interest, for these demands are of such a diverse nature that they tend to play one against the other. Hence, one Congressman representing the interests of his constituents finds himself opposed by another Congressman who finds those interests in conflict with the wishes of the citizens he represents.

"The direct result is that the interests denoted in the first instance are either canceled out or tempered by those expressed in the second instance. Counterbalancing forces spring into being throughout the whole of Congress, with the direct result that any set of section or constituent interests becomes, in effect, a compromise rather than a demand."

Representative SAMUEL L. DEVINE, Republican, of Ohio, stated:

"Although demands of constituents and sectional problems do occupy a great deal of time, I am not convinced that the national interests generally suffer. Frankly, if the problems of local constituents are met realistically, the national problems take care of themselves."

Congressmen estimated that they give from 30 to 50 percent of their time to local problems of their constituents. Most of these problems, however, are handled by clerks and staff members.

Senator James E. Murray, Democrat, of Montana, summed up the whole issue in this way:

"There is no question that Members of Congress have a considerable concern with the problems of their States, districts, and constituents. In a properly staffed office, although the bulk of staff time may be devoted to sectional affairs, it is not necessary for the Senator or Representative to give a disproportionate amount of time to them. Competent staff people handle 99 percent without bothering their principal.

"Sectional problems should not be disassociated from the national interest and welfare. Economic development anywhere in the Nation is good for the whole Nation. An implication that giving local affairs the attention they deserve is at the expense of the national welfare is unjustified."

This all brings up another related question.

QUESTION: HAVE SENATORS AND REPRESENTATIVES TENDED TO BECOME AGENTS OF THEIR STATES OR OF INDIVIDUAL INTERESTS IN STATES, RATHER THAN OF THE NATION?

There enters, at this point, a situation that was referred to by a number of Senators. Originally, Senators were chosen by State legislatures, not by direct election of the people. The 17th amendment to the Constitution called for the direct election of Senators. Point is made that Senators, as a result, tend to be agents of their own States and under increasing pressure from people back home, instead of representing the Nation as a whole.

Senator Francis Case, Republican, of South Dakota, said this:

"Since the direct election of Senators, following the 17th amendment, Senators have tended to become agents of their States rather than of the Nation. Representatives in Congress were, originally, expected to represent their individual congressional district. Senators were Senators of the United States from such-and-such a State."

Representative JAMES A. HALEY, Democrat, of Florida, described the result like this:

"To a large extent, Senators and Representatives have become agents of their States. I think that it may have been a wrong move when the Senators became elected by popular vote rather than being elected by the legislatures. I presume that up until that time, Senators could and did represent the State more than the Representatives in the House who were closer to the people.

"The Nation probably has suffered because of this change."

Senator JOHN MARSHALL BUTLER, Republican, of Maryland, said:

"As far as I am concerned, I consider myself to be a representative of the State of Maryland and it is my duty to safeguard the interests of the State and its residents, individually and collectively. I also consider myself to be a U.S. Senator with responsibilities to the Nation. Seldom, if ever, have I found myself in a position where there is a conflict between the interests of Maryland and its people and those of the Nation."

Senator OREN E. LONG, Democrat, of Hawaii, stated: "On basic issues. Members are generally motivated by national interest."

Representative FRANCIS E. WALTER, Democrat, of Pennsylvania: "It is my opinion that most of the Members of both the House and the Senate tend to favor the local interest which they represent over the national interest."

Both views appear to be widely held. A few Congressmen, in addition, see a trend toward more, not less, concern with the national interest.

Senator MIKE MANSFIELD, Democrat, of Montana, drew this conclusion:

"I would say that the Congressmen, historically, were agents of their States or districts and have tended to become, as the Nation has evolved, more and more concerned with the problems of the Nation as a whole, rather than the reverse as the question implies."

QUESTION: HAVE DEMANDS ON CONGRESS FROM INDIVIDUAL GROUPS AND LOCAL INTERESTS BECOME SO GREAT AS TO BE UNMANAGEABLE?

Influence of "pressure groups" on day-to-day workings of Congress is a growing worry to many Members, the U.S. News & World Report survey shows. Senators, especially, are critical of the rising power of organized groups that back special interests and work from both the local end and in Washington. Typical are the comments that follow:

A Senator who prefers to be anonymous: "Everyone has now found out the power of pressure groups. In my opinion, two or

three strong pressure groups now control Congress."

Senator LEVERETT SALTONSTALL, Republican, of Massachusetts: "Demands from individual groups and local interests have become greater the longer I have been here in Washington. I would not say they were unmanageable; but I would say that the so-called pressure groups sometimes exercise, in my opinion, too much power.

Senator FRANK J. LAUSCHE, Democrat, of Ohio: "During the session of Congress, Washington hotels and the lobby of the Capitol are filled with representatives of special interests wanting special legislation. They have adopted a technique to bombard the Congressman's office at various intervals with their representatives, hoping that by repeated visits of different groups, the Congressman will eventually yield or make some sort of statement upon which a claim of commitment can be made."

Pressure versus commonsense

The chairman of a powerful Senate committee: "It is my contention that we are gradually drifting away from representative government, in that pressure groups are becoming so powerful that many Congressmen and Senators are prone to yield to such pressures instead of exercising their God-given commonsense."

Senator STROM THURMOND, Democrat, of South Carolina: "Unquestionably, the demands of pressure groups at times seem to have reached the point of being unmanageable, and certainly undesirable."

That Members of the House feel the same way is shown by the following comments:

Representative BOB WILSON, Republican, of California: "A number of pressure groups wield too much power over the actions of most Representatives."

Representative WILLIAM M. COLMER, Democrat, of Mississippi: "I think the greatest evil connected with the Congress is the influence of pressure groups, whether it be individual or national. The most recent and possibly the best illustration of this was the pressure exerted on the recent sessions by Government employees for a pay increase. Of course, there are other pressure groups, such as labor."

Not all Senators and Representatives are impressed by lobbyists' pressure, as the following comments indicate:

Senator WALLACE F. BENNETT, Republican, of Utah: "If a Senator or Congressman has enough strength of character to make his own decisions," he doesn't find demands "unmanageable."

Representative WILLIAM S. BROOMFIELD, Republican, of Michigan: "There are various 'pressure groups' with well-paid lobbyists here in Washington, but I have yet to run into a situation in which I have been told what to do, 'or else.'"

Senator WILLIAM PROXMIRE, Democrat, of Wisconsin: "During 3 years in the Senate, I have received very little pressure of the arm-twisting variety. Seldom have constituents called on the telephone to urge a particular course of action. Only very rarely has a constituent come to my office to plead for a particular course in relationship to a bill. It is true that very often there has been an inundation of telegrams and letters urging a particular course. This pressure is easy to analyze, assess, and can certainly not be construed as unmanageable."

The "breakfast" technique

Senator HARRISON A. WILLIAMS, JR., Democrat, of New Jersey, describes one of the techniques invented to deal with the physical problem of meeting with all the various pressure groups that try to see Senators:

"One innovation in recent years has been the 'breakfast' system. We legislators meet with groups who discuss issues of special interest to them at a breakfast session. It seems like a good way to receive their arguments, even though sometimes the 'breakfast' doesn't end until 10:30 or 11 a.m."

Representative D. R. (BILLY) MATTHEWS, Democrat, of Florida, tells how special-interest groups have complicated the problem of the Congressman who tries to steer a middle-of-the-road course:

"There are conservatives or middle of the roaders in Congress who dare not reflect their honest convictions on certain issues, because to do so would invite political suicide.

"If their own political life was merely at stake, that would be one thing, but far more important is the fact that a consistently conservative vote would preempt their place in the Congress in the very next election and assure the seating of one whose political philosophy was much more to the left.

"This is a point that conservative constituents often overlook. They cannot understand that to vote conservative all the way down the line means the eventual death of conservatism. A Congressman today must, except in very few instances, try to maintain some sort of balance between conservatism and liberalism in order to be effective."

QUESTION: IS THE ADMINISTRATIVE STAFF OF CONGRESS, DUE TO INCREASING DEMANDS, TENDING TO BECOME TOO POWERFUL?

This is a question heard with growing frequency as congressional staffs keep expanding. Each Representative now has a staff of up to eight people, who handle much of his official business. A Senator may have as many as 22 people on his personal staff. A congressional committee usually has a staff of its own, with experts who wield considerable influence.

Senator FRANK J. LAUSCHE, Democrat, of Ohio, expresses the concern left by many about this strategically placed group in this way:

"In my opinion, the staff of the Congress and the staffs of the various committees are tremendously powerful. In fact, they frequently formulate policies without the Congressman knowing that the policy is being formulated by the staff members."

Senator FRANCIS CASE, Republican, of South Dakota, said: "The administrative staff of Congress is tending to become too powerful."

What's happened to increase the size and importance of congressional staffs? The answers followed this line:

Representative SAMUEL L. DEVINE, Republican, of Ohio, stated: "If the administrative staffs of Congress are becoming too powerful, the responsibility lies with Congress itself. I think that the staffs have become overgrown and there is too much duplication.

A southern Senator, unwilling to have his name used, wrote:

"Congressmen consistently receive requests for assistance from constituents who know nowhere else to turn for aid. Everyone is familiar with the expression, 'Write your Congressman.' As a result, Members of Congress receive a vast correspondence on subjects in which Congress has no voice and which should have been addressed, in the first place, to some other governmental official and at a different level."

Representative WILLIAM S. MOORHEAD, Democrat, of Pennsylvania, said:

"With the tremendous pressure of legislation and the variety of problems before the Congress today, it is necessary for a Congressman to have an adequate and competent administrative staff. A legislator often depends on this staff for information and advice.

"However, I have seen no example of too much power being wielded by the Members' staffs. There is a greater danger of such usurpation of power by the staff of a congressional committee."

Representative WILLIAM H. BATES, Republican, of Massachusetts, discounted the danger:

"It is quite evident that the administrative staff of Congress is tending to become very powerful. This is particularly true in reference to technical matters. While this situation warrants close scrutiny, the checks and balances of the administrative branch of Government, the lobbyists, the news media, minority clerks, and the members of the committee serve to limit the exercise of such power."

In defense of staffs

Senator HARRISON A. WILLIAMS, JR., Democrat, of New Jersey, defending the staffs in Congress, said:

"A staff broadens a legislator's viewpoint; it does not limit it. A good staff reflects the legislator's thinking and his basic purpose as a legislator; it doesn't make its own policy. There's the 'ghost writer' complaint, for instance. It's true, I haven't seen many Congressmen dictating their speeches word for word to a secretary. But usually they have discussed the speech with an assistant who then tries accurately to express those thoughts in a speech draft. It's a very personal effort by the Congressman and by staff members who have worked with him long enough to know what he thinks about many issues."

Senator MIKE MANSFIELD, Democrat, of Montana, provided this defense of the present congressional staffs:

"Compared with staff personnel in the executive branch, congressional staffs are of minute size and influence. Congressional staff employees, moreover, are without assured tenure, and are subject to full control of elected officials so that any influence which they exercise is at the direction and discretion of popularly responsible officials. Compare that situation with what exists in the executive branch."

A midwestern Senator, urging expansion of the staff system, said:

"I do not believe that the administrative staff of Congress is becoming too powerful. On the contrary, it is my distinct feeling that staffs should be increased, and the job done for the people we represent would thereby improve.

"Research and technical assistance needed to legislate and perform our other constitutional obligations should be increased. Similarly, the committees of Congress would benefit by additional, competent staff members. And I am inclined to believe that at least a portion of these staff members should be responsible politically to the majority and minority."

QUESTION: DOES CONGRESS REALLY WORK BEST IN TIME OF CRISIS WHEN THE NATIONAL INTEREST SUPERSEDES SECTIONAL OR PRIVATE INTERESTS?

It is when war threatens or economic disaster strikes that Congress appears to act fastest and pass its most important legislation affecting the Nation's basic interest. To many this indicates that the atmosphere of crisis is needed for the present machinery of Congress to work at its best.

Representative EMANUEL CELLER, Democrat, of New York, chairman of the House Committee on the Judiciary, said Congress works best in time of crisis because:

"Then sectional differences and petty sparring for place disappear in favor of a workable united front, spurred on by the emergency."

Representative CLARK W. THOMPSON, Democrat, of Texas, said:

"If we did not work best in time of crisis, the Nation would long since have fallen apart. At such a time, there is no thought except of the general good. I hasten to add the remark that it is very seldom that an effective Member of Congress lets sectional or private interests interfere with the best interests of the Nation."

Representative THOMAS J. LANE, Democrat, of Massachusetts, observed:

"I believe Congress does its best work in time of crisis when the national interest must supersede all else. At such times, Congressmen find a fulfillment that is missing during humdrum sessions when they sometimes feel that they are messenger boys rather than statesmen."

The impression that Congress may be doing its best work during a crisis could be deceiving, however, in the view of many Members of both Houses. They explain it this way:

Representative GEORGE H. MAHON, Democrat, of Texas: "There are two sides to this coin. The rubberstamp atmosphere, which at times obtains during a crisis, tends to prevent objective and critical analysis and permit mistakes which might be avoided in a less tense atmosphere. In some ways it works best; in other ways it does not."

Crisis brings haste

Senator THOMAS J. DODD, Democrat, of Connecticut: "No, it does not. In times of crisis, the Congress usually feels compelled to carry out the wishes of the President without its usual deliberative process. It is true that congressional action is greatly speeded up in crises and that many needed steps are quickly taken in time of danger. But, on the whole, I do not think the deliberative process of the Congress works best in times of crisis."

A southern Senator: "I doubt that Congress works best in time of crisis. It is prone to follow the leader at such times. For instance, during World Wars I and II Congress did little but appropriate the funds necessary to prosecute those wars. Other war and emergency measures were adopted without too much resistance to our Commander in Chief. We seem to veer away from real democracy in time of crisis."

Representative BYRON L. JOHNSON, Democrat, of Colorado: "A time of crisis frequently demands a burst of speed. Speedy consideration is not always the best consideration of legislative matters."

Representative JOHN TABOR, Republican, of New York: "Congress does not work best in time of crisis—then there is a tremendous tension. The Members work a great deal better right after a crisis is past than they do in it."

Representative WILLIAM S. MOORHEAD, Democrat, of Pennsylvania, who went along with this reasoning, summed up the feelings of many Congressmen in this way:

"I would not agree that Congress works 'best' in times of crisis. Careful, sound legislating takes time which may not be available in time of crisis. However, it is certainly true that Congress has proved its ability to work efficiently and promptly in response to a crisis."

QUESTION: IS THERE ANYTHING THAT COULD BE DONE, IN YOUR OPINION, TO IMPROVE THE WORKING OF CONGRESS?

Representative EDITH GREEN, Democrat, of Oregon, part facetiously, suggested this answer:

"1. A 4-year term for House Members.

"2. Increased staffs for Members.

"3. A 48-hour day."

The first two of her suggestions found echoes among many of the lawmakers responding to the U.S. News & World Report survey. And more than a few indicated that they felt a need for longer days, as well.

Longer House terms?

A 4-year term for Representatives—instead of 2 years—was widely advocated.

Representative ELMER J. HOLLAND, Democrat, of Pennsylvania, summed up the ideas of numerous Members with this argument:

"One main difficulty a Congressman has is the fact that he is always running for reelection. I believe a 4-year term would give a Congressman more time to attend to the business of the Nation and the people and not to force him to campaign continually during his 2-year term of office.

"In order to keep the House closer to the people and more aware of public reaction than are the Members of the Senate, one-half of the House could change every 2 years. In other words, 50 percent of the House would be up for reelection every 2 years, although the term of office would be 4 years.

"Truthfully, it takes almost 2 years for a Congressman to acclimate to Washington and learn his way about the various governmental departments and agencies and become familiar with the workings of our National Government. It is then time to run for reelection and 6 months of the 2-year term is lost in electioneering."

Representative THOMAS J. LANE, Democrat, of Massachusetts, complained:

"As it is now, no sooner is one election won than a Member must start to prepare for the next campaign. With no respite from the exigencies of 'politics,' Members cannot give their full time and effort to the work at hand as they would prefer to do."

Representative JOHN H. KYL, Republican, of Iowa, suggested that with a 4-year term "tenure in office would become a period of service rather than a 2-year campaign for the next election."

A western Congressman, speaking anonymously, added that "the pressure of groups would be greatly lessened, Members would have more time to devote to legislative matters and to study, and better legislation would be the result."

Representative FRANCIS E. WALTER, Democrat, of Pennsylvania, spoke for many House Members with this suggestion:

"Provision for an administrative assistant to a Member of the House of Representatives will do much to take from the shoulders of the Member the administrative burdens which he must now bear because of the demands of his constituents. Such a position would permit him the time to devote more effort to function as he properly should, namely, as a legislator."

Representative DANTE B. FASCELL, Democrat, of Florida, said:

"I think it would be helpful if each of us on the House side had a legislative assistant whose principal duty would be research. I think the biggest problem I face as a legislator is to obtain all the facts."

Representative EMANUEL CELLER, Democrat, of New York, agreed:

"A Representative should have a greater staff, exclusively devoted to the study of the various issues, upon whom the Congressman could call for information."

Split sessions of Congress?

Dividing a congressional session into two parts—one for general legislation and another for passage of appropriation bills—was one suggestion for expediting the work of Congress.

Senator WARREN G. MAGNUSON, Democrat, of Washington, said: "In my judgment, the work of Congress could be expedited in at least two important ways. First, a rule of germaneness would tend to reduce the length of debates. Second, division of a particular Congress into a legislative and a fiscal session would make for more orderly and efficient procedure.

"On the latter point, here briefly is what I am thinking about. The Government's fiscal year is from July 1 to July 1. The Congress, however, convenes in January and runs from 7 to 10 months. Thus, the sessions of Congress and the Government's fiscal year do not coincide. In effect, we are never able to balance our books. Legislation we pass, say in May, possibly calls for new expenditures, and as such bills multiply, continuous calls are made upon us, through supplemental budget requests, for additional appropriations.

"Private business does not encounter this type of anomalous situation. Private concerns operate in such a way that their books can be balanced at the end of their fiscal year.

"Because of the problem above outlined, I am advocating a fiscal and a legislative session. Thus, our congressional year would be broken into two parts. During the first half of the session, we would consider only legislative matters with the understanding that appropriations to finance any new programs authorized would not be considered until the next fiscal session.

"In the second part of the session, we would consider fiscal matters—bills representing appropriations needed to carry forward those legislative programs already on the books. Some deviations would be required to meet emergencies, but under such a program Congress could give its entire attention to one problem at a time and, in my judgment, by so doing could achieve more effective control of expenditures than is currently possible."

Representative JAMIE L. WHITTEN, Democrat, of Mississippi, had a similar proposal:

"It is my belief that if the Congress were to provide one period for hearings, reports on bills, etc., without legislating, and a later period for purely legislative action, requiring that its legislative action be completed in such period each year, it would be for the best. Of course, provision would have to be made to meet extraordinary situations. While I did not serve in Congress at that time, I believe we took a step backward when we eliminated the "lame duck" session. A Congress always in session gets further away from the people and more and more subservient to special-interest pressures.

"I further believe that in view of the increasing population of the United States, and increasing number of so-called Federal problems, the size of the House of Representatives, where hearings are held in much greater detail, might be enlarged to some degree—largely in order that a Member might not be required to spread his time so thinly as at present. These two suggestions would also reduce necessary reliance on congressional staffs in the handling of Federal business, including legislation."

Representative JOHN R. PILLION, Republican, of New York, had a different idea about handling appropriations:

"The House, in accordance with its rules, should prepare its own budget of appropriations and revenues. Since the House has first responsibility in this field, it should not rely on the President's budget. The present practice is a delegation of power and responsibility. It violates the theory of separation of powers.

"Under our present system, appropriations are initiated by the Federal bureaucracy that has no responsibility for raising the needed taxes.

"Today, there is very little relationship in the House or Senate, as legislative bodies, between appropriations and revenues. This procedure amounts, in fact, to a carnival pea shell game. It hides from the public the responsibility in these bodies for spending, for taxes and, in general, fiscal responsibility.

"The House also should establish a finance committee to coordinate the spending of the legislative committees with the appropriations and with the tax revenues. The function of this committee would be that of first determining the overall expenditures and the overall tax program that is in the national interest. Legislative programs, appropriations, and taxes could then be coordinated and fitted into this overall national purpose."

Representative WILLIAM S. BROOMFIELD, Republican, of Michigan, suggested:

"One big help would be to start congressional sessions about the first of September rather than the first of January. Either national elections could be rescheduled through a constitutional amendment, or else

early sessions could be limited to nonelection years. This would mean that Congress could wind up its business in spring or early summer each year and that there would be plenty of time to consider appropriation bills in detail before the next fiscal year begins. Also, this would be a help to the homelife of Congressmen, and would permit their children to remain in one school rather than the present practice of changing residences twice a year."

The "filibuster" issue

A proposal that had numerous backers was one to prevent "filibusters." A "filibuster," in congressional terminology, is the making of long speeches to delay or prevent a vote when the "filibusters" face probable defeat. It is made possible by the Senate rule which permits free and unlimited speech unless two-thirds of the Members vote for a limit.

The longest filibuster—that against civil rights legislation last March—lasted 82 hours.

House rules prevent filibustering by requiring only a majority vote to limit debate.

Senators, as well as House Members, spoke out against filibusters.

One midwestern Senator, who prefers not to be identified, said: "There should be a change in the cloture rule in the Senate to permit debate to be cut off, after ample time for all to be heard, by majority vote."

A western Senator also speaking anonymously, said: "Great freedom is needed in the Senate, but there should be a more realistic means of closing debate without prejudice to the rights of those who may be in the minority on a given question."

Representative James M. Quigley, Democrat, of Pennsylvania, said:

"The Senate rules must be changed to prohibit unlimited filibusters. The minority has its rights and certainly foremost among these is the right to be heard. But the majority has its rights, too, and foremost among them, under our system of government, is the right to rule."

A number of minor changes were proposed in rules, committee structures, schedules, and other operating procedures of Congress.

Representative CHARLES E. BENNETT, Democrat, of Florida, said:

"It seems to me that it would be an improvement on the committee structure if the chairmen of subcommittees could be elected by the subcommittee's personnel. In this way the burden of legislation could be shifted around to younger men and new leadership could develop, for persons have become so advanced in years that their physical well-being is endangered by strenuous and persistent work of the exacting type of committee chairmanships. But I would not favor this procedure for the main or full committee chairmanships."

Representative GLENN CUNNINGHAM, Republican, of Nebraska, said:

"To improve the functioning of the Congress, I would suggest, as I have in the past, that during the first 2 months of the Congress, the two bodies meet for 1 full day each week. The 4 remaining days of the week should be devoted to full-day sessions of the various committees.

"It might be advantageous during the second month of the session to have the two bodies meet 2 days a week and the committee 3 full days. The point is that there is no sense in having the Congress meet every day when nothing is ready for consideration, at least nothing of importance.

"It would then be my suggestion that there be a limit on the time when legislation could be introduced by individual members."

A southern Representative did not wish to be identified by name with this idea: "It is a wild proposal, but each district would be better off if it had two Congressmen—one to do the favors and extralegislative chores, and the other to confine himself strictly to legislation."

Representative KATHARINE ST. GEORGE, Republican, of New York, suggested several changes: "Congress would be more efficient if Senators were appointed by the State legislatures and therefore were true representatives of sovereign States, as was intended under the original Constitution. The term of a Representative in the House should be 4 years instead of 2. The Representatives should be elected with the President and their terms should coincide with his. Finally, the Speaker of the House should be an expert parliamentarian, nonpartisan, and not a party leader as at present."

Representative MELVIN R. LAIRD, Republican, of Wisconsin, thinks time can be saved in committees: "The Secretary of Defense, for example, appears before 10 or 12 different committees, often for protracted periods, during one session of Congress. This demonstrates the great duplication among committees."

Senator MIKE MANSFIELD, Democrat, of Montana, majority leader, suggested: "It is over a decade since the last Congressional Reorganization Act, and the time may be ripe for another full-scale consideration of legislative procedures which could open the way to many procedural improvements."

Senator JOHN MARSHALL BUTLER, Republican, of Maryland, was one of several Members who saw no need of changing the rules of Congress. He said:

"I believe that the Senate of the United States presently constitutes man's highest attainment in truly representative government. There has never been an organization comparable to it and, tragically, if present trends continue, there will never be one like it again.

"The Congress, in my opinion, does not need better rules—it needs better men."

HORSE-AND-BUGGY METHODS IN THE JET AGE

(By Representative WRIGHT PATMAN, Democrat, of Texas, veteran of 32 years in Congress)

Many things are wrong with Congress; but, to put them in perspective, I would say that the basic problems are two.

First, the volume and variety of duties of a Member of the House constitute a workload which the Members are very poorly equipped to handle. I am speaking mostly of legislative duties, which are almost endless in scope of subject matter and, for the most part, highly complex. The volume of errand-running and miscellaneous chores which a Member must perform for his constituents has been growing, too, and this would constitute a rather heavy workload by itself. But these duties are really not the problem.

During my 32 years in Congress, the country has moved from the T-model era into the jet age, and legislative problems have increased accordingly. Yet, in this time, Congress has improved its equipment and its methods little beyond those that would be suitable for the horse-and-buggy era.

The principal inadequacy, at least in the House, is that the Members do not have enough professional staff. And it does not help matters that the Congress operates in an obsolete and inefficient physical plant and clings to some cumbersome and time-consuming mechanical procedures.

Congress appropriates billions annually for the executive branch to have tens of thousands of scientists, technicians, and specialists in all fields, as well as clerical staffs and modern mechanical aids, down to the newest and most advanced electronic computers.

In contrast, the Congress—particularly the House—has been timid to the point of negligence in providing itself with professional assistants. House Members can vote billions for the Executive without batting an eye, but are horrified at the thought of voting a few millions to equip themselves. These millions, they feel, would constitute a personal raid on the taxpayers' pocketbooks—or at least would be interpreted as such.

This brings me to the second fundamental problem of Congress, and one which is at the root of all the others. This is in the wholly inadequate communications between Congress and the general public.

Most of the time the public does not know what Congress is doing and, all too frequently, Members of Congress do not know what they are doing. The two conditions are not unrelated.

I realize that the public press undoubtedly has its own problems and limitations, which I am unable to appraise, and I say this without impatience or disrespect: The public press is failing to inform the American people of what Congress is doing, and it frequently gives the public a spotty and misleading conception of what the Congress is doing.

Let me give two illustrations:

1. Recently, the big story was abuses of congressional expense accounts. The topic most headlined by the daily papers and most examined in the editorial columns had to do with the fact that on occasion a traveling Congressman has visited a fancy bar and put the tab on his expense account.

At the time this story was being publicized, Members of Congress were giving considerable attention to a proposal—one which is still pending—to make lobbying expenses tax deductible.

This legislation would have the general taxpayers pay the corporate lobbying expenses, which will include, you may be sure, plenty of free drinks for all Members of Congress who care to partake of them.

One question the press might ask is: "Won't it be even worse for the taxpayers to pay for the drinks the lobbyists dispense to Congressmen than to pay for the Congressman's drinks directly?"

My purpose is not to answer the question but to point out that the press has not asked the question. If the usual pattern is followed, this proposal will receive little or no attention if and when it is enacted.

2. Early last year the big story was nepotism—some Members of Congress employ their wives or other members of their families to serve as secretary, clerk, and so on. The newsman who wrote that story received a Pulitzer Prize for it. Let's examine two aspects of it.

First, the practice in question is as old as the Congress itself, and most of the facts "exposed" were long known to every newspaperman in town. Furthermore, all of the details were a matter of public record and easily available to any newsman. Isn't it rather remarkable, then, that the press had so neglected reporting facts which, when reported, warranted a Pulitzer Prize?

The second point to be noted is that the bigger part of this story was never reported. This has to do with how the story arose and how it changed the course of Congress.

The attention of the prizewinning journalist was attracted to this matter in the first place because the House was about to act on a resolution to provide each of the Members with a professional administrative assistant.

The sentiment in the House was overwhelmingly in favor of the action, although there was forceful opposition from some groups who prefer that the Members receive their information in the ways they now receive it, rather than from independent study.

The upshot of the nepotism story was that Members of the House were swept by a great wave of timidity, let the resolution die on the vine, and the public was the loser.

It is manifest that representative government depends upon an informed public. Yet it is the exceptional legislation, such, per-

haps, as medical aid for the aged, which receives anything like adequate reporting.

Many of the bills Congress passes are never mentioned in the public press, either before or after passage. And most are mentioned only in a capsuled way, characterized with slogans which frequently mislead more than they inform. There is usually someone around to supply the slogan which the press picks up.

The CONGRESSIONAL RECORD needs special comment. Relatively few copies of the daily RECORD are printed—and a few suffice.

One might judge from the appearance of this document that it is calculated to discourage readers, rather than to help the public know what the Congress is doing. The print is microscopic; it is printed on a poorer grade of newsprint than any metropolitan daily would use; it is neither organized nor indexed; and House rules permit the insertion of all manner of irrelevant materials to be intermixed into the record of the business being transacted.

It is my view that any citizen should be able to learn, without cost, what his Congress has done on the previous day. Considering the importance of what Congress is doing, measured in dollars and cents if nothing else, a clear and readable public record seems warranted.

Mr. CUNNINGHAM. Mr. Speaker, I ask unanimous consent to insert at this point in the RECORD remarks by our distinguished U.S. Senator, Senator KEATING, of New York.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Nebraska?

There was no objection.

The material referred to follows:

KEATING SETS FIVE-POINT PLAN FOR EFFICIENCY

(By J. A. O'Leary)

Senator KEATING, Republican, of New York, last night revived the controversial proposal to let the President veto individual items in appropriation bills.

He listed it as part of a five-point program to promote efficiency in government.

The other steps he recommended:

1. Establish a joint congressional committee to examine the Federal budget as a whole.

2. Hold special sessions of Congress in November and December of each year, to be devoted solely to the appropriation bills, before Congress meets in January to consider general legislation.

3. Set up a Hoover-type commission to review the entire tax structure and recommend changes "geared to the times and designed to eliminate inequities."

4. Create a "know your Government" service, which the Senator said would "break down the wall of secrecy that lies between the people and their Government."

In a speech prepared for delivery at Olean, N.Y., Senator KEATING said the establishment of the item veto would be the most effective single step Congress could take to eliminate waste and "pork barrel" items.

The item veto has been debated in Congress at intervals for many years, however, and there are no indications that this Congress is any closer to adopting it than its predecessors.

Mr. CUNNINGHAM. Mr. Speaker, I ask unanimous consent to insert at this point in the RECORD an article taken from the Washington World of September 25, 1962.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Nebraska?

There was no objection.

The material referred to follows:

IS MACHINERY OF CONGRESS BOGGING DOWN?

STAFF ANALYSIS

(Unless at least a few changes are made, the role of Congress may continue to diminish at the same time executive and administrative powers reach their alltime height.

(While some papers have made radical suggestions about congressional reform (aimed mainly at getting their pet programs enacted), sound, well-informed observers in Washington suggest the following as substantive changes which would assist future sessions of Congress to deliberate and legislate instead of merely spending the hot Washington summers chewing the legislative fat and spending money commuting to far-off districts to see constituents.)

1. The first requirement for a more effective Congress would be a year-round session (except possibly in election years) with a 3-month summer hiatus when the humidity in the Capital is most oppressive and when traditionally the least is done, anyway.

WOULD PROVIDE DEFINITE SCHEDULE

This would enable a scheduled period of time in the District with the family for each Member; with meetings planned long in advance with key constituent groups. It would also eliminate the traditional last week into which hundreds of bills are jammed in a desperate effort to quit Washington by October.

2. The second requirement would entail more scheduled meetings between the President and the legislative leadership of both parties.

While this has been done in some instances insofar as foreign policy is concerned, it is even more necessary in the domestic area where there is a great misunderstanding among Republicans as to just what the President does and does not want—and a misunderstanding on the part of the President as to what areas of his domestic program should be changed to insure congressional enactment and for the benefit of the Nation.

CAN'T EXAMINE APPROPRIATIONS PROCESS

3. Congress has no machinery to provide for an examination of the appropriations process. If some agency should spend unwisely or in violation of Federal law, no one knows about it until the General Accounting Office issues a report in 4 or 5 years.

Most Capitol Hill observers would press for a Joint Committee on Appropriations or a similar group to take into account the status of our economy, future trends of authorizations and appropriations, and recommend priorities in spending legislation. This would show Congress just what the effect of their voting for a bill would be, instead of surprising them later on with the news that we have run a $10 billion deficit for a fiscal year instead of a surplus, on account of action taken 3 or 4 years before.

4. One of the reasons why Congress, especially the House, must delay for some 20 days each election year is because of primary elections held in various States from March through September. If the primary is on a Tuesday, no legislative business of a vote-producing nature is customarily scheduled that day—nor will any work be done on Monday since Members spend that day traveling in the State involved.

DELAYED 3 WEEKS BECAUSE OF LABOR DAY

In 1962 the foreign aid bill was delayed in the House for some 3 weeks due to Labor Day and several primaries in early September. States should be encouraged to hold their primaries on the same day or at least in the same relative time of the year to eliminate this sapping of the legislative schedule.

5. The committee structure in the House is especially bad. The House usually has nothing to do for 3 months each session waiting for committee consideration and reporting of bills. The solution for this dilemma is relatively simple. During the first year of a session, many experts feel Congress should not even bother holding formal sessions until March while committees work on the Presidential program and other major legislation during the first 2 months.

Committees might well meet during November and December to work on the program for the second session so that Congress could get right to work and dispose of major issues before the political campaigns begin in earnest. To accomplish this, the Presidential program in these years must be revealed by a preliminary message 2 months before the traditional state of the Union report.

6. Finally, Congress must take action to approximate the professional staff technique as developed in English political and parliamentary systems. Minorities must receive top professional staff opportunities in order to develop programs which in time might become accepted by the majority of Congress or of the voters.

Majorities must be encouraged to use professional rather than political staff members, again so that committee work might be expedited and their final product could be justified. In this way, debate and enactment of legislation can be done on a more logical and a quicker basis in the House as a whole.

With these improvements in mind, Congress could once more become, in the eyes of most experts, the true instrument of democratic representative government it was in the past.

Mr. CUNNINGHAM. Mr. Speaker, in closing I want to offer my sincere thanks and appreciation to our great and beloved Speaker. I have not known a great many great men in my life. But this gentleman is a man who is one of the very greatest I have had the pleasure to know. His heart, in my opinion, is as big as a bathtub.

He always has time to sit down and talk with Members about their individual problems. He has taken a great deal of his time to discuss legislative matters with me. And so I want to congratulate him on the wonderful job he has done during this trying session.

I also want to pay tribute to our distinguished majority leader, the gentleman from Oklahoma [Mr. ALBERT] and, of course, to our distinguished minority leader, the gentleman from Indiana [Mr. HALLECK]. These gentlemen have given us leadership. We have had political differences, but we have worked together and, as we reach the closing days of this session, as one Member of Congress, I want to pay my tribute to them and express the hope that some of these suggestions that we have made here today may be approved by the House of Representatives in order that our Speaker, the majority leader, and the minority leader, whoever they may be, will have less bothersome problems and a better method of operating and of producing the needed legislation which we know will be before us in the coming years.

Mrs. DWYER. Mr. Speaker, it is not a pleasant prospect to contemplate the possibility of nuclear destruction in the United States, or of any other form of

national emergency which could threaten a breakdown of the orderly and effective processes of our national life.

Yet, in a world in which such destructive power exists, it would be the height of folly to close our eyes to it or to refuse to take those steps which prudence would indicate could equip us to deal with disaster effectively.

For this reason, I have introduced House Joint Resolution 893, a proposed amendment to the Constitution to enable the Congress to function effectively in time of emergency or disaster. This is only one of a number of legislative proposals which a number of us have joined together to introduce and to talk about as a way of calling attention to some of the important things Congress should do to prepare for the momentous challenges ahead.

The purpose of House Joint Resolution 893 is no less fundamental than this: to permit free and representative government to continue to function at a time when we would need it most, at a time when chaos could conceivably lead frightened survivors to abandon representative government unless advance preparations for its preservation had already been made.

We need not be fearful or despairing or unduly imaginative, Mr. Speaker, to consider this matter seriously. It is a question of commonsense—the same commonsense that has led us to invest in national defense, in personal insurance programs, in foreign aid, and in a host of other public and private precautions against possible future dangers.

Indeed, under the Constitution and by means of various statutes, we have already provided for a significant degree of continuity and succession in our public life. With respect to the Presidency, Congress in 1948 approved legislation specifying 12 successors to the office, from the Vice President, to the Speaker of the House, the President pro tempore of the Senate, and nine members of the Cabinet.

Under the Constitution, the President has authority to reconstitute the Federal judiciary, by virtue of his power to fill vacancies on the Supreme Court and other Federal benches with the advice and consent of the Senate.

The Constitution, too, through the 17th amendment, provides the basis for continuity in the Senate. Under the amendment, 49 of the 50 States have empowered the Governors to fill vacancies by appointment until elections are held.

At the State and local levels of government, great progress has been made in recent years in assuring continuity in government in the event of disaster. The Office of Civil Defense, in cooperation with State, county, and local government organizations, has developed proposed legislation and local ordinances for this purpose. At least 45 States have adopted parts of this program, and in 31 States, at last count, the legislatures had approved continuity-in-government amendments to their constitutions.

In the perspective of representative government, therefore, only the continuity of the U.S. House of Representatives has not been assured, and I find this fact deeply disturbing. Without a functioning House, freedom in America would be seriously jeopardized.

We must assume, I believe, that in the event of a nuclear attack on the United States, or other form of national disaster, casualties among Members of the House would be roughly proportionate to total casualties. If Congress were in session, of course, the proportion would undoubtedly be much greater. Under the Constitution, article I of section 2, vacancies in the House can be filled only by election. In the event of disaster, however, it would conceivably be many weeks or months before elections would be possible in many parts of the country. In the interim period, it would be essential that Government function effectively and that the Congress be in position to provide the central authority on which the Government must depend.

For these reasons, Mr. Speaker, I believe it is urgent that some method be found—a temporary method until elections can be held—whereby vacancies in the House of Representatives could be filled in the event of a disaster. I suggest that the method proposed by House Joint Resolution 893 would be simple, sound, and effective. Whenever the total number of vacancies exceeded 145, the Speaker or, if there was no Speaker, the Clerk, or such other person designated by Members of the House present and voting, would certify this fact to the President. Following the issuance of a Presidential proclamation to this effect, the executive authority of each State would be empowered to make temporary appointments to fill any vacancies from his State in the House of Representatives which might exist during a period of 90 days from the issuance of the proclamation.

Mr. Speaker, it seems to me that Congress has a special responsibility to see to its own survival as an instrument of free and representative government. To do so, we must prepare for any contingency. We cannot wish away the possibility that catastrophe might some day strike us. We must be ready to carry on in any and all eventualities.

DRUG AMENDMENTS OF 1962

The SPEAKER pro tempore (Mr. LIBONATI). Without objection, the bill, H.R. 11581, will be laid on the table.

Mr. GROSS. Mr. Speaker, reserving the right to object, may I ask what was the request?

The SPEAKER pro tempore. The provision creating this situation was in House Resolution 808 which reads:

> That after the passage of H.R. 11581, the Committee on Interstate and Foreign Commerce shall be discharged from the further consideration of the bill S. 1552; that it shall then be in order in the House to move to strike out all after the enacting clause of said Senate bill and insert in lieu thereof the provisions contained in H.R. 11581 as passed.

The only purpose here is to save the money by not printing the House bill.

Mr. GROSS. Mr. Speaker, it was my understanding that no business would be transacted after special orders were called.

I object.

BURNS CREEK MUST NOT BE INCLUDED IN ANY OMNIBUS RIVERS AND HARBORS BILL

The SPEAKER pro tempore. Under previous order of the House, the gentleman from Pennsylvania [Mr. SAYLOR] is recognized for 60 minutes.

Mr. SAYLOR. Mr. Speaker, I ask unanimous consent to revise and extend my remarks; and also that the gentleman from Texas [Mr. ROGERS] may extend his remarks following mine.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Pennsylvania?

There was no objection.

Mr. NELSEN. Mr. Speaker, will the gentleman yield?

Mr. SAYLOR. I yield to the gentleman.

Mr. NELSEN. Mr. Speaker, I ask unanimous consent that the gentleman from Iowa [Mr. KYL] be permitted to insert his remarks in the RECORD following those of the gentleman from Pennsylvania [Mr. SAYLOR] and the gentleman from Texas [Mr. ROGERS].

The SPEAKER pro tempore. Without objection, it is so ordered.

There was no objection.

Mr. SAYLOR. Mr. Speaker, we are rapidly coming close to the end of the 87th Congress. This has been an interesting and productive Congress—productive both for what it has accomplished and for what it has prevented some of the bureaucrats in the Administration from doing to deprive American citizens of some of their freedoms. I do not know of another Congress, however, which has been subjected to the raw and naked exercise of political power such as the present administration has tried to exert on the 87th Congress. I do not say this from a narrow partisan point of view; but, rather, I feel the American people have a right to know some of the intricacies of the attempted maneuvering of this youthful administration to force its will on the duly elected representatives of the people.

Mr. Speaker, I have chosen one example to discuss in detail today because of its implication on the entire legislative process and its reflection of a basic philosophy of government being espoused by some individuals. I refer to the Burns Creek public power project in southeastern Idaho.

BURNS CREEK REJECTED BY INTERIOR AND INSULAR AFFAIRS COMMITTEE

The Burns Creek Dam and Reservoir was originally proposed for construction by the Bureau of Reclamation in 1956. The first legislative bill was introduced in January 1957, and referred to the Interior and Insular Affairs Committee. This conscientious and responsible committee—on which I have had the privilege of serving for many years—held comprehensive hearings on the Burns Creek project in 1958, 1959, 1960, and

1961. We heard witnesses from the Bureau of Reclamation, proponents of the project and opponents of the project. In February of this year, 1962, with this wealth of knowledge and background at our disposal, the House Interior and Insular Affairs Committee by a positive vote rejected the Burns Creek proposal as being unnecessary, uneconomic and unworthy of construction.

Under normal circumstances, one would assume that when the appropriate legislative committee had so thoroughly studied an issue and expressed its will in positive terms that this would mark the end of an unworthy proposal. But unfortunately this was not the case with Burns Creek. In an almost unprecedented move, the administration—despite the adverse vote of the Interior and Insular Affairs Committee—instructed the Corps of Army Engineers to include a request that the Bureau of Reclamation be authorized to construct the Burns Creek project in the corps request for authority from the Public Works Committee. This was a blatant disregard for clearly established legislative processes, and I consider it to be a personal affront to the sincere and hard-working chairman and members of the Interior and Insular Affairs Committee.

With the 87th Congress having perhaps less than 2 weeks to live, the master strategists are trying to force the Burns Creek project into an omnibus rivers and harbors and flood-control bill with a thought that it could thus be steamrollered through the Congress and signed into law.

Mr. Speaker, what is this Burns Creek project that has caused the administration to attempt such an underhanded method of operation to force its will on the Congress? I have studied this project long and hard, and let me tell you, my friends and colleagues in this Chamber and the American people, just what we have here in the Burns Creek project.

The Burns Creek project would be located about 30 miles northeast of the existing Palisades Dam on the upper Snake River in southeastern Idaho. The dam would be 1,900 feet long and 176 feet high impounding about 234,000 acre-feet of water. The powerpiant would have 90,000 kilowatts of hydroelectric generating capacity.

The Bureau of Reclamation reports that this project, at 1959 price levels, would cost about $48,130,000—including $2,700,000 in interest during construction.

It is claimed—contrary to all facts submitted in the hearings—that the project is for the prime purpose of reregulation of the Palisades project; to assist in the irrigation of arid and semiarid lands; to assist in the control of floods; and to provide for the conservation and development of fish and wildlife. The bill also provides for the generation of hydroelectric power which is the true reason for the project since $46,752,000 or 97.1 percent is being allocated to power and only $1,329,000 or 2.9 percent to irrigation. Not 1 cent is allocated to river reregulation. Not 1 cent is allocated for flood control. Not 1 cent is allocated for fish and wildlife.

This project is undesirable for a number of significant reasons.

NO EVIDENCE OF NEED FOR REREGULATION

The Secretary of the Interior, in a letter dated March 10, 1961, transmitting a favorable report on the proposal, states:

> The prime purpose of the Burns Creek development is reregulation of releases from Palisades.

The Bureau of the Budget, in clearing the report, also put primary emphasis on the reregulating aspect of the project. Actually, only 17,000 acre-feet or 7 percent of the dam's total storage capacity of 234,000 acre-feet of storage is assigned for such purpose should reregulation ever be required. What is more important, however, is the fact that the Bureau of Reclamation, in allocating the project costs, did not allocate even one penny for reregulating purposes.

Extensive hearings held by the House Irrigation and Reclamation Subcommittee clearly revealed that operating experience with the Palisades project has not indicated the need for a reregulating reservoir as of the present time. The hearings further revealed that if the need for reregulation ever became apparent in the future, it could be supplied by construction of a 17,000 acre-feet reservoir estimated to cost about $6 million at current price levels—a small fraction of the cost of the proposed Burns Creek project.

Testimony presented during the hearings showed that in 1953 the Bureau of Reclamation did give consideration to construction of a small reservoir to provide for the claimed reregulation need. And, at that time, the Bureau estimated such a reregulating dam and reservoir could be constructed for approximately $2,128,000. In connection with this, a Bureau of Reclamation witness testified in August 1959:

> It was a feasible undertaking in the sense that the benefits exceed the cost.
>
> However, we could accomplish the same thing cheaper if we purchased power to firm up Palisades; therefore, we did not believe it was a justified investment [$2,128,000].

The cost of purchased power required to firm up Palisades without Burns Creek, according to Bureau of Reclamation's own studies, would be $27,000 per year; on the other hand, the Bureau would still have to spend, again according to its own studies, $23,000 per year for purchased power to firm up Palisades after construction of Burns Creek, a reduction of only $4,000 per year. The expenditure of almost $50 million for the prime purpose of reregulation when the reduction in the cost of power to firm up Palisades is only $4,000 certainly cannot be justified under the guise of reregulation.

The Bureau of Reclamation tries to make one further claim for the benefit of reregulation; that is, the generation of additional peaking power at Palisades. In this connection, it should be noted that the Bureau of Reclamation economic studies do not show any sale of, or revenue from the sale of peaking power nor the inclusion of even $1 for such claimed benefit.

We should also note that if reregulation of the Snake River downstream from the Palisades project is needed, it also would be required below the Burns Creek project, because the same water would be released into the same streambed. River surges from the 90,000 kilowatt Burns Creek project would have almost the same effect on the downstream irrigation facilities as released from the 114,000-kilowatt Palisades project.

THIS IS NOT A RECLAMATION PROJECT

Although the proponents of this Burns Creek project seek to justify the project in order to assist in the irrigation of arid and semiarid lands, actually irrigation plays a very small part in it. Out of a total estimated annual benefit of $2,886,000, only $33,000 would result from irrigation. This is only 1.1 percent of the total. Power benefits would amount to $2,851,000 or 98.8 percent and recreational benefits only $2,000. As pointed out previously, of its total cost of $48,130,000, only $1,329,000 or 2.9 percent would be allocated to reclamation. Something like 100,000 acre-feet of the storage capacity of the reservoir would, on occasion, be used for irrigation purposes. But, according to spokesmen for the Bureau of Reclamation, water stored in this space would be used by irrigators only two or three times in any 50-year period. In fact, Secretary of the Interior, Stewart Udall, in effect admitted this when he wrote:

> The relatively minor part of irrigation in this project will have little bearing on the success of the project.

Neither on the basis of the project's irrigation benefits, nor on the basis of the allocation of the project cost to irrigation, nor on the basis of its repayment schedule does it appear to be fair or appropriate to assert, as do the advocates of this project, that Burns Creek should be approved to assist in irrigation of arid and semiarid lands in the upper Snake River Valley, Idaho.

THIS IS PRIMARILY A POWER PROJECT

This project is now before the Public Works Committee masquerading as a flood control project, but Department of Interior witnesses have actually admitted that there are no flood control or significant wildlife benefits involved in it. A spokesman of the Bureau of Reclamation has admitted that this is primarily a power project. As I said a moment ago, this project is 97.1 percent power. The feasibility report on the project admitted that reclamation storage would be kept at a minimum to maximize power revenues. The report said:

> Assignment of more than 100,000 acre-feet of this total to irrigation is not financially feasible because of the reduction in power revenues that would result (85th Cong., H. Doc. No. 147, p. 12).

Although the power produced at Burns Creek standing alone would be very costly; it would be marketed at a relatively low price, substantially below its actual cost of production. This unusual

result would be accomplished by combining the power to be produced at Burns Creek with that from Palisades Dam. All of the power would be sold at rates yielding an average of about 3.7 mills per kilowatt hour.

For the power facilities of the Burns Creek project to pay out in 50 years, the resulting power would have to sell for an average of at least 4.88 mills per kilowatt-hour. Nevertheless, the Department of the Interior has indicated that power from Burns Creek would be marketed at the same rate as the power from Palisades Dam. This would mean that on the average it would be sold at about 1.18 mills per kilowatt-hour less than its cost of production, with the deficit resulting from Burns Creek power operations being made up out of whatever surplus might result from Palisades. Instead of using, as is normal, any surplus power revenues to pay reclamation costs beyond the financial ability of water users to pay, such surplus from Palisades would be diverted to subsidize the few wholesale consumers of Burns Creek power.

An Assistant Commissioner of Reclamation has said in hearings on this bill that Burns Creek power, if disposed of at the proposed rates, would be selling at less than its cost of production. In fact, he admitted, in answer to a specific question, that Burns Creek power revenues would not be sufficient to pay even the interest on the power investment.

THE PROJECT WOULD BE DETRIMENTAL TO RECLAMATION

Evidence presented shows that the Burns Creek project actually would be detrimental to reclamation, to the water users, and to the taxpayers. The Palisades project standing alone without Burns Creek would repay all of its reimbursable costs by 1988, and by the year 2006 a surplus of $22,245,333 would be built up from earnings of Palisades. Under existing law, this would go to the Treasury and, should Congress so decide, it would be available to finance additional reclamation projects, the cost of which might be beyond the financial capacity of water users.

But should Burns Creek be included in an omnibus rivers and harbors bill and construction concluded in fiscal year 1967, and should Burns Creek and Palisades market their power at the Palisades rate, then all of the reimbursable costs of the two projects would not be recovered until the end of year 2006. Palisades alone by this date would have a surplus of $22,245,333. Thus $22,245,333 would be diverted from the Treasury to subsidize the users of Burns Creek power.

Therefore, as a result of the construction of Burns Creek and the sale of its power under the Palisades rate, $22,245,333 less would be available to the Treasury that could, should Congress so decide, be used to pay reclamation costs that might be beyond their financial capacity than would be the case if Burns Creek were not built.

This would be a radical departure from the normally accepted principle of Federal reclamation policy; that is, that power is the paying partner of reclamation. For example, Harold T. Nelson, regional director of the Bureau of Reclamation for region 1, including Idaho, said in 1958 relative to power projects of the Bureau on the Snake River:

> These plans were built primarily to furnish a power supply to Federal irrigation project pumping loads but there has been surplus capacity and energy, particularly during the irrigation season to serve preference customer loads and for off-project markets for secondary energy. In every case off-project revenues are required to assist in the repayment of project costs allocated to irrigation and to maintain reasonable irrigation pumping rates.

Now, however, the Burns Creek proposal would change this established policy. Rather than power revenues helping to finance the irrigation of Western aridlands, the water users would be penalized to subsidize power production.

BURNS CREEK WOULD BE DETRIMENTAL TO COAL MINING INDUSTRY

Testimony presented by representatives of both the United Mine Workers and Coal Mine Operators reveal the fact that this project would adversely affect the already depressed coal mining industry in the Rocky Mountain area. The 500 million kilowatt-hours generated each year at Burns Creek could displace as much as 250,000 tons of coal a year with the resulting loss of 20,000 manshifts of coal mine labor, $40,000 per year in the miners' welfare fund, together with all other related benefits associated with mining that quantity of coal in an area.

BURNS CREEK DOES NOT INCREASE FIRM GENERATION AT PALISADES

Contrary to claims made for Burns Creek, it would not double the firm power generation at Palisades. A more accurate claim would have been that additional power would be generated by the proposed Burns Creek project as a result of adding 90,000 kilowatts of new generating capacity. This additional generating capacity, however, would cost over $500 per kilowatt as contrasted to costs allocated to power at Palisades of only $185 per kilowatt. If Burns Creek should be constructed, the cost allocated to power will be increased 238 percent above the cost of Palisades. Increase in revenues, however, will amount to only 94 percent.

WITH PRESENT COSTS THE BURNS CREEK PROJECT WOULD NOT BE FINANCIALLY FEASIBLE

Although the benefit-cost ratio tends to indicate that Burns Creek nominal benefits might barely exceed its nominal costs, this does not demonstrate that revenues will even equal actual costs. Actually, it has been admitted that the project's annual revenues will be less than its actual costs. At the very outset it should be understood that economic feasibility as measured by the benefit-cost ratio is a completely different test than financial feasibility in the sense that revenues will at least equal money costs. The most obvious and significant difference is that the economic benefits used in the ratio may be of such a nature that no one is willing to pay for them at their full alleged economic value. As a consequence, actual monetary revenues from a project producing even vendable commodities—such as power—frequently are much less than the estimated benefits attributed to such functions.

It is very difficult to say whether this project would be feasible economically. Even when first proposed, this project had a low ratio of benefits to cost. The Bureau in its original report—85th Congress, House Document No. 147, page v—found that on the basis of 1956 date the project would have a benefit-cost ratio of 1.26 to 1. This was assuming the project would cost only $40,267,000. In 1957 the cost of the project had increased to $44 million, and the Department then indicated that the benefit-cost ratio had declined to 1.19 to 1.

In 1959 the Bureau admitted that the project with interest during construction would cost $48,770,000 or about 20 percent more than the 1956 estimate. It has submitted no official computation of the benefit-cost ratio on this estimate to costs, but evidence adduced indicates that it probably had fallen too close to 1.14 to 1. In 1961 the Bureau contended that the project had a favorable ratio of 1.33 to 1 over 50 years. This upward revision was based on a downward revision in the allowances for depreciation and replacements.

Irrespective of whether the project allegedly would be economically feasible, its monetary revenues would be less than its reimbursable costs. This is because of the difference between theoretical power benefits and actual revenues from the sale of power. It should be remembered that frequently the so-called power benefits used in determining economic feasibility are far in excess of actual power revenues. Thus, for Burns Creek the power benefit is shown at $2,851,000, but the power revenue would be only $1,702,000—85th Congress, House Document No. 147, pages 16, 26. Further, actual annual costs might well be higher than those used in the ratio. One reason for this is that in computing the benefit-cost ratio the Department uses interest at 2.6329 percent on the power facilities although by reclamation law the power costs are to be amortized with interest at 3 percent. Why 2.6329 percent was used instead of 3 percent as required by law is not clear.

Actually, the project standing alone would not be financially feasible if its power should be sold at Palisades rates. A representative of the Bureau of Reclamation told a subcommittee of this committee in 1958:

> Burns Creek would be impossible, standing alone.

And as indicated previously, representatives of the Department of Interior have admitted that power would be sold at less than its cost and that the power revenues from this project would not even pay the interest on the power investment.

THE LIMITATION ON USE OF WATER FOR PRODUCING AGRICULTURAL COMMODITIES THAT ARE IN EXCESS SUPPLY IS MEANINGLESS

Proponents of Burns Creek claimed that for 10 years from the date the project was constructed no water should be delivered from the project for production on newly irrigated lands of agricul-

tural commodities in surplus supply. This restriction would be meaningless because the water from Burns Creek would not be used on newly irrigated lands but only as a supplementary supply for lands now under irrigation. Bureau of Reclamation witnesses, however, have admitted that power from this project would be used to pump water to irrigate from 55,000 to 65,000 acres of land not now being cultivated. This would be additional acreage not now in production, but no water from the project would be delivered to it. Thus, this limitation would not apply to production on the only new lands that would be irrigated as a result of Burns Creek. Obviously, the language designed to prevent this project from adding to agricultural surpluses is meaningless and would not attain its objective.

Testimony given in hearings on this bill substantiates this conclusion. A representative of the Bureau of Reclamation said that sugarbeets would be raised on 5,000 to 6,000 acres of the land to be irrigated through pumping power supplied by this project. Potatoes and alfalfa are other crops that also will be produced. Significant surpluses now exist for all these crops. But since the land involved would not be supplied with water from the project, this limitation would be inapplicable.

TO JUSTIFY THE PROJECT, RECLAMATION CLAIMS A UTILITY RESPONSIBILITY

Although it is a generally admitted fact that there is no power shortage in southeastern Idaho and that none is likely in the foreseeable future, the Bureau of Reclamation has, in effect, asserted that the United States has a utility responsibility to supply the increasing power needs of the preference customers in the area. The claim that such a responsibility exists was made by the present Assistant Commissioner of Reclamation, Mr. N. B. Bennett, then chief of the project development division of the Bureau of Reclamation, while appearing on another occasion to justify this project. He said:

Mr. Nelson has recently analyzed the power loads to be anticipated from the existing customers, if you please, that are now customers of the Federal Government in southern Idaho, and he finds that in order to meet that load alone we must have Burns Creek on the line starting in 1966 and that their loads will exceed the capabilities of the combined Federal system in southern Idaho by about 1972. If these are loads to be served by continuing Federal Government supply of power, it cannot possibly in my judgment have an effect on the Kemmerer steamplant.

True, if the Utah Power & Light, or the Idaho Power, in whose market area most of these customers are, is the agency to serve these increased loads, then that is a different question, but these people now have contracts for power with the Federal Government and we believe that they should continue to receive from the Federal Government power to meet their growing loads.

Further, in the hearings on this bill held by a subcommittee of this committee in March 1960, Mr. Bennett said:

I think it has been known probably for quite some time that, along about 1962–63, in there somewhere, the ability of the existing Federal plant in that area would not be sufficient to furnish the growing loads of the customers then served.

From this second quotation it is apparent that Mr. Bennett was attempting to justfy Burns Creek as being needed to meet the growing power needs of the present customers of the Bureau of Reclamation. In fact he went on to point out that the load of these customers will continue to grow and would exceed the capacity of Palisades by 1963 and of Burns Creek by 1972, and that by the latter date still more power would be needed.

Further, the Bureau wants to continue to serve these customers even though this would require the construction of additional projects. Thus in effect the Bureau is saying to Congress that it has a responsibiilty to build electric power projects because they would be needed to meet the increasing load of the Bureau's own customers. The net result of this attitude would be that the Bureau of Reclamation should assume a utility responsibility toward its power customers. In this way, it would be taking on an obligation of an investor-owned electric company to build generating plants primarily to meet the forthcoming load of its power customers.

AFTER BURNS CREEK, WHAT NEXT?

In the quotations previously set forth the spokesman for the Department of Interior pointed out that Burns Creek would meet the power needs of its service area only until 1962. After that, what will happen? What would be next? What will the Bureau want to do after that to meet the probably increasing power load? Mr. Harold T. Nelson, the regional director of the Bureau of Reclamation, said on another occasion concerning the prospect that the increasing preference customer load might exceed the Bureau's capacity to supply power from reclamation projects:

So, we are sort of in a position of a banker who has more loans than he has funds, and we would certainly like to do something about it.

On that occasion he endorsed the construction of the Burns Creek project and he pointed out that there are at least two other projects in the Snake River Valley with large amounts of generating capacity. One of them is the Garden Valley division of the Snake River project which would have an ultimate generating capacity of 368,500 kilowatts, and the other is the Guffey unit of the Mountain Home division, which would have a capacity of 140,000 kilowatts. The Bureau already has underway a $1,300,000 study to determine the feasibility of these projects. Of this sum about $916,000 has already been spent.

In addition, just over the line in Wyoming above the Palisades project is the site of the as yet unauthorized Snake Narrows project. The Bureau expects shortly to complete a planning report on this project. This feasibility report cost over $191,000. The project would have a 270,000-kilowatt powerplant and about 90 percent of its total cost would be allocated to power. The irrigation storage that would be provided would be used only about once in 26 years.

On the Bear River in southeastern Idaho the Bureau also is studying the feasibility of another hydro project involving about 45,000 kilowatts of generating capacity. This $1,065,000 study probably is close to completion. Congress probably will be asked in the next few years to authorize some or all of these projects on the ground that they too will be necessary to meet the Bureau's preference customers' ever-growing need for power.

Further, the regional director of the Bureau has intimated to another committee that when the Bureau runs out of hydro projects in the area, it would seek authority to build steam projects. Only 2 years ago he said:

I have enough confidence in the development picture that I see ahead in the Northwest to know that before too many years we are going to have to have a large thermal electric component in order to make a better use of our hydro.

Inasmuch as he was speaking as a regional director of the Bureau of Reclamation, the "we" and the "our" can logically refer only to the Bureau of Reclamation.

WHY DO BUREAU CUSTOMERS WANT IT TO ASSUME A UTILITY RESPONSIBILITY?

Why is it that the Bureau's preference customers in the Snake River Valley look to the Bureau of Reclamation to supply their growing power needs? It is not because there is any power shortage in the area. A number of proponents of the project admitted this under questioning. Among these was Assistant Secretary of the Interior Kenneth Holum. The feasibility study justifying Burns Creek mentioned 65,000 acres west of Idaho Falls in need of water to be supplied by pumping—85th Congress, House Document No. 147, page 9. Since this report appeared in 1957 over 30,000 of these acres have been irrigated by pumping with power supplied by an investor-owned electric company, and probably more than 10,000 additional acres in this area will be so supplied this year. In fact Assistant Secretary Holum admitted that there is sufficient power available to bring water to this land. A report of the Federal Power Commission indicated that in 1959 in southern Idaho there was a power reserve or surplus of 376,000 kilowatts with an installed generating capacity of 1,560,000 kilowatts. By 1963 the two electric companies will have 1,700,000 kilowatts of generating capacity, and by 1972 this will increase to about 2,900,000 kilowatts. All during the next decade there will be a substantial area reserve or surplus capacity at times amounting to as much as 636,000 kilowatts.

If no power shortage exists or is likely to develop in the next decade, why do the preference customers insist that Reclamation assume a utility responsibility? The answer is simple; they want subsidized power, that is power to be sold at a price below its true cost. Such low price would be made possible only because of significant tax and interest subsidies from all the Nation's taxpayers.

It should be remembered that electric companies pay about 23 percent of their gross revenues in Federal, State, and

local taxes. This means that about 23 percent of the electric bills of their customers goes to pay for taxes. Electric customers who consume power from Federal projects do not have to pay a comparable tax burden through their power bills. Further, the rates for power from reclamation projects must reflect—in addition to other costs—interest at only 3 percent on the power investment. Actually 3 percent is substantially below the cost of new long-term money now being borrowed by the Treasury. The interest yield on long-term Treasury bonds is in excess of 4 percent at present. The net result is that money costing the Government at least 4 percent is used for power projects; but the power users through their power rates have to pay only 3-percent interest on the power facilities. As a consequence of these significant subsidies, it is not surprising that the relatively few preference customers demand construction of Federal power projects to meet their growing needs and even insist that the Government has a responsibility to build them for that purpose.

Actually this is what they are now doing in the Snake valley. For example: the mayor of Burley, Idaho, told another committee of this House:

> It is the city's position and contention that the Bureau of Reclamation does have a power responsibility to the city and other public power distributors. These moral and physical factors coupled with the expressed provisions of a written contract clearly spell out a utility obligation and responsibility to the public power distributors. The first and primary problem is future supply of power and secondarily is the price to be paid.

In the hearings on this bill this same mayor said:

> Sir, since the city has never received power from any other source, I feel that we do have some justification to look to the Federal Government for continued supply inasmuch as they have been serving us for 55 years and have been the only supplier we have had. It would be a change of economy to go to a higher source of electrical energy.

The mayor of Idaho Falls also said in 1955:

> I could not honestly say of my own knowledge that there is a shortage of power in this area. I do say there is a shortage of public power, so we are going to work with the Bureau of Reclamation and also the Army Engineers, to see if it isn't possible to get this reregulating dam built downstream from Palisades, which will also produce an additional 25,000, 30,000, or 40,000 kilowatts of power.

Obviously he is referring to Burns Creek.

A representative of a cooperative in Idaho said that the cooperatives did not want to buy power from the electric company because such power cost them more than they would have to pay for similar power bought from the Bureau of Reclamation.

In 1955 a Member of the House of Representatives asked the regional director of the Bureau of Reclamation why cities did not build their own power plants as Idaho Falls had done. Mr. Nelson replied:

> They could do that. I think it is a question of economics with them.

And then the Congressman asked him:

> It is a question of whether they want to do that, and they are not going to want to do that if they can persuade the Bureau of Reclamation and the Federal Government to provide it for them. Isn't that the answer to that question?

Mr. Nelson replied:

> I think they would prefer to—it is a question of economics.

Preference customers make such demands even though the Commissioner of Reclamation on May 4, 1955 wrote:

> All power sales contracts which the Bureau has made during the past 8 or 10 months contain a provision as follows: "Nothing in this contract contained shall obligate or be construed to obligate the United States to increase any contract rate of delivery hereunder. If additional power is not available from the United States, the responsibility for securing additional power shall rest solely with the contractor." Although this provision was not included in the older contracts in the Minidoka area, nevertheless, it is the guiding principle now in effect throughout the Bureau system.

Obviously for more than 6 years the Bureau's customers in this area have been on notice that the obligation to secure additional power to provide for their growing need is wholly their responsibility. For this reason, it is rather incongruous now for Reclamation to assume such a responsibility.

BURNS CREEK MUST NOT BE INCLUDED IN OMNIBUS RIVERS AND HARBORS BILL

Mr. Speaker, it was based upon these facts that the House Interior and Insular Affairs Committee in 1962 clearly refused to authorize construction of this project. The Burns Creek project obviously is not a genuine reclamation proposal; but rather is a flagrant example of an attempt to use the good name of reclamation as a vehicle for furthering public power. To approve this project in this way would cause irreparable harm to the Nation's whole western reclamation program. When this attempt failed in the Interior Committee, the proponents of this unworthy project again tried to mislead the Congress and the American people with the claim that it was a flood control project; and, therefore, worthy of consideration as a part of the omnibus flood control bill.

This is not a flood control project any more than it is a reclamation project. It is a hydroelectric power proposal being put forth in an effort to have the Federal Government assume a utility responsibility for supplying subsidized power for the growing needs of a very small handful of preferred public power customers. The project will admittedly drain revenues from the Palisades project in order to make Burns Creek appear to be economically palatable. Succinctly stated, Burns Creek is unnecessary, uneconomical, unworthy of construction.

The present attempt to force the Congress to accept this project as a part of the omnibus flood control bill must fail. The proponents of this project seem to have so little regard for the integrity and backbone of the Members of this House that they feel we will not have the courage to vote against any project in such a bill.

It is because of this apparent contempt for the integrity of individual Members of Congress and the flagrant disregard for clearly established rules of congressional procedures that this proposal must be soundly rejected.

I, for one, have enough confidence and trust in the sound judgment and integrity of my colleagues to believe they will not allow an overbearing administration to coerce them into accepting a proposal which they know to be unworthy.

I yield to the gentleman from Wyoming [Mr. HARRISON].

Mr. HARRISON of Wyoming. I thank the gentleman.

Mr. Speaker, I want to compliment the gentleman for taking the time today to bring to the attention of the House and the Members of Congress as well as the general public the situation surrounding the so-called Burns Creek project which had previously been introduced and assigned to the Committee on Interior and Insular Affairs of the House.

I am a member of that committee with the gentleman from Pennsylvania. I am also a member with him on the Subcommittee on Irrigation and Reclamation. We sat together for many days of hearing on this bill, which was submitted as a reclamation project. Following fair and intensive hearings, this project was rejected by the full committee.

I want to point out that during the time of the hearings and the time of the testimony from the witnesses no testimony whatsoever was introduced regarding the flood control provisions or benefits of this project. It was placed before the committee strictly as a reclamation project. But the testimony did show that it was over 98 percent public power, less than 1 percent reclamation, and the balance for wildlife and fish and recreation.

The State of Wyoming is very much interested in this project because we feel it will be very detrimental and very injurious to our State. For that reason we oppose it. It would prevent the mining of coal and the use of coal in the State. It would, under testimony which was not refuted, mean a loss of 250,000 tons of coal from the Kemmerer area in Wyoming which could be used should this project not be built.

The Utah Power & Light Co. is constructing at the present time a steam generation plant in that area which will when completed serve the whole area which this proposed Burns Creek project is supposed to serve as a public power project.

The Utah Power & Light Co. project would pay taxes not only to the Federal Government but also to the State of Wyoming, and would supply employment to the miners in that area, who are desperately in need of that work.

For this reason, the State of Wyoming and I oppose this project strenuously.

The peculiar situation to me is that within 2 months from the time our committee in good faith considered this legislation I received a notice that the Corps of Engineers was contemplating

taking this project over as a flood control project. No notice was received by me. No notice was received by the State of Wyoming. When I contacted the Army Engineers they said that because this project was wholly within the State of Idaho, Wyoming was not notified, nor was this congressional delegation. It seems strange to me because the Army Engineers also said that they were well aware of the situation in the House Committee on Interior and Insular Affairs and the objections by the State of Wyoming and others to this project, but they deliberately refused to notify either the State or the congressional delegation.

I certainly protest the way this project will be brought before the House in the public works authorization bill. It is my understanding that both the subcommittee handling it and the full committee have now approved it. No testimony was ever adduced before the House Committee on Interior and Insular Affairs as to the flood control benefits of this project, yet it was considered in a closed hearing, and no testimony was allowed by anyone who might want to oppose this project. The cost was raised. To my knowledge, the only witness was one witness from the Corps of Engineers.

I say that this is a very peculiar way to handle legislation which once has been acted upon in good faith and rejected by one committee in the House, a major committee, for it then to be taken to another committee in great secrecy, the cost of the project raised, closed hearings held so that no opposition could be raised, and then be passed and brought before the House. I say that if there is flood control in this legislation for the Burns Creek project there should be an open hearing. The general public should have an opportunity to know what their money will be spent for. If under those circumstances it can be shown that it is a fair and reasonable project, of course I have no objection to its being approved.

I do, however, strenuously protest the way this legislation is being brought before the House. I think it is very peculiar and I shall not use any stronger words. I think this project should be removed from the so-called public works appropriation bill until at least it has had further study, a fair study, and an open study.

I thank the gentleman for yielding to me at this time, and I want to commend him again for his action. He has been one of the outstanding Members of the House of Representatives and of the Committee on Interior and Insular Affairs. It is through his efforts that the public of this country have been saved many, many millions of dollars which would otherwise have been spent on wasteful projects on which authorization has been sought. The gentleman from Pennsylvania is doing good work and I assure you it is a privilege for me to serve on the same committee.

Mr. SAYLOR. I thank my colleague, the gentleman from Wyoming.

Mr. ROGERS of Texas. Mr. Speaker, the omnibus rivers and harbors and flood control bill drawn up by the Committee on Public Works includes language which would authorize the Bureau of Reclamation to construct the Burns Creek project in southeastern Idaho at a cost of about $50 million. To put it mildly, inclusion of this project in the omnibus authorization bill came as a distinct surprise and shock to me, for I was of the opinion that the Committee on Interior and Insular Affairs had settled the question of this project earlier this year.

As the Members know, I am a member of the Committee on Interior and Insular Affairs and I am privileged to serve as chairman of the Subcommittee on Irrigation and Reclamation. My subcommittee has jurisdiction over irrigation and reclamation project authorization requests and as a result, considered the Burns Creek project frequently and carefully over the years since the first Burns Creek bill was introduced in 1957.

During the 86th Congress, for example, the Subcommittee on Irrigation and Reclamation heard 36 witnesses during hearings on the Burns Creek project. These witnesses represented the Federal agencies concerned and also many non-Government organizations. In addition, the subcommittee incorporated in the record of the hearings 51 statements concerning the Burns Creek project.

Further hearings on Burns Creek were held by the subcommittee in this Congress, at which time 27 witnesses testified before the Subcommittee on Irrigation and Reclamation and 45 statements were received and incorporated in the hearing record. As before, these witnesses and the statements filed with the subcommittee represented a wide cross-section of interest in the Burns Creek project.

Subsequent to the close of public hearings on Burns Creek in this Congress, my subcommittee took under advisement the many views expressed in support of and in opposition to the project. The subcommittee considered, for instance, the fact that hydroelectric power from the Burns Creek project would be used to pump-irrigate large tracts of new land which would be used for the production of sugarbeets, thereby increasing such production in an area where it is not needed at all.

After careful and objective consideration of all the technical and economic facts and all the views expressed concerning the project, the Committee on Interior and Insular Affairs, on February 7, 1962, voted to reject the project.

Mr. Speaker, we find now that a project rejected by one committee of the House, after extensive investigation and careful consideration of all the facts, has been revived by another and thrust upon the floor of this House with practically no study and investigation. If the Committee on Public Works took time to read the records of the hearings held by my subcommittee in this Congress and the last, it is inconceivable to me that the committee could have reached a conclusion that this was a worthy project.

But it is doubtful that the Committee on Public Works read the records of the Committee on Interior and Insular Affairs on this matter, for I am led to understand that the Committee, in considering Burns Creek as part of this omnibus bill, took testimony only from the Corps of Engineers and permitted the filing of absolutely no statements by others interested in this project.

Having studied all facets of this project over a period of several years, I am convinced that no intelligent Member can cast a meaningful vote on this project in the absence of detailed information on Burns Creek. The Committee on Interior and Insular Affairs declined to even report the project to the House for consideration, but had it chosen to do so it could have provided each Member with volumes of data concerning the project. The Committee on Public Works has seen fit to report Burns Creek to the House for consideration, but it cannot provide the Members with detailed information on the project because it was unable to obtain any significant information on the basis of brief testimony from only one witness.

Mr. Speaker, I suggest to the Members that the course of action taken by the Interior Committee on Burns Creek was the wiser and more proper and that the Members can, in good conscience, vote to strike this project from the authorization bill concerning these rivers and harbors and flood control projects.

Mr. KYL. Mr. Speaker, I have listened carefully and with great interest in what the distinguished gentleman from Pennsylvania [Mr. SAYLOR], had to say about this Burns Creek project. As a member of the Interior and Insular Affairs Committee, I would like to compliment him on the thoroughness with which he has exposed this unworthy proposal for just what it is. I wish to associate myself with him in this expression of concern over the attempt to include Burns Creek in the omnibus rivers and harbors and flood control bill.

Mr. Speaker, this is not a flood control project and should not even have been considered by the Committee on Public Works. Has our legislative committee system deteriorated to such a low point that it can be manipulated at the will of the executive agencies like a magician manipulates his props to pull a rabbit out of the hat? Whether the administration recognizes it or not, the Congress is a coequal arm of the Government; and, in fact, according to constitutional precedence should be the most important arm. The Congress makes the laws and policies and the executive agencies merely carry them out.

There are several important points that our colleagues should keep in mind when they consider whether this Burns Creek project should be left in the omnibus bill.

The report of the Interior Department to Congress on Burns Creek—upon which the Corps of Engineers reported to the Public Works Committee—was prepared in March 1956, and was based on January 1956 price levels, and 1955 or 1956 data. These data are, therefore, out of date at this time. In this original report, the estimated cost of the project was about $40 million and the benefit-cost ratio was 1.26 to 1. This assumed

a 50-year payout for the costs, rather than the 3 percent required by the reclamation laws. By 1957 the Interior Department estimated the cost would be nearer $44 million and the benefit-cost ratio dropped to 1.19 to 1, still using the 2¼-percent interest figure. The costs are estimated now to be almost $50 million or a 20-percent increase over the past 5 years. The Bureau of Reclamation, however, has not undertaken a new study nor made a recomputation of the benefit-cost ratio based upon 1960 price data and using a 3-percent interest figure. A special report, prepared in February 1960, by a staff member of the House Appropriations Committee revealed that a benefit-cost ratio for Burns Creek calculated on a proper basis would be less than 0.8 to 1. For this reason, the Corps of Engineers should at least be requested to prepare a new report showing economic justification data based on 1961 or 1962 prices, power supply and demand data, and using the 3-percent interest payments required by law.

Evidence was presented at the House Irrigation and Reclamation Subcommittee hearings in 1958, 1959, 1960, and 1961, to indicate that Burns Creek is not a genuine reclamation project in the generally accepted sense of the reclamation laws. Rather, it is purely and simply a hydroelectric power project proposed to supply the growing power needs for a few preference customers. The historical concept of incidental power production to aid water users would be changed to deprive water users of future funds for the benefit of preference power users.

Proponents of the Burns Creek project have attempted to hide its true purpose under the mantle of assistance to irrigation and the need for river reregulation below the existing Palisades Dam and flood control. However, even the authors of the legislation in the 87th Congress admit that not one single acre of new land would be brought under irrigation as a result of water stored in this project. Furthermore, no evidence exists, after about 5 years of operating Palisades, to prove a need for reregulation at this point of the Snake River. Actually, if such reregulation were necessary to control surges of water from the 114,000 kilowatt Palisades Dam, reregulation would also be necessary below the 90,000 kilowatt Burns Creek Dam because there would be the same water surges in the same river bed. It is further shown by the record that less than 2 percent of the total project costs are allocated to irrigation and not 1 single cent is allocated to river reregulation. About 97.1 percent of the almost $50 million cost is allocated to power. Testimony before the House subcommittee revealed clearly there is no flood control in the project and no fish and wildlife conservation.

There is no power shortage in the area now nor will there be in the foreseeable future. Electric companies now serving the area have and are planning to provide for all the power needs for their own and preference customers. The only shortage which might arise in the next few years is in tax-subsidized Federal power for a few preferred customers, who are mostly industries, commercial establishments, or residents of urban areas.

The Burns Creek project is economically unsound. Considered alone, it will never repay the initial construction costs. In fact, it will not even repay the interest charges on the construction costs. Estimated net annual revenues derived by adding Burns Creek would be about $1.125 million which would be almost $311,000 short of paying the annual interest charges on the original construction costs figures on the basis of 3 percent. It must be integrated financially with the sound Palisades project in order to show a payout at all, thereby weakening the financial status of the later project. Such integration would extend the payout period on Palisades for a period of 26 years; thus, depriving the reclamation fund of about $30 million of power revenues over the years which could be used for genuine and necessary water development projects, if the Burns Creek were not constructed.

Since Burns Creek would be purely a Federal power project and would be built in an area where there are already ample supplies of power, the question arises as to why it should be built at all. The answer to this appears to be that some, who are categorized as preference customers under the law, feel the Federal Government should assume a utility responsibility to supply all their future power needs, regardless of cost to the Nation's taxpayers. Burns Creek, therefore, is to meet the future power needs of a few preference customers in southeastern Idaho—mainly municipalities—over half the Government power produced in the area is allocated to the three municipalities of Idaho Falls, Burley, and Rupert. Thus the principal beneficiaries of this power will be urban residents and businesses. Originally preference customers came into being when power was incidental to a truly multiple-purpose project. Now the needs of these preference customers have grown beyond the available incidental power so they want the Federal Government to build power projects to serve their needs.

This is what is involved in this issue. And this is why it is important to realize that Burns Creek is not a flood control project, not an irrigation project, but a power project. It should not be allowed to slip through this Congress by such a subterfuge.

H.R. 11581 LAID ON THE TABLE

Mr. WILLIAMS. Mr. Speaker, I ask unanimous consent that the bill, H.R. 11581, be laid on the table, it being a bill similar to the Senate bill, S. 1552 which was passed earlier today.

The SPEAKER pro tempore (Mr. LIBONATI). Without objection, it is so ordered.

There was no objection.

A TRIBUTE TO SAM RAYBURN

The SPEAKER pro tempore (Mr. LIBONATI). Under previous order of the House, the gentleman from Texas [Mr. ROBERTS] is recognized for 60 minutes.

Mr. ROBERTS of Texas. Mr. Speaker, this statement has been prepared as a small and personal memorial to Speaker Sam Rayburn. It is the story of the man in action in his element, against the background of his almost one-man struggle to have built the national monument that is the new east front extension of the Capitol Building. It is my hope that this short recountance will give a glimpse of the man himself and the unusual combination of qualities that made him a great national leader. Sam Rayburn possessed immense power, but greater than his power was his love for his fellow man and his country. His deep humor and love of a skirmish enabled him to accomplish more than many other powerful men.

It is a great tragedy that he did not get to enjoy the fruits of his labor.

THE EAST FRONT OF OUR CAPITOL

Recently completed atop Capitol Hill in Washington, D.C., is a project that brought cries of "outrage" and "desecration" from a lot of people several years ago. Now, in its final stage of completion, the words used to describe the new east front extension of the Capitol Building have changed from harshness to praise.

The serene marble masterpiece of the new addition in no way reflects the decades of controversy that make up the stormy story behind the stone.

It took a man with great foresight, great courage of his convictions, and the willingness and savvy to overcome the tremendous obstacles of public opinion and reactionary thinking to get the job underway. That man, of course, was Sam Rayburn.

The east front extension is more than just an extension. It is a new monument. It is the latest addition in that magnificently unified hodgepodge that is our Capitol. Physically the new extension stretches on either side of the grand east portico almost to the east fronts of the House and Senate wings. It provides long-needed architectural balance and at the same time provides much-needed space. That the new extension even exists is somewhat marvelous, considering the history and harangue that stretches back more than 150 years.

In 1859, as the sweeping House and Senate wings were being added to the Capitol, another project was underway: the construction of the great dome. The architects who planned the enlargement of the building realized that the old dome designed by Charles Bullfinch would seem squatty and undersized on the new, larger structure. The breathtaking magnificence of the building demanded a new centerpiece. In order to build a dome that was of the size to properly dominate the extended mass of the Capitol, some method had to be devised to support the structure that was actually bigger than the walls it was to rest on. The great center room, or rotunda, which had been under the old dome was too small to directly support the huge new dome.

An ingenious system of brackets was devised by which the outer edge of the new dome was supported. And there is the root of all the controversy.

The stately columns of the dome and the octagonal skirt below them appeared to rest entirely on the roof of the pediment over the east portico. No other support was visible. What this means is that any visitor looking at the east front of the Capitol would be struck by the illusion that part of the dome was hanging over the edge by 15 feet or so.

This fault and other more subtle architectural faults were well known to the Capitol Architect at the time of the dome's construction. Thomas Walter, the designer of the wings and dome, stated in his annual report of 1864:

> Now that the new dome and the wings are approaching completion, it must be apparent to everyone that the extension of the center building on the east, to the line of the new wings, is an architectural necessity.

Walter left plans for the completion of the work to be concluded "in harmony"—architecturally—with what had already been done. Remember, all this was taking place before 1865. And, it might be added, nothing was concluded at all for a hundred years, and then with considerably more noise—nonarchitectural—than harmony.

It was after the Civil War, in fact quite a bit after, that enough agreement could be scraped together to start trying to amend the flaws. The House of Representatives passed an approval to extend the east front and appropriated the initial money for the job in 1903. The bill died in the Senate. The Senate itself passed bills twice authorizing the extension—in 1935 and 1937. These bills could not get over the House hurdles. In the meantime, the dome just kept hanging over the east front wall of the Capitol.

In 1955 Sam Rayburn decided it was time something was done about the situation.

Rayburn was an eminently practical man. His first consideration of the matter stemmed from the fact that the growing Congress was desperately in need of space. This is not to say that he was not a man capable of appreciating the artistic values and traditions of our national buildings. It simply means that he was a practical man first. Mr. "Sam" was actually recognized as one of the ablest lay spokesmen in Washington on classical architecture.

Other practical men had felt the squeeze of space in the burgeoning National Government. Speaker Joe Cannon was fed up with the elbow-to-elbow situation in 1903, and he sparked the first attempt at Capitol expansion. The result was the construction of the original House and Senate Office Buildings. The squeeze play was on again in the 1930's when the matter came up twice more. The new congressional office buildings were born in that attempt.

But in 1955 the problem was different. Every possible committee had been moved to the office buildings. There were no more Congressmen's offices in the Capitol Building. It was simply a matter of too many people. The tourist load in the building was growing constantly, totaling more than 5 million eager souls per year by 1955. A Congressman with visitors from home might have to wait half an hour or more, standing in the hall trying to get a place in the Capitol lunch room. The Joint Committee on Atomic Energy had commandeered the Old Senate Chamber for its important work and needed to expand still farther.

Rayburn went to work. He incorporated in the Legislative Appropriation Act of 1955 authorization for the extension. The act authorized a portion of the money for the job, a commission to oversee the undertaking, and a complete study of what was needed to solve all existing and future problems on the matter. The commission was made up of Rayburn, Vice President Nixon, House Minority Leader Joseph Martin, and Senate Minority Leader William Knowland, along with the Capitol Architect, George Stewart. By getting himself elected chairman of the commission, Rayburn was assured that he could keep watch over the project and guide it away from the many dead ends in the Congress with which he was so familiar.

The act passed both the Senate and the House this time. All might have seemed in good order to the outsider. The bill had now passed the Senate three times and was safely through the House for the second time. The behind-the-scenes work was started. But Rayburn knew what lay ahead, and he was preparing for the storm that was bound to break.

By 1957, all plans and engineering studies were sufficiently complete to report to the Commission on the progress.

About this time a new Republican Congressman, FRED SCHWENGEL, from Iowa, decided to nip the project in the purse strings and submitted a bill to halt proceedings. However, SCHWENGEL, an ex-history teacher, looked further into the background of the east front extension and withdrew his bill. During a speech to the House he said that Rayburn was right, the project was called for, both by tradition and practicality. Some say the Speaker personally brought SCHWENGEL up to date on the subject, but the Republican Congressman says this was not the case.

SCHWENGEL's withdrawal was a major step in making House support of the extension a bipartisan matter.

In 1958 all was in readiness, and the Commission gave the go-ahead for work on the east front. Suddenly the cat was out of the Pandora's box.

Newspapers across the country carried the story that the Capitol Building was to be modified. The news was read with horror, if with considerable lack of comprehension, by civic groups, patriotic organizations, architectural associations and historic societies.

The fulmination was immediate and overwhelming.

That is, it would have overwhelmed any man, perhaps, except the imperturbable Sam Rayburn.

Telegrams and petitions, letters, and phone calls poured into the Congress. What was this desecration of our best known building? Had the Congress no respect for historic tradition? The DAR and the National Trust for Historic Preservation, the Oregon Historical Society, and the Museum of New Mexico, the Preservation of Historic Buildings Committee, and the American Institute of Architects, and dozens of other groups bombarded Washington with protests, vilifications, and denunciations concerning the proposed expansion.

Jovial Master Architect Roscoe DeWitt, of Dallas, one of the planners of the extension, commented:

> We got one telegram from somebody in Oregon telling us we were horrible to be thinking about changing the White House. That's how much they knew.

But nothing gets action in Washington like a flood of protests from the voters. Immediately a large group of Senators declared that they did not know anything about the authorization back in 1955, and that the whole thing had been "sneaked through" by that foxy old devil, Rayburn. The Capitol Architect's Office says this is rather difficult to swallow since the CONGRESSIONAL RECORD shows considerable attention was given to the provision by the Senate at the time the bill was passed. "They just wanted an out," said one of the Assistant Architects with a smile.

A bill was quickly introduced in the Senate that would have halted everything concerning the extension. The bill itself was pretty much of a case of locking the barn after the foxy old devil was out. Preparatory work was well underway. The contracts were drawn up, and the pens were practically poised above the dotted lines, waiting until the panicky Senate voted on its bill.

The Subcommittee on Public Works held a furious hearing that resulted in 80 pages of testimony, a good portion of which involved the printing of telegrams and letters against the construction.

Rayburn, meanwhile, was quietly lining up support among the leveler heads in the upper body. Senate majority leader—and longtime compatriot—LYNDON JOHNSON took up the fight. Bill Knowland and DICK RUSSELL gave their considerable support. Craggy CARL HAYDEN threw in, saying, "If Sam's for it, it's OK."

The press in Washington was split on the issue, but around the country papers generally were on the side of the clamoring, uninformed public. They took up the cry of the hesitant Senators, that Sam Rayburn is putting one over on us. Editorials called for the national conscience to put a halt to all this mess. Letters to the editors crammed aside Sputnik and moratoriums to accuse Rayburn of thinking he owned the Capitol and of being a tyrannical dictator. There are rumors of mysterious guffaws coming from Rayburn's office when he read the papers in those days.

However, if Rayburn didn't kowtow to public foibles, he at least appreciated the power of public opinion. So he set out to put the public straight. He mobilized the highly respected architects on the project into a veritable public relations juggernaut. This group consisted of the working architects, Roscoe DeWitt, of Dallas, Alfred Easton Poor, of New York, and Jesse M. Shelton, of Atlanta; along with the consultants, John F. Harbeson, of Philadelphia;

Henry R. Shepley, of Boston; Arthur Brown, Jr., of San Francisco; and Gilmore Clarke, of New York. This redoubtable group produced a fusillade of speeches, articles, letters and press releases to enlighten the architectural community to the absolute necessity and propriety of the extension.

The men in Congress who were lining up behind Rayburn for the showdown were armed by the architects with extensive information in defense of the action.

And Rayburn himself went to the hard core of the news world, the National Press Club, to state his case before the public. He did something he rarely did—spoke from a prepared manuscript rather than off the cuff.

He started his talk to the influential gathering in a jocular manner, then quickly got down to facts and fallacies. The fallacies he dismissed with a flush of statistics and historical references. The facts he presented flawlessly and in tall Texan good humor.

He politely slapped down the arguments of those who cried out to preserve our national monuments. The most important purpose of the east front extension, he said, is the preservation of the building itself. He proceeded to document the terrible shape of the soft sandstone of the old front. The weather-beaten old stone was cracking, flaking, and generally attaining an unrepairable condition.

Sections of the cornice have fallen off, varying in size from a baseball—

He said holding a fist in demonstration—

to chunks weighing as much as 60 pounds. It would be rather tragic to have even a stone as big as a baseball fall on the head of a President—getting inaugurated—as he comes to be sworn in—much less a slab weighing 60 pounds.

There was not really much left for the preservationists to say.

The Press Club listened with great interest. They knew a master rebuttal was in progress.

The old stones we can't save. The design we can save.

The indisputable logic rang reminiscent of many a Rayburn-won battle on the House floor.

He then launched into a complete and authoritative defense of the architectural correctness of the extension. He ran through the historical background, kicking over, one after the other, the misinformed arguments, the misplaced pleas for tradition, and the incorrect generalities about desecration.

He told of Capitol Architect Thomas U. Walter advising President Lincoln that the east front must be extended to correct the architectural fault. With a deadpan expression the veteran Speaker said:

Now this is going back into the history of the thing * * * even longer than I have been dealing with it.

The venerable old statesman paused for the laughter to die down and continued:

This is nothing new. Rayburn is not trying to spring something new on the folks. The overwhelming weight of expert professional opinion has been behind this project for generations.

He pointed out to the red-faced American Institute of Architects that a long list of revered American architects approved the east front extension. Such men as John Russell Pope, whose work included the Jefferson Memorial, the National Archives, and the National Gallery of Art; and Henry Bacon, designer of the Lincoln Memorial, were on record as being solidly behind the extension.

Without giving his opponents time to catch a breath, Rayburn let fly with a list of contemporary architects intimately involved with Capitol Building projects. They were all behind him.

Riding high on the wave of indisputability, Rayburn debunked the traditionalists by pointing out that the Capitol was really a remarkable conglomeration of endless changes, modifications, and extensions. Maybe, he suggested, we should never have put in electric lighting or air conditioning or even fixed sagging roofs or slanting floors. He did not laugh down the objectors. He did not have to. The National Press Club did it for him.

So the bill to stop the work was roundly defeated in the Senate, and the next day contracts were let and the gears started turning. Rayburn's inexhaustible energy and flawless strategy, that he could bring to bear on issues in which he believed, had overcome immense obstacles.

Sam Rayburn did not live to see the completion of the project, nor did he ever occupy the new Speaker's chambers in the extension. But he did live to see the completion of the exterior of the new east front in time for the inauguration of President Kennedy, and he was visibly pleased when the President-elect climbed the steps for his inaugural ceremony.

The beautiful and practical east front extension of the U.S. Capitol Building stands now as another tangible tribute to a man who had the courage—some say the only man who could have managed—to "get something done about the situation."

THE DILEMMA OF OUR TIME

The SPEAKER pro tempore (Mr. LIBONATI). Under previous order of the House, the gentleman from California [Mr. HOLIFIELD] is recognized for 30 minutes.

Mr. HOLIFIELD. Mr. Speaker, our Nation is dedicated to the establishment and preservation of a universal peace. We reject the practice of military aggression as a national technique.

Yet we find ourselves devoting our scientific talent and our great industrial capability to the building of the strongest military force in the world.

Our annual tax burden is in the neighborhood of $85 billion. In the face of great domestic needs for education, vocational training, hospitals and medical care, modern roads and housing, we turn from the fulfillment of those needs and divert approximately 60 percent of our tax revenues—almost $50 billion—annually to military expenditures.

We yearn for peace.

We need vital domestic improvements and services.

But, our major national efforts are directed to preserving our Nation through military strength.

This is the dilemma of our day and time.

On March 3, President Kennedy said:

Seventeen years ago man unleashed the power of the atom. He thereby took into his hands the power of self-extinction.

In my opinion, this is a true statement but it does not foreclose the possibility that man will not use this dread power to the point of self-extinction.

Certainly the most important objective which men of good will can pursue in the 20th century is that of preventing nuclear war. Any kind of nuclear war whether it be partial or total carries with it such grave consequences to the lives of millions now living and the genetic damage to billions yet unborn, that reason decrees that it shall not come to pass.

We look at the history of man and sadly we realize that reason has not always been enthroned as the director of human events.

In century after century, greed for markets, political and territorial ambitions, religious emotions and racial hatreds have hurled reason from her throne and dictated for the human race of each era its bitter fate of suffering and death.

Can we suddenly conclude that the evil forces, which have so often betrayed the rule of reason, have now suddenly changed into benevolent forces? Can we now determine that ideological fanaticism, national ambition, greed and covetousness for the land and goods of others has been magically eliminated?

We know that we cannot answer affirmatively to these questions. As we look at a world in turmoil and revolution; as we stand on the free world side of the Iron and Bamboo Curtains we know, if we are honest, that we must report we live in a world of turmoil, violence, and denial of human rights and moral and spiritual values.

We know naked, ruthless force has replaced reason and justice for more than half of the human race.

We also know, if we are honest, the naked force of totalitarianism grows upon the basic principle of expansionism. Like a malignant cancer it not only destroys the normal body cells in the area of original infection, but it spreads and spreads its roots and tentacles to every section of its perimeter.

Malignancy, whether it be somatic or political, is a dynamic force whose very existence depends on growth on an ever-widening circle of domination.

Some may say, "Yes, we admit that as a matter of objective analysis you have reported honestly the condition of the world." But, these deeply concerned people say, "Somehow we must find a way to combat this malignant and dangerous situation."

I agree with the necessity for such a quest. However, while we are looking for ways and means to combat or overcome these dangers, we cannot assume the quest itself, eliminates the danger. The danger persists and continues to

threaten our existence as individuals and nations.

Others will say, "The new power embodied in nuclear weapons is so great, its misuse would be so catastrophic to mankind that nuclear war is unthinkable."

It is true that any kind of a nuclear war would be terribly damaging to the human race. It would be catastrophic if it is massive in scope. The concerned person who says it would be unthinkable actually means it would be so unreasonable, so horrible that not only should all nuclear powers reject the use of nuclear weapons, but we should immediately conclude there will not be a nuclear war. If we follow this line of argument we, in effect, say reason is enthroned and is now directing and will continue to direct the destiny of the human race.

I wish I could follow this line of argument and reach this comforting conclusion. I almost said "delusion."

Suffice it to say that from my point of vantage, I cannot in honesty reach such a conclusion. I cannot allow my fear of nuclear war, my love for family and mankind, and my intense desire for peace to cause me to shut my eyes to the evil forces which, in their purpose and design of malignant growth, are pushing against the Iron Curtain, the Berlin wall, and the Bamboo Curtain.

I must, because of my access to classified as well as unclassified information, retain my capacity for objectivity in evaluating the various hazards facing our persons and our institutions. I must not let my emotions blind me to the malignant and evil forces of our time.

If we, as most of us do, exercise reasonable objectivity, and if we do conclude that we live in the most dangerous time in human history, then where do we as enlightened and objective analysts find ourselves?

How can we, who believe we are possessed of high ethical, moral and spiritual principles, accommodate our high principles with the necessity to live in this dangerous age and cope with these malignant forces which threaten—not only our lives—but every precious advance the generations of man have made from the pits of savagery to the present level of human dignity?

Some of us can solve our dilemma by escaping into pure pacifism, into a world of illusion where we demand immediate reformation of human behavior.

We can shut our eyes to the realities, the horrible, the "unthinkable" realities which surround us and which persist despite the powers of love, justice and reason.

Some of us can refuse to try to find a solution because the problems are unpleasant, even frightening and because they are most difficult they seem insoluble. We will therefore ignore them—turn our minds toward pleasant or inconsequential things, and presto. Some day the problems will disappear.

Frankly, I sometimes envy the quietude of mind, the flight from reality and possibly the happiness of people who practice these forms of escapism from our dangerous problems. As I said, I sometimes envy these people who have found havens which free them from the quest for solutions to the great and frightening challenges of our time.

I am sure I do not stand alone today as one who has not found a haven of escapism. Along with millions, I seek for answers to problems which seem insoluble.

I believe it mandatory that we gain time while the people behind the curtains develop to the point where they have a stake in a standard of living, a stake which is high enough to cause them to fear losing that stake in a game of world conquest by force.

I am hopeful that if we gain enough time, the advance in literacy which is occurring behind the curtains will cause a constructive quality of intellectual curiosity to arise in their minds. This intellectual curiosity could be the base for criticism and evaluation of comparative economic and political institutions.

If this should occur in the period of time which we hope to gain, then evolution may help to solve our problem of a genuine peaceful coexistence.

During this period of time which we hope to gain there is now, and will continue to be, exploding problems of evolution and revolution throughout the neutral and uncommitted world. These new nations will be deciding between the democratic way of life and the Communist way. The quality of leadership we offer them through technical, economic, and political techniques will help to determine their fate and ours.

How do we gain this period of time which we need so badly and which we must use so wisely?

I must conclude we cannot gain time by surrender to Communist threats to use force. If we surrender and retreat from any legitimate bastion of liberty we will start a chain of similar retreats throughout the world. We must, therefore, stand firm in support of the ideals of liberty and freedom wherever they are challenged. This standing firm means that there must be no comparative dimunition of our military strength and the will to use that strength if we are to put to the test.

This is a grim statement. It is fraught with danger. But it is a statement I must make because I do believe our military strength and the credibility of our willingness to use that strength is the dominant factor in halting the timetable of Communist world conquest.

Unfortunately, the Soviets are not responsive to the moral and spiritual principles of the Judeo-Christian concept. They worship force and utilize force as a justifiable procedure to gain their objective. They respect counterforce and will refrain from pursuing their objective. If they fear a collision with a counterforce which could defeat them in a test of strength or inflict too much damage.

The maintenance of our military strength, therefore, furnishes a deterrence at this time against war. It is true that the time we gain is gained because of a stalemate in military strength. It is a situation which Winston Churchill once called a "peace based on a balance of terror."

I know of no other means of gaining a period of time for evolution behind the curtains and elsewhere.

The alternative is, first, surrender on our part to Communist world-wide aggression through force; or, second, a Soviet decision to renounce their basic ideology of eventual world conquest.

I do not accept the thesis of surrender to communism.

I do not anticipate a formal renouncement by the Soviets of their ideological goal of world conquest.

Although I do not expect a formal renouncement, I have hopes of a gradual decrease in their fervent advocacy of achieving this goal through force.

This redirection of Soviet strategy is indicated in several areas and I list a few:

First. The postponement of violent Soviet action in Berlin notwithstanding their ultimatum.

Second. The growing gulf between Peiping and Moscow.

Third. The Khrushchev struggle within the Cominform to obtain acceptance of the principle of coexistence.

We know there is a substantial group of traditional believers in the Marx-Lenin doctrine of Socialist expansionism by force, and of course, this Cominform pressure could explain, at least in part, Mr. Khrushchev's truculence and periodic resorts to nuclear missile rattling.

In any event, we have had an uneasy time period of some 17 years since the ending of World War II in 1945. During that time period tremendous changes, mostly evolutionary in nature, have been occurring in the nondeveloped and underdeveloped and war-devastated free world.

Our firmness in defending the principles of democratic government in Korea, Laos, Vietnam, Jordan and Africa has been invaluable in assisting the process of political evolution.

Our firmness in supporting the United Nations organization has, in my opinion, kept this noble attempt to substitute international negotiation for international armed conflict from destruction.

But, the struggle to enthrone reason as an arbiter of human destiny has not ended. Seventeen years is a short time in which to reverse the centuries-old behavior patterns of nations steeped with ambitions, hatreds and jealousies.

We may need many decades of time to establish international order under the rule of law and reason.

No man can peer through the darkening clouds of tension and terror and see with certainty that humanity will not again follow its age-old pattern of using force and violence.

If it does, and if it chooses to use total nuclear war to decide its controversies then indeed we can write finis to civilization.

I choose to hope that we who carry the torch of liberty may so acquit ourselves that others may join their strength with ours. I dare to hope man's destiny is not in the abyss of suicidal action.

I hope through our dedication to the preservation of freedom and the establishment of individual human dignity, we may save mankind from following a

pattern of past behavior which is inadequate for today's challenges.

Let us then face our problems with realistic appraisal of the dangers we face.

Let us make the effort. Let us accept the sacrifices, whatever they may be, to buy the time we need and let us use every precious moment of that time to enthrone reason and law as the arbiter of human destiny.

REPORT TO THE PEOPLE OF THE 14TH DISTRICT OF ILLINOIS BY CONGRESSMAN ELMER J. HOFFMAN

Mr. NELSEN. Mr. Speaker, I ask unanimous consent that the gentleman from Illinois [Mr. HOFFMAN] may extend his remarks at this point in the RECORD and include extraneous matter.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Minnesota?

There was no objection.

Mr. HOFFMAN of Illinois. Mr. Speaker, as the 87th Congress draws to a close, I am submitting this report to my constituents of the 14th District of Illinois covering a résumé of major legislation and my activities as your Representative in Washington. In reading this, you will have a better understanding and an appreciation of the reasons why I have not been able to come back to the district as much as I would like to visit with you and personally take part in the fall campaign.

The 2d session of the 87th Congress convened at noon January 10, 1962. At the close of business of the House Friday, September 21, 1962, 15,468 bills and resolutions had been introduced and we have had 141 legislative days.

MEDICAL CARE FOR THE AGED

This has been a major issue in the Congress even before I was elected as your Representative. Since assuming office and particularly during this session, a great deal of discussion has been had on this subject. The House did not have an opportunity to consider this subject in the 87th Congress as no bill was reported by the Ways and Means Committee. The Senate considered and defeated the proposal sponsored by the administration embodied in the King-Anderson bills in spite of the fact that the membership of the Senate is composed of 64 Democrats and 36 Republicans. The proponents of this legislation attempted, and in many cases succeeded, in instilling in the minds of our elderly citizens that the King-Anderson bill is an overall coverage of medical care. This is not true. If enacted, it would provide certain health care benefits for those over 65 who are eligible for social security benefits. It is estimated that 4.5 million persons 65 and over would not be eligible because they are not covered under the social security system. It would cover a limited amount of hospitalization and some nursing home care, home health services and outpatient diagnostic services.

It would not cover cost of a doctor's services at home, office, or hospital.

It would not pay for medicines used outside a hospital or nursing home.

It would not cover costs of preventive medicine—beneficiaries could not collect anything until they were sick enough to go to a hospital or nursing home.

It would not cover all hospital costs—the patient would be required to pay $10 a day for the first 9 days of hospitalization, with a minimum of $20 for each complete diagnostic study.

The King-Anderson bill would establish a compulsory plan for everyone covered by social security—regardless of need, or financial status. It calls for a tax increase of one-fourth of 1 percent for employees and employers alike, three-eighths of 1 percent for the self-employed. Let me emphasize again that this would be a compulsory tax for everyone covered by social security.

The proponents of the provisions of the King-Anderson bills also attempted to have our elderly citizens believe we Republicans are calloused and have no realization of their needs. The gentleman from Ohio, Congressman FRANK BOW, Republican, of the 16th District, introduced a major bill which, had it been enacted, would have permitted all persons over 65 who pay Federal income tax to deduct from such tax $125 per year for the purpose of purchasing a noncancelable health insurance policy. Those who do not pay any tax would still be able to obtain from the Government a $125 certificate—$250 per couple to be used to pay the annual premium. Said policy to be issued by duly licensed companies. The Kerr-Mills Act passed in the 86th Congress provided Federal funds to the States to enable each State to furnish financial medical assistance to aged needy individuals. The Illinois Legislature passed enabling legislation and services thereunder began in September 1961. If the administration had exerted its efforts in behalf of the complete coverage of the Kerr-Mills Act, rather than attempting to force new legislation in the form of the King-Anderson bill, it would now be operating successfully in most of the States.

MANPOWER DEVELOPMENT AND TRAINING ACT

This is one of the major pieces of legislation sponsored by the administration to pass early this session. I voted against this measure because it would place the Federal Government into the business of guaranteeing jobs. Private industry does not guarantee jobs, and I question if the Federal Government can. It places in the hands of the Secretary of Labor vast executive power and entails large expenditures by the Federal Government. It will not cure unemployment. There will have to be a comprehensive survey first covering the impact of automation, imports, labor disputes, screening and an analysis to evaluate a man's skill to determine whether or not he possesses the skills to take such training. It is impractical to administer. Many States are already carrying out such a training program, and the Federal Government entering into such a program would seem unwise.

NATIONAL DEBT LIMIT

The Congress was called upon for the third time within a year to raise the national debt limit. A bill raising the debt limit from $300 billion to $308 billion was passed by a vote of 211 yeas to 192 nays. I opposed this measure. If the administration had held nonmilitary expenditures within the amount estimated in the summer of 1961 when we voted the last increase in debt limitation, this action would not have been necessary. As the debt goes up, so must interest payments. The projected rate of expenditures by the Federal Government has increased by more than $1 billion per month and is still increasing. In fiscal 1962 our debt reached the highest point in history, and we are told that a further increase in the debt limit will be required in the future.

DEPARTMENT OF URBAN AFFAIRS AND HOUSING

This came to the House in the form of a reorganization plan submitted by the administration to set up a new Cabinet post. It was rejected by an overwhelming vote of 264 yeas to 150 nays. I voted with the majority against this proposal. It would not accomplish what its proponents represented, and would have provided the mechanism with which the Federal Government could involve itself in every imaginable local activity. This would be contrary to sound principles of Government organization that the States and local entities manage their own affairs. The cost and size of this proposed new Department was staggering.

ADMINISTRATION'S TAX BILL

This measure passed the House in March by a record vote of 219 yeas to 196 nays. Prior to passage, a Republican motion to recommit the bill to eliminate the 7-percent investment tax carried for new business equipment, and to eliminate the provisions for withholding 20 percent of dividends and interest was defeated by a vote of 190 yeas to 225 nays. I voted for the motion to recommit and against final passage of the bill. I voted against the bill because it violates the conception of sound tax policy and fiscal responsibility. This approach to tax reform cannot provide this Nation with the tax structure that will insure continuing health and noninflationary economic growth. This measure then went to conference. It is expected that the conferees will file their compromise recommendations within the next few days.

PEACE CORPS

Legislation making the Peace Corps a permanent agency of the Federal Government passed the House September 14, 1961, by a record vote of 287 yeas to 97 nays. I voted against this legislation in the first place because it was presented by the President in an Executive order issued March 1, 1961, on a temporary pilot basis under existing authority of the Mutual Security Act. On the same day the President sent a message to the Congress recommending that it be established as a permanent agency of the

Federal Government. Many of us felt that an opportunity should be given, in all fairness to the Corps, to prove itself before making it a permanent agency. During the House debate, an amendment was offered to establish the Peace Corps for a period of 3 years. Under strong pressures from the administration, this amendment was rejected and its insistence that the Corps become a permanent agency prevailed.

Over and over again we hear the word "volunteers" as a selling point in recruiting personnel for the Corps. "Volunteers" to most of us means rendering services free, or at least for nominal remuneration. Second, the cost of its operation is phenomenal. For the fiscal year 1962, $30 million was appropriated for the operation of the Peace Corps.

An appropriation of $52 million has been approved to finance the activities of the Corps during fiscal year 1963, or an increase of $22 million above the 1962 appropriation. The appropriation for 1963 will provide Peace Corps strength of approximately 8,270 volunteers. Information supplied to the Appropriations Committee of the House indicated that if the Peace Corps were to stabilize its operations at approximately 10,000 volunteers, the cost would be approximately $90 million per year. It was called to the attention of the House, during the debate, that the Peace Corps is the fastest growing agency in the Federal Government and there never has been in the history of our Federal Government an agency that has grown as fast. Of the 1962 appropriation, approximately $10,300,000 was spent for the administration alone.

The Director and Deputy Director receive $20,000 and $19,500 per annum, respectively. Volunteer leaders—supervisors, or special duty services—who are employed at a ratio of 1 to 25 volunteers receive termination pay at the rate of $125 per month of satisfactory service, as well as living, travel, leave allowances, housing, transportation, subsistence, health care, orientation, language, and other training for their spouses and minor children. Such personnel are also entitled to the benefits of the Federal Employment Compensation Act, Federal Tort Claims Act, seniority rights for subsequent employment and benefits under the Civil Service Retirement Act.

In addition, not to exceed 275 persons may be permanently employed in the United States; 30 of this number may be compensated without regard to the provisions of the Classification Act of 1949, as amended, of whom not to exceed 20 may be compensated at rates higher than those provided for in grade GS–15—$13,000 per annum—and of these not to exceed 2 may be compensated at a rate not in excess of the highest rate for grades of such general schedule, but not in excess of $19,000 per year. These positions shall be in addition to those filled by Presidential appointment. The act making the Peace Corps a permanent agency also provides participation of foreign nationals, a 25-member Advisory Council, and employment of experts and consultants on a per diem basis.

UNITED NATIONS BOND BILL

This legislation was introduced as a result of the President's special message to the Congress concerning the financial deficit of the United Nations, and the General Assembly's proposal that the issuance of bonds in the amount of $200 million to bear interest at 2 percent per annum, with principal and interest to be paid in 25 annual installments. The President requested legislation to promote the foreign policy of the United States by authorizing the purchase of United Nations bonds and the appropriation therefor in the amount of $100 million. Accordingly, the bill was introduced January 30, 1962.

I recognize the need for an international forum in which representatives of sovereign nations may sit down together to discuss and negotiate international issues. Evidence produced during the hearings pointed to a single, virtually inescapable conclusion that the financial difficulties of the U.N. can be attributed almost solely to the expense of U.N. operations in the Congo. U.N. military operations in the Congo were initiated pursuant to a series of resolutions adopted by the U.N. Security Council, and a resolution of the General Assembly. Since July of 1960 these operations have cost over $240 million. As of June 30, 1962, they accounted for an estimated $82.7 million of the U.N. deficit of $137 million. Article I of the U.N. charter envisions collective action on the part of its members to maintain international peace and security. The U.N. force is not in the Congo to resolve an international crisis. It is there to resolve a conflict between political subdivisions within the Congo, a conflict which is domestic in nature. On June 30, 1962, of the 104 members of the U.N., 66 were in arrears on their Congo account and 56 were in arrears for the Middle East assessment. The result is that the United States has paid 47.70 percent—$114.5 million—of the Congo military costs and 46.95 percent—$57.6 million—of the U.N. emergency forces. It is interesting to note what two of my colleagues, one a Democrat and one a Republican, who are knowledgeable in the operation of the U.N. had to say:

We also noted a continuous expansion of activities by the United Nations through interpretations given to the broad language of its charter. In our opinion it would have been more beneficial for the organization to have proceeded at a slower pace in developing its many agencies and programs. There has been a persistent tendency for the United Nations to assume more tasks than its resources of men and money can properly support. The result has been a proliferation of the ranks of an international bureaucracy that finds endless problems to engage its attention and to assure its perpetuation. The present financial plight of the United Nations points up its most serious limitation. This in itself should impress upon our policymakers that further expansion of activities should not be supported by our Government. The organization has already undertaken too many programs that involve heavy financial commitments, the greater portion of which is expected to be, and probably will be, paid by the United States. More important, this trend if unchecked may result in the gradual erosion of large measures of our national sovereignty. To this we are unalterably opposed.

In this connection, we think that the United States has hurt its own position, and similarly has hurt, rather than helped, the United Nations by assuming a totally disproportionate share of the expenses. The vitality and effectiveness of the organization could be increased if it were forced to "cut the pattern to fit the cloth." It certainly would increase the degree of responsibility of other member nations if they were paying their proportionate share. It would lessen suspicion of and resentment toward the United States. A benefactor who overassumes and overpays his legitimate share invariably produces such a reaction.

Certainly we do not believe that a further unfair financial burden should be placed on our taxpayers. Nor can we fail to consider the effect on our mounting national debt.

Because of the above considerations, I am not convinced that the U.N. bond issue approach will solve the current deficit problems or that it will not be used again and again as the U.N. encounters difficulties in the future. This legislation was debated and passed the House on September 14, 1962, by a vote of 256 yeas to 134 nays. Prior to final passage, an amendment was offered to recommit the bill to the House Committee on Foreign Affairs with instructions to report it back forthwith, with the following amendment:

SEC. 5. No loan may be made to the United Nations under this Act until the General Assembly of the United Nations adopts the advisory opinion of the International Court of Justice on the financial obligations of members of the United Nations.

The motion was rejected by a vote of 171 yeas to 219 nays. I voted for the motion to recommit and against final passage of the bill.

FARM BILL

On June 21 this year by a narrow margin of 215 yeas to 205 nays the House recommitted the President's farm bill. I voted for the motion to recommit. Forty-eight members of the President's own party voted with we Republican Members to recommit the legislation. A new bill was introduced and it passed the House July 19 by a vote of 229 yeas to 163 nays. After it passed the Senate, amended, on August 22 it went to conference to iron out the differences of the bill as passed by the House and Senate. The conference report was adopted September 20 by a narrow margin of 202 yeas to 197 nays. I voted against passage of the bill and against the adoption of the conference report. I believe in flexible price supports and I am opposed to a continuation of subsidies of any sort. While we must continue to search for solutions to the farm problem and what to do about huge surpluses, the answer does not lie in legislation which will give the Secretary of Agriculture virtually unlimited power to put stringent controls on American farmers. The bill extends the temporary feed grain program for the 1963

crops. I do not favor this program because it gives the Secretary of Agriculture broad authority to influence prices in the open market. Its provisions relating to the dairy industry do not represent a sound solution for the serious dairy problem or for assisting this industry. Just as the problems of our urban areas cannot be resolved by transferring them to Washington, the farm problem will not be solved by legislating broad powers in the hands of the Secretary of Agriculture.

TRADE EXPANSION ACT

While we need a wide market for American manufactured goods and American products, protection of our own industries, farmers, and laborers against foreign competition is greater now than at any other time. The measure passed by the House in June goes far beyond the existing trade agreements program. The President is empowered to reduce tariffs by 50 percent over a 5-year period in return for mutual concessions from countries with whom we trade; moreover, the President is granted authority to repeal outright, duties on items exported between the Common Market and the United States of America. Finally, the President is authorized to negotiate on mutual tariff reductions on broad categories of goods rather than on the usual item-to-item basis.

Under section 241 of the bill, the President shall appoint, by and with the advice and consent of the Senate, a Special Representative for Trade Negotiations with the rank of Ambassador, who shall be the chief representative of the United States in negotiations and ex-officio member of the Interagency Trade Organization to be set up by the President. The adjustment and assistance provisions of the bill set up a super unemployment compensation system in addition to individual programs of our 50 States. The bill permits workers or management to seek a finding that they are injured by imports. Should the Secretary of Labor determine workers are entitled to receive assistance they then become eligible for a special program of unemployment compensation and training. Unemployment compensation and training, no matter how liberal, is a poor substitute for a job. Should the Secretary of Commerce determine that firms are entitled to receive assistance, the bill provides a long and complicated procedure for technical, financial, and tax assistance.

In view of the above and other ramifications of this all-important phase of our American economy, it would seem that a wise course would have been to extend the present law for 1 year. The bill passed the House June 28, 1962, by a vote of 299 yeas to 125 nays. Prior to passage, a motion was made to recommit the bill with instructions to report back a 1-year extension of the present law. The motion to recommit was defeated by a vote of 171 yeas to 253 nays. I voted for the motion to recommit and against final passage of the bill. The measure went to conference to iron out the differences of the provisions as passed by the House and Senate. It is expected that the conferees will file their compromise recommendations within the next few days.

TO ESTABLISH A U.S. ARMS CONTROL AND DISARMAMENT AGENCY

I voted against the establishment of this agency for several reasons. Since World War II there have been some 70 international conferences and meetings concerning disarmament attended by both the United States and the Soviet Union. On June 29, 1961, the President requested legislative authority to establish a strengthened and enlarged Disarmament Agency. In the House there were some 70 identical, or similar bills, for the establishment of this Agency. In the first place there was considerable confusion as to the intent and purposes of this Agency. The bill, as originally introduced in the House, carried the title, "To Establish a United States Disarmament Agency for World Peace and Security." In the course of the hearings objection was raised by the American Legion and other veteran organizations to the word "disarmament." The bill reported by the committee carried the title, "To Establish a U.S. Arms Control Agency," yet contained provisions for disarmament. During the debate on the floor, the question was raised as to why the word "disarmament" was dropped from the title of the bill. An amendment was then offered to change the title to read "U.S. Peace Agency for World Disarmament and Security."

This amendment was rejected and the title of the bill as passed by the House was "To Establish a U.S. Arms Control Agency." After passage by the House and Senate, the conferees agreed upon the title "To Establish a U.S. Arms Control and Disarmament Agency," which became law.

In addition to the above, we are spending $47 billion to build up our arms. Also it would indicate to our allies, or supposed to be allies, a sign of our weakness; and furthermore, I cannot see any reason why we should be spending millions to set up an agency that would grow and grow and not have any foreseeable success.

The act provides the Director's annual salary will be $22,500; the Deputy Director shall receive an annual salary of $21,500; four Assistant Directors at an annual salary of $20,000. The President may appoint by and with the advice and consent of the Senate, a General Advisory Committee consisting of not more than 15 members.

FOREIGN AID

The appropriation bill this year for foreign aid and related agencies was the highest in amount of any money bill reported for this program in the past 8 years. Since the end of World War II, we have carried this foreign aid program into 101 of the 113 nations of the world, including those who will receive aid this year. This aid program is not limited to so-called free nations but we are pouring funds into dictatorships, so-called neutral nations, Communist-influenced and Communist-dominated nations, and into outright Communist countries. This giveaway program is a major factor contributing to the continuing annual increase in our public debt; it is primarily responsible for our annual budget deficits; it is responsible to a large extent for the depletion of our gold reserves; it is depleting our wealth and resources and frankly many of the nations which are recipients of our aid are rapidly losing faith in our ability to manage our economic and monetary system. Furthermore, I do not believe that this pending program is the solution to the problems in our struggle against communism.

Last year, 1961, it took 12,856 persons employed by the Federal Government to operate the foreign aid program; 6,478 of them were Americans, of whom 4,466 were in oversea positions. In addition, the services of 4,600 foreign nationals overseas and 1,778 persons employed by the U.S. contractors were used. All of these were paid out of American foreign aid funds from your tax dollars.

In several instances the Soviet Union has actually made use of American funds to further the Soviet foreign aid program. This information is contained in a report issued by the House Committee on Government Operations on June 25, 1962.

The President's request was for $7.2 billion for foreign aid and related agencies; $4.7 billion of this amount was for foreign aid, from which the House cut $1.33 billion. Cries about cuts in the foreign aid program are not new. We have wrecked this program about 10 or 15 times but it is still going stronger today than ever before. I voted against this appropriation when it passed the House September 20, 1962. This legislation is pending in the Senate.

TO SET THE RECORD STRAIGHT ON THE SO-CALLED HOFFA SPEECH

Mr. NELSEN. Mr. Speaker, I ask unanimous consent that the gentleman from Iowa [Mr. SCHWENGEL] may extend his remarks at this point in the RECORD and include extraneous matter.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Minnesota?

There was no objection.

Mr. SCHWENGEL. Mr. Speaker, politicians are often the target of arrows and javelins of cruel and unfair criticisms. It is my opinion that false accusations are terrible things to happen to anybody but there is some comfort in knowing that when the truth finally prevails the public responds magnificently.

There is no better evidence of this than in the tribute we now pay to Lincoln. It was during Lincoln's Presidential administration, which of course was also the period of his greatest service to his country when he received more of these arrows and javelins of cruel and unfair criticism than any person at that time and since.

Robert Taft received more than his share when some labor bills were passed and when he criticized the Government's method of handling the criminal question in the German trials.

That justice finally prevails is evidenced in the fact that both of these men now have impressive monuments

built to their memories. It was mainly because they were men of principle.

Recently, I, with other Members of the Congress, have been the subject of a news article that implied we were in some way coordinating our efforts to interfere with the orderly procedures of the courts in this land, that we were in league with the forces of evil somehow and that we were trying to impede the cause of justice. This news story, Mr. Speaker, was written by one of America's finest, most honored, and I believe, thorough reporters. However, the implications left have not had what I would call a desired result nor has the result of it been entirely fair to the participants.

Since only the accused or guilty can testify or confess to the facts, and because I have great confidence in the character of the men who spoke on this subject, I am taking this opportunity to set the record straight.

The article I am referring to appeared in the Des Moines Register, September 21, 1962. It is headed, "Bobby Unfair to Hoffa, Say 11 in House." Then the article reads as follows in the first three paragraphs:

Eleven Congressmen have launched a sharp attack on Robert F. Kennedy, saying they fear unfair tactics are being used in prosecution of Teamster President James R. Hoffa.

A torrent of speeches on the House floor Wednesday coincided with a similar attack Hoffa's attorneys were making in Federal court in Nashville, Tenn.

The critics of the Attorney General included three Democrats and eight Republicans. The Democrats were Representatives JAMES ROOSEVELT, of California; DON MAGNUSON, of Washington; and JOHN BLATNIK, of Minnesota.

This is followed by the subtitle, in bold type, which reads, "Include SCHWENGEL," followed by the list of the Republican Members.

I should like to point out, Mr. Speaker, that this implies that I made a speech on this subject. I did not and the RECORD clearly says so on page 19961.

Now, Mr. Speaker, in the first place I should point out the difference in extending remarks and making a speech. I did not speak from the floor of the House at that time; I submitted my remarks to tbe printed in the RECORD. Mr. Speaker, I was there and I listened to all who did make speeches. They included Mr. BRAY, who had asked for and received unanimous consent to speak 30 minutes on the subject. During the time he held the floor, and on his time, Mr. MCGREGOR, Mr. CURTIS, and Mr. ROOSEVELT spoke, and I believe Mr. PELLY, Mr. MAGNUSON, and Mr. MOORE, of West Virginia spoke.

All of these people, as I interpreted their speeches, indicated to me that they had no sympathy whatsoever for Hoffa—indeed they may not have known all of the facts of the Hoffa conflict with the Attorney General's Office. They, as I understood it, were questioning the method and procedure and some were even lamenting, as I have in the past, the fact that this situation has not been properly dealt with.

It is significant to note, too, that of all the people who were there that day—and there were many Members on the floor—none rose to defend the Attorney General. So, I think it is clear then that everybody there understood that no one was defending Hoffa or anything sinister in government, or had the least desire to impede the wheels of justice. Rather, they were deeply concerned, as I am, when established principles of law and accepted procedures of law are not recognized—indeed may even be violated.

Now, Mr. Speaker, I have a great interest in this discussion because in April, when the steel crisis was on, I, as every citizen of the United States, was well aware of some very grave mistakes that were made by both the President and the Attorney General. I voiced concern privately and publicly many times since that time about the fact that the heavy hand of Government threatened to reach in and assume the position and attitude of a police state. Because one of the most brilliant speeches made on that subject was made by a Congressman from Iowa, and because it said so clearly and effectively what I had in mind on the subject, and because I though it would serve the public interest, on May 31, I took occasion to insert in the CONGRESSIONAL RECORD a copy of this speech. At that time I made the following introduction:

Mr. Speaker, my esteemed colleague, the Honorable JAMES E. BROMWELL, of Iowa's Second Congressional District, delivered an address on May 14 at the annual teachers' appreciation dinner, sponsored by the Johnson School Parent-Teacher Association, in Cedar Rapids, Iowa, which sounds an alarm as important today as those sounded by Thomas Paine and Samuel Adams at the time of the American Revolution. At that time, the danger was from another system of government directed from outside our shores. The danger to which Congressman BROMWELL refers, "the deadly growth of power in the executive arm of the Federal Government," is a threat within our own system, within our own shores. I commend this address to my colleagues. I urge them to read it, to talk about it, and to circulate it among their constituents so that all of us can have their help in seeing that we do not pass the point of no return in this situation.

Then, I asked for permission to have this brilliant speech put in the RECORD. In this speech he says:

Some historian may someday name the month of the year in which things got out of hand; someone bolder may do better and tell us the early symptoms of a breakdown in popular control of our national affairs. So far he or she has not been generally recognized and proven sound, and until these things happen we shall feed on fear.

It has happened more than once since Sumter and it can happen again. A chain of events begins, effect follows cause with acceleration, the point of no return is passed, the tide becomes irreversible, then unchangeable, and we come to a time of troubles in which even the best of us can only make the best of it.

Where are we going? The answer lies in the future and is speculative. As your Congressman I shall give you my opinion. Unless citizens act by public opinion and the franchise we shall continue to surrender rights to the Government, uncheck and unbalance its powers, and grant power to the Presidency until we shall have reverted to despotism. Mr. Lincoln's word is good enough for me. The tyrant will not come to America from across the seas. If he comes, he will ride down Pennsylvania Avenue from his inauguration and take his residence in the White House. We have, in the last 15 months in the Congress, inadvertently and carelessly, we must assume, moved at a hellish rate to establish preconditions of dictatorship. There will be no coup d'etat. Rather, at the worst, there will be an extension and vigorous exercise of the powers we have granted.

Because of this, Mr. Speaker, and because I voiced the belief of many people in Government that the Attorney General's Office is the most important office so far as the enforcement of the law is concerned that can be found anywhere in the world, and it calls for appointment of the best attorney that is available in the whole United States, and because I firmly believe that our present Attorney General is not the best attorney, I have some concern about the way that Office has been and will be run.

Therefore, I decided, during the period these other speeches were being made, that I should write out a statement to be extended in the RECORD to indicate my concerns, to make some pertinent observations, and in this way serve notice that this problem was being noted in the halls of Congress.

Now, Mr. Speaker, I reiterate I did not make a speech, so I could not have said what this fine reporter quoted me as saying. Second, I say to you that I do not know enough about the Nashville, Tenn., situation to talk intelligently about it. I do know, judging from visits with other Members of the Congress, that there is some truth to the statement attributed to O'KONSKI, which I was reported to have spoken on, but I did not. The article quotes the earlier statement attributed to me and O'KONSKI, but it made no mention of my introduction, which reads as follows:

I compliment the gentleman from Indiana, who is leading the discussion that involves basic principle of law.

Mr. Speaker, the passing of impartial laws to apply equally and fairly to every citizen of the United States is the sole ultimate purpose of the Congress of the United States.

Whenever we legislate on matters that deal with the courts or in any way to knowingly pass laws that can or will influence the outcome of a trial, we are ourselves violating the basic principle and of accepted principle of law that has become almost sacred.

If this had also been published it would have been obvious that the statement about the Nashville, Tenn., situation does not naturally follow these opening remarks.

The reporter reported it as it was printed in the CONGRESSIONAL RECORD. Evidently something happened in the printers' office or the reporters' office because I followed this opening statement with a reference to the fact that the Attorney General who was on trial before the Congress today is also the same Attorney General who has recommended certain legislation to legalize wire tapping and according to his testimony goes far beyond anything ever contemplated and clearly is an invasion of private and personal rights guaranteed in the Constitution. In my remarks I referred to a statement I had made in May and to

the brilliant speech made by Congressman JAMES BROMWELL on the steel crisis and its implications. This did not appear in the RECORD.

Then, as I recall, I commented on the fact that this was the same Attorney General who mistreats his dog by bringing him down to the office and assuming that a dog enjoys being led around by pretty girls in violation of the law and in an atmosphere where there is much danger for a dog to be loose and to run free when we all know a dog would rather be out in the country atmosphere where he could enjoy the company of little children and if it could not be one's own little children there are always neighbor children who would be glad to have the opportunity to play with such a fine and lovable animal as this dog must be. Then I observed maybe this was the New Frontier's new way to kick or drag a dog around. These remarks did not appear in the RECORD either. I have asked and been granted the privilege to have the RECORD amended and corrected.

Let me say, in addition to all of this, that my record on attacking corruption, dishonesty, collusion in Government I think is pretty clear. I, as most Members of the Congress know, was the first to recommend a watchdog committee for the Interstate Highway System which has and is saving millions.

I was the first to introduce a resolution on the Estes scandal and it was not until that resolution was introduced and I started making some speeches on the importance of this matter and did some investigating of some facts that the hearings began in the House and Senate.

Further, I reiterate that I hope the Hoffa proposition and all other scandals in Government and in which the Attorney General and others have a responsibility will be prosecuted to the limit under the established laws and procedures of government without any undue interference by anybody anywhere.

CONGRESSMAN SCHADEBERG'S RECORD ON ECONOMY

Mr. NELSEN. Mr. Speaker, I ask unanimous consent that the gentleman from New York [Mr. KING] may extend his remarks at this point in the RECORD and include extraneous matter.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Minnesota?

There was no objection.

Mr. KING of New York. Mr. Speaker, I have watched with great interest the voting record of my colleague, the gentleman from Wisconsin's First District, the Honorable HENRY C. SCHADEBERG. He has consistently made his decisions in favor of economy with a respect for the taxpayer. He has repeatedly reminded us that the Government has nothing to give anyone which it does not first take from the people.

It was with more than passing interest that I noted that each free publication the residents of the First District of Wisconsin will be receiving in the future will bear a reminder that they, the taxpayers, are paying for the services they receive from their congressional office. Instead of the usual message "With the compliments of the Honorable John Dough, Member of Congress" used by most of his colleagues, Mr. SCHADEBERG is stamping all material sent to his constituents "From the office of Congressman HENRY C. SCHADEBERG, with the compliments of the American taxpayers." I want to commend my colleague for his realistic approach in trying to inform his people on the subject of "who pays."

HALF-TRUTHS AND DISTORTIONS BY SECRETARY OF AGRICULTURE

Mr. NELSEN. Mr. Speaker, I ask unanimous consent that the gentleman from Kansas [Mr. DOLE] may extend his remarks at this point in the RECORD and include extraneous matter.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Minnesota?

There was no objection.

Mr. DOLE. Mr. Speaker, perhaps at this time of the year those of us in public office who are candidates for reelection should be accustomed to half-truths and distortions. This has not been my policy, and therefore those Members who may have opposed any of Secretary of Agriculture Orville Freeman's policies in the past should be aware of his possible direct activity in your campaign. Perhaps it is not surprising to learn this member of the President's Cabinet is guilty of distortion and outright untruths in replying to an inquiry from any Member of Congress. I feel it is my duty as a Member who has felt the wrath of this political Secretary to point out what I consider to be proof that Freeman has become a political hatchetman for the Kennedy administration.

On September 20 I directed a letter to Mr. Freeman, protesting the shipment of Kansas grain from Kansas farms and elevators to the west coast. In that letter I stated:

> It seems to me that wheat should remain in the general area where it was produced, if storage space is available, and should be moved only to meet domestic and export needs.

Certainly we should move grain for export or domestic purposes, but not just for the purpose of relocating and storing it in other areas. Last year Kansas farmers and grainmen were threatened with the possible relocation of many millions of bushels of Kansas wheat under the guise of civil defense which would have cost the American taxpayers some $47.2 million. Also yet unexplained is the shipment of over 5 million bushels of wheat from Kansas elevators to the Billie Sol Estes empire in Plainview, Tex. At any rate, I felt justified in asking the Secretary how much wheat he planned on moving from Kansas for purposes other than for export or domestic needs, and this was the purpose of my September 20 letter.

In his reply delivered by special messenger on the 24th day of September, Mr. Freeman completely evaded the question, but in an obvious effort to assist my opponent who is campaigning in Kansas, distorted the truth, misrepresented my inquiry, and falsely accused me of opposing export development programs and of favoring the storage of wheat rather than shipping it to Japan and other countries. He stated, "In joining with the grain trade to protest the efforts of wheatgrowers to increase wheat exports, you have taken a most short-sighted position."

I take this time to point this out and would caution you against writing anything to Mr. Freeman as this would give him an opportunity to deliberately misinterpret and misconstrue it. Remember, we are dealing with a man who only last year sought quotas on every known agricultural commodity, including livestock, with a man who this year sought legislative authority to confine dairy farmers in the Federal penitentiary for not keeping proper books and records and who sought authority to fine wheat producers up to $5,000 for not keeping proper books and records or following departmental regulations, but above all we should remember that Secretary Freeman seeks to control American agriculture, and it was under his administration that the Billie Sol Estes scandal mushroomed.

Remember, too, just a few days ago Freeman, at the insistence of a fellow Democrat House colleague, apologized to ODIN LANGEN, a Republican member of the House committee investigating the Estes case. Freeman accused LANGEN of "the grossest kind of irresponsibility," and the fact that Freeman apologized only after urging by the subcommittee chairman reflects who is guilty of gross irresponsibility.

Mr. Freeman is certainly welcome to come to Kansas, and I invite his participation in my campaign, but believe it should be restricted to outright campaign activity rather than issuance of false statements under the cover and protection of his office.

COMMITTEE ON MERCHANT MARINE AND FISHERIES

Mr. WAGGONNER. Mr. Speaker, I ask unanimous consent that the Committee on Merchant Marine and Fisheries may have until midnight tonight to file certain reports.

The SPEAKER. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

PUBLIC REACTION TO FOUNDATION STUDY

Mr. WAGGONNER. Mr. Speaker, I ask unanimous consent that the gentleman from Texas [Mr. PATMAN] may extend his remarks at this point in the RECORD and include extraneous matter.

The SPEAKER. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

Mr. PATMAN. Mr. Speaker, on July 23, 1962, and August 20, 1962, I presented to the House my first and second interim

reports on the study of 524 tax-exempt foundations, which has been conducted by the House Small Business Committee. They appear in the CONGRESSIONAL RECORD of those dates.

Our study has been confined to privately controlled, tax-exempt foundations that are required to file tax return form 990–A or 1041–A. This excludes, first, religious organizations; second, educational organizations if they normally maintain a regular faculty and curriculum and normally have a regularly organized body of pupils or students in attendance at the place where their educational activities are regularly carried on; third, charitable organizations, or organizations for the prevention of cruelty to children or animals, if supported in whole or in part by funds contributed by the United States or any State or political subdivision thereof, or primarily supported by contributions of the general public; and, fourth, or organizations operated, supervised, or controlled by or in connection with a religious organization described in section 501(c)(3) of the Internal Revenue Code.

Since July 23, I have received thousands of letters in support of our investigation. They express deep concern over the ever-growing number and influence of tax-exempt foundations.

The reactions to our study will no doubt be of interest to the Members. I, therefore, wish to insert in the RECORD at this point excerpts from a few of the letters received to date. These are in addition to those which I placed in the RECORD of August 23, 1962, and September 6, 1962.

M.A.S., Jr., Fresno, Calif.: "Please send me a copy of the tax exempt foundations study. I appreciate your dedication to the United States of America and to good government."

E.C., Miami Beach, Fla.: "You are to be congratulated on your efforts to oppose the tax-free foundations."

J.M.H., Eureka, Mo.: "I would appreciate receiving a copy of your report on tax exemptions to foundations. Wishing you success in your much-needed service."

A.B.L., Manhattan Beach, Calif.: "I was especially impressed by the charge you made, to the effect that there is great danger in the increasing concentration of economic power in various foundations."

T.D.C., Chula Vista, Calif.: "I wish to thank you for the courage which you displayed in speaking out against the 'legalized tax dodging' of tax exempt foundations. As you know, many of these foundations are engaged in political activities—especially the Ford, Carnegie, and Rockefeller Foundations. Such organizations should not be tax exempt."

C.M.M., Corpus Christi, Tex.: "I am for you 100 percent in your battle with the foundations. Keep after them."

C.E.R., Chevy Chase, Md.: "You are to be commended for your investigation of tax-exempt foundations, and I wish you much success in getting the facts about them. Such foundations, like commercial banks, are growing and attempting to enter all fields of activity in our commercial and social life. Some, for example, run restaurants in their tax-free buildings, in competition with taxpaying restaurants in their neighborhood; some print or distribute books, in competition with taxpaying bookstores, etc. I hope you are able to get them back on the tax rolls, to some extent at least."

O.B., Wallingford, Pa.: "First, I must congratulate you for launching your investigation of the tax-free foundations. * * * To me it is outrageous that these groups which are set up to avoid paying taxes can use that money to indoctrinate a whole generation and bring about, through them, a complete change in our form of government. To me this is legalized theft (if there is such a thing)."

L.C., Chicago, Ill.: "Your comments on the necessity of an 'agonizing reappraisal' by Congress on the control of foundations deserves the wholehearted support of all concerned Americans."

C.H.K., Houston, Tex.: "I am very pleased to know that someone has taken a peek into so-called philanthropic foundations. Clean out the foundations."

B.B., Berlin, N.H.: "Good for you. For being against tax-free foundations. There is too much of this going on in this country. So few of us are paying all the taxes and don't think I am of the so-called well to do, but my husband makes a little over $6,000 a year and the taxes he pays makes us both ill when we realize where the money is going."

B.E.W., Amarillo, Tex.: "We read about your attack on the misuse of tax-free foundations. We are most fortunate to have capable men like you to defend the people of the United States before the Congress."

J.W., Wichita Falls, Tex.: "Your stand on tax-exempt foundations is well taken. I believe with you that the profits of some of these foundations are being used for political activity against the best interests of freedom in the United States."

C.A.S., Laguna Beach, Calif.: "Congratulations on your recent report regarding the tax-exempt foundations. Please advise us if there is anything we can do to help."

L.F.M., Seattle, Wash.: "What you said concerning tax-exempt foundations 'hit the nail on the head.' Thanks so much for the rare courage to say what needed to be said for a long time. We stand firmly behind you. * * * God be with you as most of the American people will be when they learn the truth about these foundations."

M.K.M., Orange, Calif.: "I'm herewith thanking you for your rare courage in attacking our tax-exempt foundations. Please continue until you awaken the lax Internal Revenue Service."

J.E.R., Seattle, Wash.: "I would like to know if there is any chance that a law could be passed whereby these so-called foundations must be taxed? Why must the multimillionaires be allowed to put their money into tax-free foundations, the poor people pay no taxes and live on welfare, and we in the middle are caught in the squeeze and carrying the financial burden for the whole Nation? Is this ruining our middle class—what is happening to America?

P.H., Jamaica, N.Y.: "The article (in the New York Herald Tribune) tells of a report issued by you dealing with the assets of many of our largest tax-free charitable trusts. I would like to commend you for your work in this field because I believe that a study of this kind has been needed for many years. I, myself, have frequently questioned the altruism of some of our charitable foundations. If any tax loopholes or other unfair preferential treatment exist in this area, I hope your report will help to improve the situation.

D.J.D., Stamford, Conn.: "It is indeed a pleasure to congratulate you and wish you happy hunting as you gun for big game—the tax-exempt subversive foundations. They are public enemy No. 1. * * * You should be backed vehemently in your major offensive against subversion and tax dodging."

E.H., Phoenix, Ariz.: "My main complaint with the operations of some of our larger foundations is that they come under the control of men who use these huge resources and the power that goes with it to put into practice ideas of their own or even ideas that are alien to the American way. You are on the trail of real pay dirt, Congressman, keep on the trial. This quest, if carried to its conclusion, combined with income tax revision, could do this Nation a world of good."

F.W.N., Pompano Beach, Fla: "I want to thank you for your courageous speech of July 23 to Congress"

E.S., Bradford, Pa.: "I do wish to thank you and wish you well in this probe."

S.S., Brooklyn, N.Y.: "I am sure the findings of your committee will illuminate an important though heretofore neglected area of tax exempt foundation operations."

H.L., Wethersfield, Conn.: "I have just read in our newspaper today of your position concerning tax-exempt foundations and you certainly have my prayers and support for a project badly needed and long overdue by our Congress. It is becoming increasingly obvious, Congressman PATMAN, that the chief objective of some foundations is tax avoidance rather than pure philanthropy. Thank you and may God grant you courage to see this through."

B.J., Butler, N.J.: "Thank God someone is directing a few minutes to this foundation racket. Too many of us are fed up to the teeth with what the Government does and does not do to bring some fairness in our tax situation. Personally, I have known for years on end that many so-called foundations are merely blinds for big business."

A.E.A., New York City: "I have been watching your commendable exposé of the tax-free foundation with much satisfaction. It is time these people were made to bear their fair share of the national tax burden."

W.A.F., Highland Park, N.J.: "Would you be kind enough to send me a copy of the report of the investigation of 'tax-exempt foundations' by your fine and able committee. Over the years I have followed with great interest and admiration your congressional career since the magnificent bonus victory of some decades ago. Thanking you and wishing you the best."

D.E.L., Oxford, Pa.: "This letter is in encouragement of your stand on tax-free foundations. While in theory the foundations are to be commended, in practice they have produced a Frankenstein, which if unchecked or not ameliorated can threaten to become a source of (financial) power to rival and maybe threaten the Government. Perhaps some sort of antitrust regulation could be designed to circumscribe their growth to reasonable proportions."

G.W., Chambersburg, Pa.: "I think that your investigation into the improper use of foundations is a most essential step to stop the obvious abuses to which this enabling legislation has been subjected. We have a privately owned girls' school here which has been run for profit for many years. This operation has been made into a foundation, with no change in the operation or management. It now claims tax exemption on all levels, including the local real estate levy. I hope that you will be able to show that the creation of foundations has offered a substantial tax loophole and is materially narrowing the tax base, and can influence the Congress to take the necessary steps to correct these abuses."

C.J.R., Houston, Tex.: "We are 100-percent behind you. Thank you and God bless you."

H.W.S., La Mesa, Calif.: "You and your committee are to be commended, I am sure, by the voters and taxpayers, for initiating a study of this very important subject."

M.B.D., Washington, D.C.: "Please allow me to congratulate you on the magnificent job you have done in the study on foundations. It is an excellent report and provides volumes of information on this facet of our economy."

V.W.L., Shreveport, La.: "Since we are down here not so far from 'home' we will write you to let you know that we admire your stand on the foundations issue. They certainly need investigating, and something done about them."

J.R.H., Kansas City, Mo.: "I can appreciate the interest your committee has shown in the tax exemption status of many foundations existent in our society today. If our tax structure were not so antiquated and unworkable, would we have these tax-dodging devices? The greatest thing this country could do to strengthen its own position immeasurably, and indirectly the position of the rest of the free world which depends so strongly upon us, is to revamp this tax structure. If we can afford to reequip corporate producers overseas, why can't we do it here? If we can give millions and billions away over there, why can't we give our own people a break that will pay off over there quickly? I realize we do not live in a vacuum, but this business of trying to reshape the entire world in the American dream with American money don't work. We can spend a lot of this money on better educational facilities for our children and gifted students who will assure us of supremacy in these technological races linked definitely to our security. We can spend much of this money on medical research. We can build a network of superhighways which will certainly give our economy a much-needed boost. We can also spend a great deal of it on promoting better understanding between labor and management, which I believe is a crying necessity."

M.F.F., Bronx, N.Y.: "I have often wondered about these organizations and their operations and you are to be congratulated on undertaking your inquiry of them. May good luck and lots of cooperation attend your undertaking in this matter."

A.M.S., New York City: "I have noticed with great interest the excellent work which you and your committee is doing in respect of making public possible abuses of some foundations. It would be very much appreciated if you would be good enough to send me a copy of any report or reports."

A.J.K., Elkhorn, Wis.: "I would like to commend your courage in opposing the tax evasions of powerful foundations."

B.W.K., Philadelphia, Pa.: "I have been deeply impressed by the information conveyed in press reports, based on the second part of your report to the House of Representatives, on your investigation into the activities of tax-exempt foundations. You have surely brought clearly to the minds of intelligent people, a number of abuses of which such foundations may be guilty if there is not closer supervision by duly appointed Government representatives. I know that the work of investigation is frequently not pleasant, but the dangers which you have brought to the public mind are surely worth any such discomfort."

F.S., Jr., Canyon, Tex.: "I see in the local paper that you are attempting to get the enormously wealthy tax-free foundations brought under taxes. As an overburdened taxpayer this makes a lot of sense. With all of the billions at their disposal why shouldn't they carry their share of the Federal expenditures the same as you and I, and the masses of small people?"

F.E.S., New York City: "You are absolutely correct in your statement regarding the tax-exempt million-dollar foundations. I have never seen it estimated what the total worth of all these exemptions amount to—but I do know that they are, in some instances, in the real estate business in competition with taxpaying realtors; that they earn large fees with mortgage loans and are free to do most any kind of lending business. I will look forward to hearing more from your research along these lines."

W.B.G., Santa Paula, Calif.: "We support your courageous investigation of the powerful tax-exempt foundations. It is most unfair to the small taxpayer, like ours, that these wealthy organizations should not pay their share because that makes the burden all the heavier on us. We urge legislation to prohibit any foundations from tax-exempt status."

J.S., Oaks, Pa.: "I am one person of millions in this country who operate as a one-man business, and am fortunate enough to be able to pay my way, by the grace of God, as long as my health continues and work comes my way.

"I must give you an estimate of my income, because I have a business, and am obliged to pay in advance 25 percent of the estimate quarterly. In 1961 my earnings were $5,000. my tax $800. My self-employment tax $216. After food, shelter, clothing, nothing left.

"Why don't foundations * * * come under the same kind of scrutiny annually and eliminate the need for millions of dollars for investigations?

"I wish I had some money on my credit sheet that I might plough back into my business. At this writing my business is down several thousand dollars below what I made last year. Will there be any tax relief? Exemptions such as cover foundations * * * are detrimental to our morale."

C.I.M., Sarasota, Fla.: "You are to be commended for your efforts in behalf of the American people. There are entirely too many organizations in this country operating tax free."

J.U., Spokane, Wash: "Could we have a moratorium until revised laws can be made?"

A.L., Forest Lake, Minn.: "I am writing to you in strong support for your courage in speaking on tax exempt foundations. It is time these tax dodgers were made to foot the bill the same as the rest of us."

R.E.M., Jackson, Miss.: "I certainly concur with your thinking in this matter. In 10 years, the foundations will be as large as all the businesses in the country."

F.W.E., Venice, Calif.: "This card is to commend you on the report in re the tax exempt foundations. May I have two copies of this?"

G.S., Asheville, N.C.: "So glad to hear you are investigating tax-free foundations. * * * Great harm has been done the citizens of this country and taxpayers, I might add, by these foundations."

A.B., Santa Monica, Calif.: "There is obviously a need for Congress to devise new laws for foundations."

V.W., Manhasset, Long Island, N.Y.: "I commend you for your study of foundations and think an investigation is long overdue. I am in a study course with 50 women. How can we help?"

T.L., Kinston, N.C.: "Please keep up your splendid work investigating tax-exempt foundations."

J.N., Los Angeles, Calif.: "Congratulations on your investigation of foundations, the most needed ever to confront Congress. Just about 60 years overdue but you're starting so we're ahead. Don't let pressure stop you."

C.D.H., Amarillo, Tex.: "We thank you for all you are doing along this line. We pray that you may be successful."

C.A.C., Washington, D.C.: "The logic and the truth are all with you—so please use both fists relentlessly."

E.F., Northridge, Calif.: "I want to take this means of congratulating you in this wonderful and courageous effort. Please don't let anyone or anything intimidate you in having this matter fully brought to the attention of all Americans. Once again I want you to know that all good Americans are behind you 100 percent."

SELF-ANALYSIS BY MINING LAW ADMINISTRATORS

Mr. WAGGONNER. Mr. Speaker, I ask unanimous consent that the gentleman from Colorado [Mr. ASPINALL] may extend his remarks at this point in the RECORD and include extraneous matter.

The SPEAKER. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

Mr. ASPINALL. Mr. Speaker, on Tuesday, September 25, 1962, at the 1962 convention of the American Mining Congress in San Francisco, I acted as chairman of a session on the public lands. It was my privilege at that time to introduce as a speaker one of the outstanding executives of the Kennedy administration, a young man who is among the most able and most industrious officials of the Department of the Interior, the Assistant Secretary of the Interior for Public Land Management, John A. Carver, Jr.

Mr. Carver's speech was a discerning and refreshingly frank discussion of executive agency operations. It furnishes a background against which we can understand past actions while at the same time, it serves to form the frame within which we may anticipate the future. As chairman of the Committee on Interior and Insular Affairs, I welcome this self analysis.

I am pleased to include the text of Mr. Carver's speech for the benefit of all.

REMARKS OF ASSISTANT SECRETARY OF THE INTERIOR, JOHN A. CARVER, JR., ANNUAL CONVENTION OF THE AMERICAN MINING CONGRESS, SAN FRANCISCO, CALIF., SEPTEMBER 25, 1962

On his return from the Soviet Union recently, Secretary of the Interior Udall told me about a conversation that took place between one of the American group and his Russian counterpart at a large Soviet hydroelectric project. The American asked the Russian what kind of delays they experienced in condemnation of rights-of-way for the reservoir and the project area.

I chuckled at the story for, after all, everyone who thinks about it knows that in the Soviet system there is neither private property to be condemned nor procedural obstacles to the state taking what land it needs without regard to the impact on the individual occupant.

Unthinkably, I had asked a similarly foolish question a few years ago when visiting a Swedish sawmill. I asked the manager what his workmen's compensation insurance rates were, forgetting that in his country there is universal medical care by the state.

We can't, I hope these stories show, achieve insight without an understanding of the governmental environment. A Swedish sawmill, or a Russian hydro project, may look very much like their American counterpart—operating or building them may pose entirely different challenges.

The administration of the mining laws by the Department of the Interior can be understood only with knowledge of the Department, and the relationships of the Department with the Congress, with the public, and with the courts. This is the governmental environment.

I would like to suggest the nature of this environment by the use of a metaphor. The Department of the Interior is the manager of certain lands and resources. Part of its authority derives from the President by delegation or redelegation of Executive pow-

er, but for the purposes of our metaphor, I am speaking primarily of those managerial functions committed to the Department or its head by our board of directors, the Congress of the United States.

The relationship of a board of directors to its hired general manager tends to vary. Boards can be strong or weak, sometimes changing as the stockholders, the voters in our case, shake them up. Boards can be strong in some areas and weak in others, depending on their collective interest or the personalities of their senior members, and boards of directors can show a minute interest as to some kinds of programs and an airy and magnanimous disinterest as to others.

The general manager's responsibilities are a resultant of many forces. He may be power hungry or timid, or both at once. A strong manager encroaches on the policy formulating prerogatives of his board, and a weak one may exasperate his board by petty questions and general indecisiveness. Good managers willingly take responsibility, but keep the board fully informed; bad ones duck responsibility, and conceal errors. First and foremost, and above everything else, the brilliant manager understands the nature of the relationship itself—the paramountcy of law, the necessity for both deference and dash, the willingness to share successes and to shoulder failures generously.

So it is in the various mining laws which this Department is called upon to manage. Our board of directors has time and again expressed confidence in the Department as a true and faithful servant of the interest of the stockholders, the people of the United States. It has done this by committing much of the decisionmaking process to the discretion of the head of the Department. Some managers have carried this too far; others have been diffident and timid. A Secretary like Carl Schurz or Harold Ickes could lecture or cow a Congress into submission or subservience on a given issue, or at a given time, but the most flamboyant of Secretaries in this custodial Department's long history could never successfully arrogate to themselves the lawmaking power for very long.

When administrators take over the function of legislating, free government ends.

The metaphor invites further pursuit, but lest you think it too simple and easy, let me suggest a couple of complicating conditions. It is only very, very rarely that the Secretary of a major Government Department makes the action-decision which fixes, for good or ill, the impact of a law upon the individual citizen. Mostly the Department's action is taken by one of the dozen or so bureaus and offices into which the management responsibilities of the Department have been divided.

So whether a Secretary is strong or weak, grasping or retiring, noisy or quiet, does not fully tell the story of the relationship of the manager to its board. The Department is an institution, and it tends to take to itself the personality of its Secretary. But bureaus have personalities, too, and there may be wide variance among them and within each of them. The Department is not so much a manager as a management team, and sometimes the team is not very unified.

The different specialists on the management team often have to consider, each from his own viewpoint, proposed actions in furtherance of the managerial responsibilities committed to the Department. Particularly in the fields of public lands and mineral administration where responsibilities are frequently shared, it is more common than not that bureaus reporting to different assistant secretaries must act in concert.

The Solicitor, as the general counsel on the management team, must measure the impact of the law upon given fact situations, and where he deems it advisable, he may expound what the board of directors really meant or didn't mean when it used certain language. Occasionally these measured and assured phrases fall less than lightly on the ears of the members of the board, still around and active, who devised the language in the first place.

The board itself has contemplated that its general instructions, the laws, shall be translated into detailed regulations, which are promulgated and published in the Code of Federal Regulations. The body of regulations assumes in certain areas truly formidable proportions—consider the regulations implementing the Mineral Leasing Act of 1920.

The board may be aware of, but it hasn't affirmatively authorized, a different kind of compendium of what the managers think its real intentions were. That is the persistent, and occasionally pernicious, adjunct of the Code of Federal Regulations, the "Manual." The Manual, any manual, as those of you who are veterans of Government service know, is a device intended for the dissemination of internal instructions and procedures. Where these procedures involve substantive matters that are more properly regulative it too frequently then becomes the device to remove commonsense from the administrative process. It is internal; not designed for the public; it is revered by its authors and some of its users, because in its attempt to produce uniformity it may convert decisionmaking into a rote or mechanical process. Manuals try to anticipate and provide for all conceivable contingencies, and inferentially to invite total inaction if a given situation doesn't fit, at least until the manual is changed. I believe that instructions which guide departmental decisionmaking ought to be public and published, not concealed in manuals.

Manuals interpret regulations; regulations interpret statutes; but, in theory at least, the facts and law are wedded in published decisions and opinions. These, taken together, form a distinct reference source for one who seeks insight into the governmental environment. Indexed, cross-referenced, and digested, they are the departmental equivalent of precedent case law which fills out the chinks of the legislative structure.

I hope I have not inferred that the failure of the Department to be monolithic is a bad thing, by itself. On the contrary, this fractionation of responsibility serves a useful purpose. An inbuilt system of checks and balances has restrained or prevented many a hasty or ill-advised effort to exercise improvidently the management responsibilities committed to the Department.

Congress occasionally plays a part in this fractionation. It commits programs to specific bureaus; it created an assistant secretaryship for a specific program interest, although it earlier had approved a reorganization plan which left the assignment of responsibilities among lesser officials as a prerogative of the Secretary.

Congress pronouncements for different programs within the Department sometimes seem difficult to reconcile each with the others as the different bureaus seek to carry them out.

Complexity alone, however, is neither a check nor a balance. Let me repeat: I believe that instructions which guide Departmental decision making ought to be public and published, not concealed in manuals. And I firmly contend that stare decisis is a peculiarly inappropriate crutch to justify decisions if those decisions fly in the face of the facts and commonsense.

An appellate system independent of command channels is vital to procedural due process. But an independent appellate review does not necessarily require an abdication of supervisory responsibility. Some of the Department's actions at the field level are affirmed on appeal in circumstances where a supervisory reconsideration would admittedly have resulted in a different decision or action. Furthermore, an appellate system develops a great deal of information which may never be fed back to the administrators. Constant vigilance as to the efficacy of existing law and regulations to accomplish the objectives laid down by the Congress is the duty of all. Conformance with the intricacies of regulations is a necessary requisite to the acquisition of the valuable rights which Congress has authorized the Department to dispense. But time and attention should go too to a consideration of whether the rules could be made less intricate and the procedures more simple.

A manager who comes to a board meeting without suggestions for action by the board is only partly doing his job. An institutional manager, like the Interior Department, needs all the information it can get as to where and how the system might be improved, both internally, and by revisions of the laws. The Department—any department—automatically and instinctively insists that things are always going perfectly until the fact that they are going highly imperfectly becomes painfully obvious to the whole world.

At some point in time, I must relate all of this metaphorical generality to the administration of the mining laws, and I suspect I can't put it off any longer.

What can I say about the administration of the mining laws in this governmental environment which isn't a justification of action or inaction, or a rationale of decisions made?

The mining law of 1872, as currently interpreted and administered, gives rather more authority to the Department in the matter of controlling the acquisition of public land for mining purposes, and control of its occupancy, than the Congress would be likely to give it in any general revision which we might suggest.

What does the Mining Act of 1872 permit us to do? Section 2319 of the Revised Statutes provides now, as it has since 1872, that certain "valuable mineral deposits in lands belonging to the United States * * * shall be free and open to exploration and purchase." Section 2322 still purports to give locators exclusive and inheritable rights of possession and enjoyment of the surface, even though it was modified to provide for multiple use of the surface in 1955.

A 90-year-old law ought to have achieved some precision of meaning. In law school I read Mr. Lindley's treatise, and found, as did a succession of generations of western lawyers, a test which still seems to me to be adequate for the administrator of the public land laws:

"While it is difficult to formulate a definition sufficiently comprehensive in itself to cover all possible exigencies, we think that a conservative application of the rules governing statutory construction, heretofore enumerated in connection with the adjudicated cases and rulings of the land department, permits us to deduce the following:

"The mineral character of the land is established when it is shown to have upon or within it such a substance as—

"(a) Is recognized as mineral, according to its chemical composition, by the standard authorities on the subject; or

"(b) Is classified as a mineral product in trade or commerce; or

"(c) Such a substance (other than the mere surface which may be used for agricultural purposes) as possesses economic value for use in trade, manufacture, the sciences, or in the mechanical or ornamental arts;

"And it is demonstrated that such substance exists therein or thereon in such quantities as render the land more valuable for the purpose of removing and marketing the substance than for any other purpose, and the removing and marketing of which will yield a profit; or it is established that such substance exists in the lands in such quantities as would justify a prudent man in expending labor and capital in the effort to obtain it."

Now let us examine the rule of discovery and the so-called marketability test as it presently applies. In a memorandum to me, the Bureau of Land Management quite boldly states that our interpretation of the basic statute has undergone considerable change:

"The Department continually reiterates that it consistently adheres to the prudent man rule as a test for determining validity of discovery in mining claims located under the general mining laws of 1872. Nevertheless, from a review and comparison of the decisions of today as against those of yesteryear it is readily apparent that the concept of 'prudence' has undergone a radical change and is unquestionably more strict today than previously. While the rule appears unchanged, the criteria now required to show a valid discovery have become much more stringent."

In the other instance we found ourselves bound by an interpretive standard of the mining laws which constituted a separate and additional standard to the prudent man rule laid down by Judge Lindley. In it, we found the doctrine of present marketability carried to the extreme of rejecting good judgment and commonsense.

The question was whether a patent could issue to certain claims for nonmetallic minerals not necessarily of widespread occurrence. Two paragraphs summarize the issues:

"The probabilities of success in any mining venture are never certain. Unforeseen and unknown circumstances may work to bring disaster upon the most prudent of plans. However, in this situation it appears to us, after considering all known factors, that an ordinary prudent man would be justified in further expenditure of time and effort in the reasonable expectation of developing a paying mine. This we conclude despite the fact that it has not been demonstrated that the product can be presently marketed at a profit. We base this conclusion upon the following considerations: (1) there is an existing market for the product, (2) this market, over the past 10 years, has shown considerable expansion and increase, (3) the applicant for patent is a reputable company of recognized management ability and to date had expended approximately $30,000 in the development of this deposit with the expectation of an ultimate profitable operation, (4) no other significant conflicting use exists for the land and the applicant has apparently acted in good faith and does not seek the land for nonmining purposes, (5) nonmineral surface land values are insignificant, (6) two operations mining this product now exist within the State.

"Only two issues are involved: (1) the deposit is of medium quality and due to certain color variations may command a restricted market, and (2) the establishment of a profitable operation would depend upon the negotiation of a favorable freight rate. Considering these two points it appears reasonable to conclude that the applicant may have the management ability to develop or expand existing outlets or to capture a portion of the existing market. The question of freight rates is one of negotiation. The issues here are very narrow and the success or failure of the operation is largely dependent upon the business acumen and managerial ability of the applicant. In these circumstances it appears unnecessarily restrictive to require, as an absolute certainty, that there be a demonstration of present marketability of the product at profit. We are of the opinion that the prudent man concept has been met in this case and if reexamination of the rule of the decisions previously mentioned will permit, we recommend that patent issue."

The application of the present marketability rule in the case discussed above may now be reviewed in light of a new memorandum opinion which stresses two points:

"There are two points which we wish to stress. The first is that the marketability test is only one aspect of the prudent man test, albeit a very important aspect since in the absence of marketability no prudent man would seem justified in the expenditure of time and money. The second is that each case must be judged on its own facts. The rigid application of rules mistakenly interpreted from departmental decisions could lead to incorrect decisions in the field."

For another expression of view on this subject, I refer you to the comments of Mr. Byron Mock, who traces the bootstrap odyssey of the "present marketability" test in a fine paper delivered at the Rocky Mountain Mineral Law Institute last year.

If this case, taken as an illustrative example only, were controlled by the present marketability doctrine in the manner just outlined, it would not have stood, in my view, for a desirable management objective, unless denying patent is by itself always a desirable objective. *Foster* v. *Seaton*, often cited to be judicial recognition of the present marketability test, said that the Department's application of the test to deny a mineral patent in favor of a competing and departmentally favored use of the land, was not unreasonable. Denial of patent in my illustration might be said to have had the virtue of saving the stockholders of the claims from the recklessness of their board and managers, who presumably would have spent further money developing the property notwithstanding a governmental conclusion that they were bound to lose. But not all cases are this simple.

Today a multitude of beneficial uses competes for a dwindling public land inheritance, compelling those who administer the public land laws (including the mining laws) to be ever more mindful of the trust reposed in them. If, in these circumstances the mineral industry should insist upon use of the "prudent man" rule as a cure-all for the land tenure problem, it would do itself a signal disservice. Can we honestly expect a local public land administrator to decide whether or not it would be prudent to invest in the development of, say, a porphyry copper deposit, a titaniferous magnetite deposit, or a limestone deposit, lying undeveloped and far from existing markets? Corporate decisions in such cases must be based largely on economic factors not only unavailable for consideration by public land administrators, but also beyond their capacity to evaluate, even if made available to them. Local administrators cannot be expected to realistically second-guess such major corporate decisions as the erection of copper smelters, steelworks, or cement plants, with only drill logs and engineer's reports before them. It thus becomes clear that when we attempt to apply the "prudent man" rule to the exploitation of major mineral resources, we find we are no longer evaluating the mineral resource itself, but rather the good faith and the corporate ability of the mining company. And if the mining company is unwilling or unable to demonstrate factually a high probability of future profit from such undeveloped mineral resources, then the public land administrator, faced as he is with the necessity of balancing so many aspects of broad public interest, can scarcely be blamed if he concludes the venture to be merely speculative and not worthy of investment of a "prudent man's" risk capital.

The matter of possession of the surface also presents a somewhat different situation, for here the courts' early pronouncements decried surface occupancy for nonmining purposes. Even so, we can find evidence of a major change in the attitude of the Department. Formerly, the sovereign reviewed nonmining surface use when it was called to its attention—generally when other rights were challenged or other governmental use or disposition interfered with. I should mention, of course, that the 1955 act restricted the use of the surface for nonmining purposes.

Consequently, section 2322 of the Revised Statutes, which specifically provides for an inheritable possessory right to the surface where a valid mineral location is made and the laws are complied with, has been relied upon by whole communities in some mineralized areas which are built on unpatented mining claims.

But reliance on this kind of title is illusory, and this Department, seeking to make the land available for other uses, and responding to some extent to public criticism for "permitting" nonmining use of these claims, undertook to oust as squatters, some people who had remained in peaceful and undisturbed possession of an unpatented mining claim for a half century or so.

The impact of this program was so harsh, and seemed so inequitable, that the Department did what a good manager should—it took the matter up with its board. Cooperating with the Congressman of the district most seriously involved, legislative action was recommended by the Department to permit these "equities" to be recognized. Congressman JOHNSON'S bill and Senator CHURCH'S similar bill have passed the two Houses of Congress and are awaiting final resolution of differences between them.

Here I do not conceive that the manager can fairly be charged with any relaxation of his stewardship of public resources. Making recommendation for legislative action in a situation where any impartial student would conclude that the rules governing were changed in midstream is a duty of the manager. To make recommendations which conform with a basic standard of fairness and fairplay is also indicated.

One final instance: In 1955 the Congress amended the Materials Act to withdraw deposits of common varieties of sand, stone, gravel, pumice, pumicite, and cinders from locatability under the historic mining law. During legislative consideration of the bill, the Senate Interior Committee pondered whether limestone suitable for use in the manufacture of portland cement would continue to be locatable, and that committee concluded in its report that it should.

A legal opinion in rather unfortunate language concluded that, as vast deposits of limestone exist throughout the United States and could be manufactured into portland cement, limestone was not subject to location under the mining laws. Accordingly, the language in the Senate report could not be relied upon to modify an unambiguous statute, and would have to be ignored.

This matter eventually was resolved by a clarifying amendment of our regulations, conforming to the expression of legislative intent. I discuss the case, not to criticize the opinion, but to call attention to the reason this matter engendered so much concern.

It is not always appreciated that as it is administered and interpreted in this Department, the basic 1872 act grants to the Department a power much broader than the

right to deny a patent. A denial of a patent usually means that the claim is void. Its voidness, logically, relates to its very beginning, the failure to make a discovery of a valuable mineral deposit. So in recent years, the Department has uniformly accompanied a denial of patent with a cancellation of the claim.

Thus, a decision or an opinion in a particular case has significance far beyond the one claim or the one locator in question. Equal treatment of persons similarly situated as well as proper protection of the public interest demands prompt and affirmative action to void all claims in the same category. So a single decision creates a sword of Damocles suspended over the collective head of any industry whose future is dependent upon located claims of that character—or a community of third-generation residential occupants. The stakes become enormously high, even when the immediate claim in controversy is of modest proportions.

The most restrictive position which the Department could take with reference to the mining laws of 1872 is their administrative repeal—to retain land in Federal ownership by administration and interpretation so that acquisition of title to mining claims as a practical matter becomes impossible. A simple thing like failing to get around to the mineral examination which is necessary prior to patent can stall a claim until all but the hardiest applicants give up.

This involves a perfectly moral objective. There isn't anything sacred about the principle of free exploration and purchase of valuable deposits of minerals on the public lands of the United States. When we were asked recently to suggest legislative approaches to eliminate the nonmining use of the surface of mining claims, I suggested (unofficially) that a perfectly constitutional and supportable law could be passed making all minerals leasable.

But a moral objective does not justify an immoral procedure. Disagreement with a law's objective does not relieve the responsibility of its enforcement. Repeal or amendment of statutes is as much the legislature's prerogative as is their enactment. This Department can interpret the words "valuable mineral deposit" until the courts or the Congress say to us nay, but to use this power of administration and interpretation to repeal the law itself ought to be beyond the pale.

I have discussed with several distinguished Western lawyers, long experienced in the mining business, how it has come about that such a sweeping change could take place in the interpretation of a very simple statute.

Scholarly legal papers have been written on the anatomy of the change. Philosophically, I would guess that the root of the matter is in the word "free"—"valuable mineral deposits in lands belonging to the United States, shall be free"—in the 1872 act. Courts have been willing to accord to the manager considerable leeway in interpreting statutes which authorize transfer of property from public to private ownership for less than full consideration. Judge Lindley could not have written his summary of the law as including the "prudent man" concept in the early part of this century had this not been the case.

And as the country has become more and more crowded, this original interpretive process has simply been extended, until the process of extension itself has achieved a measure of judicial recognition.

Of late, getting judicial review has been difficult. This is usually the case where one of the parties is the sovereign, and the sovereign is almost always an interested party now that the remaining public land is in a withdrawn status.

As to our own hearing and appellate system, I can only observe that the hearing examiners seem to a considerable extent to be prisoners of the intradepartmental system of jurisprudence, if citation of authority is any measure.

I have said to this association in the past that I think the mining laws were conceived in a Jeffersonian philosophy for handling of the public lands and settling the West with which I agree. The right to explore the public domain lands for minerals provided for in 1872 has been relatively little interfered with; certainly not so much as the concomitant right to occupy and purchase. This right to explore continues to serve a useful public purpose.

Furthermore, I defend this Department's right and duty to manage the lands and mineral resources in the light of the changed and changing conditions of the 20th century, and I know that the Congress and the people demand that we hold to that standard.

That we have the ability to nullify the mining laws by interpretation and administration does not mean that we have done so. Quite to the contrary, it seems that not only the land speculators, unscrupulous leeches on the poor and the defenseless, but the exotic, promotional type mining operators have been able to make quite a good thing out of the mining laws, particularly placers.

Modern technology makes even present marketability a test which can be met in certain low-grade mineral values. The gold dry placering operation and the so-called black sands, alluvial deposits of magnetite, ilmenite, hematite, garnet, rutile, chromite, and the like, have accounted for probably a half million acres of recent locational activity in Arizona. Since that State's laws require a discovery hole, grazing and other permitted surface uses are being interfered with.

Misuse of the mining laws by the land speculators is a particularly virulent evil, which works its damage before the Government can do much about it.

The absence of a mining claim recordation system is an extremely hurtful administrative handicap.

But you don't get rid of bad laws by bad administration, nor do you get rid of the bad features of good laws by bad administration. Where we face administrative difficulties by reason of misuse of the mining laws, money to get more policemen to drive off the occupants is a stopgap measure, and no substitute for legislative assault upon the evil itself.

No, the answer I think lies to some extent in what I have tried to do here today—to suggest that we've pulled, twisted, and hauled on the mining laws until we've virtually paralyzed ourselves in achieving the necessary improvements.

A necessary first step toward relieving this paralysis is to lay open, before the interested public, the details of the workings of the entire organism of mining law administration—the governmental environment, I called it earlier.

Now that I've done part of this job, or tried to, I am sure I shall be charged with advocating that the Department be more liberal in its interpretations of the present mining law. This I deny, just as I deny that I advocate being more strict. All I advocate is the quite unexceptionable proposition that we ought to leave to the legislature that which is legislative, and try to do a great deal better job of administering.

Mining law administration must be seen in the context of the relationship of the Department to the Congress, in the context of the somewhat divided administrative responsibility within the Department, and in the philosophical context of how courts interpret laws which give administrators the right to dispense privileges or benefits.

If the Mining Act of 1872 has become a weapon of the administrator, as well as a refuge of the miner, as I think it has, then recognition of the fact may further the consideration by the Congress of what amendments are indicated.

I look at this as an exercise in the art of government, a subject which delights me, This free Government of ours is worth all the time and attention it can get from each and all of us.

Others on this panel may see in the growing conservatism which I have described an erosion of the laws of discovery. But so long as the mining laws remain blind to the broader aspects of public land management and continue to grant supplemental benefits in land and resources unrelated to mining, the administration of those laws must inevitably demand of miners an ever stricter demonstration that a valuable mineral deposit exists upon their claims. If this gives miners a chilly feeling of exposure, it is not because the Department of the Interior is trying to pull away from them the warm blanket of the law's protection, but because the needs and problems of the mining industry have grown too large for adequate coverage by this statute. Our mutual concern is properly a hand-in-glove effort for an improved statute which could be administered in the interests of mineral development, free from the interplay of tensions between a frustrated industry and an apprehensive public.

Like Mark Twain's reference to the weather, it is almost habitual to say that the mining laws are outmoded and demand revision. Unlike the weather, however, it is within our competence to solve this problem and to conform these laws to the needs of the current time. But talking about it doesn't get the job done.

For the better part of an hour now I have engaged in something of an intellectual striptease—an introspective analysis of the processes which have been at work in the administration of the mining laws. Most of you are familiar, in one degree or another, with the results of this process. Some of you have been vocal in your criticism of these results. One of my purposes has been to show that there is a logical pattern of cause and effect for the situation in which we find ourselves—not as an apology, but to lay the groundwork for what I believe to be the lessons of this experience.

No devotee of self-flagellation, I have not indulged in this process as a public confession of administrative fault. Nor can I be satisfied with carping criticism aimed at those who conduct the governmental process—whether they be lawyers, geologists, economists, or any other variety of land management specialists. The present state of the mining law is a complex of many influences—all of which fall under the umbrella of a changing society in a world of change. The plain, cold fact of the matter is that in 1962 we are trying to do business in a building whose cornerstone reads "1872." It has been added to, patched up, and propped up—but its basic character still remains as the primary influence on our method of doing business. So long as we work in an antiquated environment, those who are charged with doing the job will be forced to devise ways of making the result compatible with the prevailing public interest, as they see it.

What I am really saying is that every incentive and motivation in the present framework of Federal mining law tends toward the kinds of tortured construction that I have cited. It is morally offensive to any person dedicated to the public interest to see hundreds of thousands of acres of a public trust siphoned off under the guise of "free and

open" access for mineral development when it seems obvious that the highest and best use of this land lies in some other direction. I maintain that it is totally unrealistic to expect this attitude to change until we bring the legal framework of the mining system into conformity with the actual social and industrial environment of this decade.

Is it the obligation of the Government to assume this burden alone? I think not. If not, who else has the most direct interest and responsibility? My frank answer is that you—the organization and the people present in this room and those you represent—must make your constribution out of your own self-interest as well as a decent respect to your own peculiar obligation to the public interest.

I say this, not as a way of shirking my part of the job, but out of a realistic appreciation that success can come only with your cooperation. Certainly, if the industry comes out in monolithic opposition to sensible change, we will be condemned to wallow in this morass until an aroused public demands radical reform. History teaches us that many unwise things are done in the heated atmosphere of such crusades.

I have been intentionally open and frank in my self-analysis here. It seems to me incumbent upon a responsible industry to do likewise—not in open forum, but with equal honesty in your own councils. Your industrial future is at stake and you owe it to yourselves and the Nation to take a comprehensive inventory which will permit a precise definition of the mining industry's proper stake in the public land heritage of the American people.

The objective of the Department of the Interior in this administration is to manage the public land resources in a manner which will promote the total national welfare. This means, among other things, the intelligent development of the mineral resources to meet the needs of an expanding economy. It means full recognition of the legitimate interests of the mining industry to the end that it participates in the Nation's prosperity. I call upon you to define the metes and bounds of that interest and to join in a mutual effort to translate that definition into a public lands mining policy which the Congress can adopt as the law of a prosperous land.

TRIBUTE TO COUNTY AND COMMUNITY AGRICULTURE COMMITTEES

Mr. WAGGONNER. Mr. Speaker, I ask unanimous consent that the gentleman from Alabama [Mr. RAINS] may extend his remarks at this point in the RECORD and include extraneous matter.

The SPEAKER. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

Mr. RAINS. Mr. Speaker, during our recent deliberations in an attempt to solve our so-called agriculture problem through the enactment of suitable legislation, I could not help but think of the men who make up the 3,056 county committees in this great Nation of ours and the 27,000 community committees who will have the enormous task of taking these laws we pass here and implementing and administering them to their fellow farmers there at home.

I think it is only fitting that we recognize the tremendous task that is theirs and the achievements they have accomplished in the past. Under our existing law, which I hope will never be changed, the local administrative responsibility for administering farm programs is placed with these farmers through the community, county, and State committees. Farmers participating in programs in the community elect annually from their number a community committee of three members. The newly elected chairman or vice chairman, respectively, of the community committee serves as a delegate to the county convention. These delegates elect from the farmers participating in the programs in the county a county committee of three members. The county agent is an ex officio member of the committee unless elected secretary of the committee. As I said before, there are 27,000 community committees and 3,056 county committees.

Community committees provide local leadership and supervision in assisting the county committees in carrying out programs assigned to them. They inform the farmers of the purposes and provisions of programs and arrange for and conduct community meetings of program participants. In addition to the above, they perform such other duties as may be assigned by the office manager under the direction of the county committee. Farmer-elected ASCS committeemen are aware of the impact of the farm income on the economy, not only on his immediate community but also upon the Nation as a whole. These farmer-committeemen know that their fellow businessmen are almost completely relying upon the income received from farms, which moves from the hands of the farmers to the businessman.

This makes the farmer-committee system of utmost importance to the overall economy of the Nation and the will of the Nation to resist communism and preserve our American way of life and strive to free the enslaved people throughout the world.

We owe our farmer-elected ASCS committeemen a great debt of gratitude for giving freely of their time to help their fellow farmer and the Nation as a whole in trying to make our farm programs work as efficiently and as effectively as possible.

I want to take this opportunity to point out to each of you and to the Nation as a whole the contributions being made by these men and I strongly feel that they should be commended for their efforts.

GOVERNOR BARNETT, OF MISSISSIPPI

Mr. WAGGONNER. Mr. Speaker, I ask unanimous consent that the gentleman from Pennsylvania [Mr. NIX] may extend his remarks at this point in the RECORD and include extraneous matter.

The SPEAKER. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

Mr. NIX. Mr. Speaker, the recent defiance of Federal authority by Gov. Ross Barnett, of Mississippi, evokes and merits the condemnation of millions of our law-abiding citizens. I, therefore, herewith bring to the attention of my colleagues my telegram to President Kennedy dispatched this day:

SEPTEMBER 27, 1962.

President JOHN F. KENNEDY,
The White House,
Washington, D.C.:

In the event that Gov. Ross Barnett, of Mississippi, refuses to appear before the Fifth U.S. Circuit Court of Appeals in New Orleans, La., on Friday, September 28, the power of the Federal Government must be invoked immediately. Yes, even the use of U.S. troops must be utilized to bring the offenders to book.

I urge in the strongest possible terms that prompt and positive action be taken against Barnett and all others found to be in contempt, as an assurance to the millions of law-abiding people of this country that this administration will not tolerate any threat to this Nation whether it comes from within or without.

Respectfully,

ROBERT N. C. NIX,
Member of Congress.

RETIREMENT OF ASSISTANT SURGEON GENERAL ARNOLD B. KURLANDER

Mr. WAGGONNER. Mr. Speaker, I ask unanimous consent that the gentleman from Rhode Island [Mr. FOGARTY] may extend his remarks at this point in the RECORD.

The SPEAKER. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

Mr. FOGARTY. Mr. Speaker, I would like to draw the attention of the House to the retirement on September 30 of one of our distinguished commissioned officers of the Public Health Service.

I refer to Assistant Surgeon General Arnold B. Kurlander, who is leaving after 23 years of outstanding service to this Nation.

Dr. Kurlander has devoted his professional career to the Public Health Service. A native of Cleveland, Ohio, he attended Western Reserve University and obtained his medical degree from Ohio State University's School of Medicine in 1939. He earned his master of public health degree from the University of Michigan in 1947.

Upon completion of his internship at the Public Health Service hospital in New Orleans in 1939, Dr. Kurlander became a commissioned officer and served in Public Health Service hospitals in Galveston, Tex.; Norfolk, Va.; and Boston, Mass. Following assignment to the Arizona State Health Department from 1945 to 1946, he was detailed to the Ohio State Health Department for 3 years.

In 1950, Dr. Kurlander was given his first headquarters post in Washington as Chief of the Program Development Branch, Division of Tuberculosis Control. He was then made Assistant Chief of the Division of Chronic Diseases and Tuberculosis Control and subsequently Chief of the chronic disease program.

In 1957 he was named Assistant to the Surgeon General and a year later, Assistant Surgeon General for program. In June of 1958 he was promoted to Deputy Chief of the Service's Bureau of

Medical Services. He was appointed Assistant Surgeon General of the Service in January 1960.

During World War II, Dr. Kurlander served as Assistant Surgeon of the U.S. Coast Guard, whose medical care program is under the direction of the Public Health Service. From 1948 to 1950 he was instructor and then assistant professor of preventive medicine at Ohio State University's School of Medicine.

Like most of his colleagues in the Public Health Service, Dr. Kurlander belongs to a number of professional associations and is an active participant in several organizations in the field of disease prevention. He is on the board of directors of the Chronic Disease Research Institute, of Buffalo, N.Y., and is a trustee of the Health Research Foundation, Inc., of Asheville, N.C. He is a diplomate of the American Board of Preventive Medicine and Public Health, a fellow of the American Public Health Association and the American College of Preventive Medicine, and a member of the American Medical Association and the Association of Military Surgeons.

Although he is primarily concerned with public health, Dr. Kurlander has had practical experience as a clinician and surgeon. And he is, of course, a veteran administrator of Federal, State, and local programs whose impact on the Nation's health has been widespread and deeply felt.

A career such as his typifies the kind of genuine service, devotion to duty, integrity and high-level performance that we have come to expect from members of the Public Health Service commissioned officers.

Now, after more than a score of years in public service, Dr. Kurlander stands on the threshold of a new career. He has accepted the post of director of Sinai Hospital in Baltimore, Md., a position for which he is ably qualified.

On behalf of the American people I want to thank him for a job well done and wish him continued success in his new undertaking.

H.R. 11581

Mr. WAGGONNER. Mr. Speaker, I ask unanimous consent that the gentleman from West Virginia [Mr. HECHLER] may extend his remarks at this point in the RECORD and include extraneous matter.

The SPEAKER. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

Mr. HECHLER. Mr. Speaker, I call the attention of the House to the following telegram which I received today:

Hon. KEN HECHLER,
House Office Building,
Washington, D.C.:

The Friedel amendment to H.R. 11581 would gravely impede medical progress. Discussions with other responsible medical investigators indicates that were the opportunity provided they would have testified to the strangling effect that such a provision would have on the development of new weapons in our fight against disease. The public welfare will be harmed grievously by this amendment.

NATHAN S. L. KLINE, M.D.,
Director of Research, Rockland State Hospital.
LOUIS LASAGNA, M.D.,
Associate Professor of Pharmacology, Johns Hopkins Medical School.

THE 25TH ANNIVERSARY OF HOUSING PROGRAM

Mr. WAGGONNER. Mr. Speaker, I ask unanimous consent that the gentleman from Texas [Mr. GONZALEZ] may extend his remarks at this point in the RECORD and include extraneous matter.

The SPEAKER. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

Mr. GONZALEZ. Mr. Speaker, this month marks the beginning of the 25th anniversary year of public housing, of a congressional charter, if you will, that has served notice that decent housing for every American is a matter of governmental concern and action.

We can pay tribute today to the humanity and farsightedness of the 75th Congress and to President Roosevelt in setting this foundation stone of governmental assistance in housing and urban affairs.

The Honorable Marie C. McGuire is the eighth appointed PHA Commissioner since the low-rent program was established, and the first woman to hold this post. Her agency works with more than 1,700 communities in a partnership designed to meet the housing needs of low-income families.

Although she was born here in the Nation's Capital, Mrs. McGuire showed rare judgment and perspicacity at an early age by "going West" to Texas. She studied community planning and design at the Architectural School of the University of Texas, and the theory of real estate practices and property management at the University of Houston.

At San Antonio, this adopted daughter of our fair State administered the Housing Authority—12 public housing projects with a total of 5,154 dwellings, still the largest program in the country to be directed by a woman. In 1960, the justly celebrated Victoria Plaza opened its 9 floors and 185 apartments for persons over 65. The first floor community center, always a beehive of activity, is operated jointly by the Housing Authority and the Community Welfare Council of San Antonio. Victoria Plaza is a realization of the ideal in housing for the elderly, in design criteria, as well as in community and social services.

Since enactment of the Housing Act of 1961, 136 new local authorities have been created, 18 of them in counties. More than 60 percent of housing authorities is in the smaller, rather than in the larger cities and towns—areas under 2,500. For example, of these new local housing authorities, 47 are in areas under 2,500 population, 45 in communities under 10,000, 21 in cities between 10,000 and 49,999, 4 in the 50 to 99,000 category, and 1 in a city of 126,000. Here in the East, even that last one is practically a whistlestop by today's big city standards.

In my own sovereign State of Texas, interest, activity, and construction is snowballing in low-income public housing for senior citizens. In 50 separate localities, a total of 1,798 dwelling units have been earmarked for the elderly, with 225 already under management.

Public Housing is 25 years old—an occasion, I am gratified to note, that is receiving widespread recognition by all responsible elements of the press. I hold here in my hands an editorial of the Weekly Bond Buyer, a journal dedicated to business interests. They took occasion to note the 25th anniversary at length and in depth. I would hope that this recognition that public housing has come of age augurs a trend among enlightened business interests concerned, in a spirit of constructive self-interest, with the well-being of all our citizens and the health and happiness of our Nation. With such support, this program, serving the greatest area of housing need, can be encouraged to find solutions which, until recently, were made more difficult in an atmosphere of unenlightened and specious controversy.

This front-page editorial is titled "A House Can Be a Home," and was written by Mr. John Gerrity, Washington editor for the Daily and the Weekly Bond Buyer. Following is the statement:

A HOUSE CAN BE A HOME

(By John Gerrity)

WASHINGTON, September 1.—Humanism, once a concept scorned by cynics and decried by pragmatists as no better than maudlin, has come of age in the Nation.

Vivid proof of this abounds today, as the Public Housing Administration—possibly the best of all Government efforts to portray a country's concern for its young and its aged, its poor and infirm—marks its 25th anniversary, and the start of a year that hopefully will see the beginnings of grand new schemes to erase forever the awful blight of subordinate citizenship.

Few endeavors undertaken by this Government, or any other, for that matter, can equal the performance of public housing over the last quarter of a century as a showcase of democracy at work.

Along with the Marshall plan, the Truman doctrine and the vision and hope that fostered the conception of the Alliance for Progress, it is one of the most exportable and exploitable items of evidence that a democratic system, encumbered though it may be, can generate and sustain great progress, without infringing on the rights of the individual.

Viewed from a domestic aspect it is a prime case history of the workability of the system of federalism.

DEMONSTRATION OF THE PROPER FEDERAL ROLE

Since its very inception, the public housing law has functioned on a completely cooperative basis between the Federal Government and local housing authorities. In so doing, it has demonstrated that a central government can perform efficiently without usurping the prerogatives of local governments or their agencies.

The statistical record of the past 25 years is bright and impressive. This local Federal program has produced more than a half million homes, and during this period, adequate, if not elaborate, shelter for more than

5 million persons at one time or another—half of them children, and nearly 125,000 elderly citizens, possessed of small or very modest incomes.

Today, it affords homes for nearly 2 million persons, and there are under construction some 40,000 low-rent dwellings and more than 100,000 others in various stages of preconstruction planning and design.

In some 1,400 cities and counties scattered across the Nation it has worked tirelessly to banish the awful blemish of slums, to restore simple dignity to those whose only fault was to be poor or relatively so, to help erase the stigma that somehow still clings to pigmentary prejudices—and to accommodate itself to the gigantic task of building the great metropolitan areas and strip cities that have come to characterize the population and industrial complex of the Nation today—and, even more so, of tomorrow.

The evolution of public housing as an instrument of social and economic advance, contains elements not revealed in the mere recitation of housing statistics—and it is in these elements that the factors that stir men's imaginations move.

At the very outset, the program, of course, was devised and initiated primarily to meet an insistent need: livable homes for the indigent or near-indigent, the jobless, the unemployables, the untrained, uneducated and handicapped, the aged and the young, all part of the vast army of casualties who wandered homeless, or nearly so, throughout the land in the wake of the economic upheavals of the thirties.

CREATION OF AGENCY MEETS OPPOSITION

In the beginning, as is the lot of all government agencies that appear at least on the surface to be invading the sector of the economy set aside for private interests, the Public Housing Administration met with considerable hostility.

In time this hostility softened into grudging acceptance, and then during the war years, when a hiatus enveloped nearly all housing, public and private, the program retreated into the obscurity of war-enforced inactivity. In the immediate postwar period, however, when much of the social structure of the Nation was disjointed by large numbers of returning veterans, a sudden influx of new families and a shift in industrial emphasis, with resulting dislocations of migrant workers, the PHA was restored to its own, in a manner of speaking.

Again there was a mix of hostility, and suspicion on the part of some and frank enthusiasm on the part of others, but in a short time this mix faded with the widespread acknowledgement of the basic fact that in housing that there will always be a level below which private enterprise cannot produce homes for fair profits, or on acceptable economic standards.

Thus, the choice was apparent. Either this void was to be filled by worsening slums, or else public housing would function in an uneconomic area for private enterprise.

Once this hurdle was successfully surmounted the emergence of two other new concepts followed in natural course.

While the initial objective of public housing was to provide safe, decent, and inhabitable homes for low-income groups, with the consequent emphasis on construction to meet a need, this is not the sole aim today. In short, the broader goal is to meet the basic need, but to place the emphasis on people, rather than on the sheer accomplishment of building.

THE REALIZED IDEAL OF ESTHETICS

Collateral to this development was the mass awakening to the fact that to be useful and economical didn't necessarily mean that a project had to be grim or ugly; that there would be nothing abortive in a union of architectural attractiveness with utilitarianism.

Stimulating this awareness, of course, was recognition of the fact that somehow or other low-cost public housing ought to be fitted in with the overall rehabilitation of the Nation's great cities.

Today no more forceful advocate of these two ideas exists than Marie C. McGuire, Commissioner of the Public Housing Administration. To her, the future development of metropolitan areas and public housing projects are virtually indivisible, if for no other reason than the fact that population shifts which have today placed 8 out of every 10 Americans in urban areas will continue rather than diminish.

She makes no bones about her horror at the thought of expansion of "stratified Government projects" or the barracks-type structure that is only small improvement over the slums it replaces.

"Public housing in its development," she says, "should not be clearly identifiable, even when faced with density problems.

"Unfortunately, too often in cities around the country, public housing facilities have been so designed that, instead of blending with the architectural patterns surrounding them, they stick out like sore thumbs creating a sense of pride neither in the occupant nor in the community. This certainly need not be. It costs no more to produce good design than poor design."

SURVEYS UNDERWAY IN THREE AREAS

To prove this point an on-the-spot survey, under the sponsorship of the PHA, the Community Facilities Administration and the Housing and Home Finance Agency, is now being made of Houston, San Francisco, and Greater New York, to determine how well and in what ways public housing can be fitted into the architectural schemes of areas where density is one of the worst problems.

Mrs. McGuire, a seasoned veteran of the housing wars for more than 20 years, is a visionary, but one not addicted to pie-in-the-sky dreams. A tough fighter for lofty but attainable goals (she handles a cigarette like a man, but smokes like a lady), and rigid in her adherence to the principles of public service, she is satisfied but not exhilarated over the performance of public housing in the past.

She thinks the program has adequately met the challenges of the past. But since public housing will be with us so long as the poor will be, she is convinced that the acid test will come in the next few years.

It is largely because of her efforts, for instance, that the new homes being built for the low-income aged are tailored to meet the demands and needs of people first, and construction specifications second. Similarly, she perceives a growing need for low-cost housing for the thousands of youngsters who will be building new families within the next 4 or 5 years.

And these homes for the young, as well as those for the aged, she thinks, ought to be livable in broader terms than those that are merely equated in symbols like a roof overhead and four walls and a floor.

Despite the fact that public housing has been part of the American scene in its present form for a quarter of a century, Mrs. McGuire thinks that much must still be done to educate the public to its needs and potentials.

THE CENTRALIZING JOB OF THE PHA

She commends most local housing authorities for their initiative and drive. Nevertheless, it is a continuing job to enforce the basic concept of partnership between governments and to induce local governments to assume a larger share of what is fundamentally a local responsibility.

She is convinced that a department of urban affairs is essential. Not because she has any great love or tolerance for bureaucracymaking, but simply because she finds it impossible to separate the problems of area redevelopment for mass transportation, for example, from those of mass living.

And mass living is Mrs. McGuire's business. But building for building's sake is not her concern. Her's is a problem of people. How they live together in ever diminishing space, and do so healthily and sanely, falls within the province of public housing, possibly more so in many ways than it does with private housing.

In this context, a 25th anniversary to her is not a terminal point; it is merely the beginning of a new era, when very probably the challenges will be greater, but so, too, will the rewards of achievement.

CALIFORNIA WINES

Mr. CLEM MILLER. Mr. Speaker, I ask unanimous consent to extend my remarks at this point in the RECORD and include extraneous matter.

The SPEAKER. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. CLEM MILLER. Mr. Speaker, I wish to draw attention to the present-day maturity of a great California industry. This is spelled out in an article by John D. Weaver, appearing in Holiday magazine, September 1961. It gives an accurate and interesting account of the California wine industry.

The achievements of this industry impels us to cast a fresh, appraising eye over our old ideas about wines. It seems France has been regarded by Americans as the very synonym for fine wine. Since Roman times, there can be no doubt France has produced distinguished vintages. Rabelais wrote long passages extolling the wines of France, two centuries before this country came into existence.

Thus, our respect is well founded. It takes time for great wines to come into being. Our California wines have now come into their own. It is established opinion, all over the world, by those who know wines, that our California wines are of the best. This high quality and high standard of production of our American wines now demand respect. Over the past century, we in California have developed a tradition of distinctive wine production. Our vines prosper in the rich soil and favorable climate of California, and particularly in the district I am privileged to represent. Our casks and fermentation processes are closely watched to protect the health of the consumer to a degree that would startle continental wineries. The result is an excellent selection of delicate wines not to be surpassed anywhere in the world.

I am confident that Mr. Weaver's article, which follows, will supplement our knowledge of this great and rising industry:

THE VINEYARDS OF CALIFORNIA

(By John D. Weaver)

Although I have lived in Los Angeles for 20 years, I had never explored the California

wine country until last spring. "Don't drink the water," a friend warned me before I set out, then added as an afterthought, "And don't drink the wine." He was right about the water, but wrong about the wine. American wines, I discovered, are somewhat in the same position as American literature before Emerson declared its independence of England. Our wines, like our literature, are capable of standing on their own sturdy feet but they still bear the "domestic" stigma. As I drove happily from winery to winery, I felt rather like an expatriate American stumbling for the first time across the work of Mark Twain.

The countryside in spring was a blend of the Atlantic seaboard and the California coast range, of pink dogwood and gnarled manzanita, of lilac and redwood, snowball bushes, and camellias. The budding vineyards were ablaze with yellow mustard, the gently sloping hills sprinkled with orange poppies and blue lupine. Deer darted out from pine and cypress groves. Magpies gossiped on every fencepost. Sheep and white-faced cattle were grazing in the foothills, the lambs standing knock kneed in the range grass, the calves bawling, an occasional colt frisking on its spindly, uncertain legs.

Spring is the quiet time when the vines are leafing and the young wines of the last crush are being tested in the laboratory and tasted in the wood. The winegrower scrambles up a ladder to the top of a 2,000-gallon oak cask, carrying a curved glass tube—the French pipette, the American "wine thief." Samples of the aging wine are "thiefed" from the cask and released into tulip-shaped tasting glasses. The wine is held to the light for color, then swirled, sniffed, and tasted. The swirling releases the wine's aroma (the fragrance of the grape) and bouquet (the fragrance of the wine). What the nose detects, the palate confirms, perhaps elaborates. This is the time of decision, when the wine is either graduated to the bottle or held back in the wood.

The winemaking cycle begins in September, when the grapes of the new vintage are harvested. This is the time of fairs and festivals, the start of the winegrower's new year. The vineyards come alive with pickers, the roads with trucks. The wineries are drenched in the overpowering fragrance of freshly crushed grapes. Visitors walk into a montage of whirling crushers, flowing troughs and bubbling tanks. They see the grapes crushed and stemmed, the free-run juice, or must, pumped into tanks where fermentation is touched off by wild yeasts. The fermented juice becomes wine through the conversion of sugar to alcohol. It is essentially a simple, natural process, ageless and universal.

A new vintage, like a newborn child, is a perpetual source of wonder, its character as yet unformed, its future unpredictable. Wine is a living thing. As it grows, it takes on individual traits. In the equable climate of California, vintages are much alike, but to the makers of wine each crush is as distinct as the children of a large family. One may be harsh, another smooth; one mellow with age, another sour. The precocious child may never fulfill his promise, whereas the backward wine, apparently born to the ignominy of a commercial blend, may turn out in 10 or 15 years to be the family's pride.

"With children and wine, you should always use gentle guidance, never rigid regimentation," John Daniel, Jr., tells guests at his Inglenook Vineyards, speaking as a father and as a winemaker.

The wineries are always open to visitors, who are piloted through grapy forests of oak and redwood casks and tanks, where white hoses lie coiled like cobras on freshly washed floors, and into dark, cool, limestone tunnels, where the wine ages in carved-oak cooperage. Their tour completed, visitors are ushered into the tasting room, where they learn to distinguish among generic labels which bear the name of the wine's characteristic grape. Thus, a burgundy becomes a binot noir, a beaujolais, a gamay, a chablis, a chardonnay, a sauterne, a sauvignon blanc or semillon. Cabernet sauvignon is the aristocratic grape of the red wines of Bordeaux, the Englishman's claret.

Innocents abroad in the wine country are often surprised to discover that most of the vineyards of California and the Continent are planted in the same classic varieties of Old World grapes grafted onto the same New World rootstock. This marriage of convenience came about because of phylloxers, an American vine louse which slipped across the Atlantic on some native cuttings in the mid-19th century and, after nearly wiping out the European wine industry, hitchhiked home on foreign vines to decimate the California vineyards. The louse was finally subdued by mating the European vines (Vitis vinifera) with phylloxera-resistant American roots (Vitis rupestris).

The California vineyards have recovered from phylloxera, but they have yet to recover from a more devastating blight—prohibition. This folly not only laid waste the vineyards, a few of which survived by producing sacramental and medicinal wines, but also changed the drinking habits of an essentially temperate people. The California vines have sprung back to life since the long drought, but the growers, in one generation, have not been able to graft a wine tradition onto a Martini root stock.

"California is superior in all the conditions of soil, climate and other natural advantages to the most favored wine-producing districts of Europe," Agoston Haraszthy told the State legislature in 1862. Haraszthy was a high-born Hungarian political exile who settled in California after founding Sauk City, Wis. When he reported to the California Legislature, he had just returned from a 5-month trip to the Côte d'Or, Johannesberg, Asi, and Malaga vineyards in Europe, where he had purchased 100,000 cuttings, of some 300 grape varieties, which established European vines in the north coast vineyards of California.

Count Haraszthy (he picked up the title in Wisconsin) had been experimenting with European vines ever since his arrival in America. One spring day in 1852 he was looking over a bale of imported cuttings, some of which had come from Hungary, when he noticed a faded inscription which seemed to identify a certain vine as a "Zinfandel," a variety he had never tracked down. He planted the cuttings in his vineyards south of San Francisco and was delighted to discover these curious Zinfandel vines were highly productive. The reddish-black grapes grew in large, heavy clusters. The fragrant, fruity Zinfandel wine, with a distinctive flavor reminiscent of a freshly crushed blackberry, proved worthy of the now legendary grape of California's vineyards.

Colonel Haraszthy (he went in for titles) later developed the Buena Vista estate in Sonoma, where at one time he controlled some 6,000 acres, the world's largest vineyard. It is now the property of Frank Bartholomew, the president of United Press International, who has a deep affection for the count, whose restless, imaginative spirit still seems to hover over the Buena Vista Vineyards. The Bartholomews may have felt the presence one Sunday afternoon in November 1943, when they were spending a weekend in Sonoma. As they were driving with friends through Haraszthy's old estate, overrun with weeds and scrub growth, someone casually remarked that the property was to be sold next day in competitive bidding at Sacramento.

"We had no intention of buying a vineyard," Bartholomew recalls, "but we fell in love with the place. We broke open our piggy banks, cashed in our E bonds, put the bite on our friends and next morning at 10 o'clock, there we were in Sacramento."

The Bartholomews have now restored the two old stone wineries. Visitors, with the pleasant feeling of having wandered into a French clos, park beside a brook, shaded by eucalyptus trees, one of which is thought to be the largest in California. In a candlelit underground tasting room the Buena Vista wines are set out for sampling. Some visitors ask for the Green Hungarian, since only one other California winery (Souverain) makes it. Others prefer a Pinot Noir or a chilled Chardonnay. The history-bent sentimentalist will select the Buena Vista Zinfandel and, in the count's own cellers, toast the happy accident which entrusted this distinctive California red wine to Haraszthy's hands, like a waif left in a church doorway.

Plaques on the restored winery and in Sonoma's historic plaze salute Haraszthy as "the father of California viticulture," but his real monument is to be found in the vineyards themselves. Grapes now grow from the Mexican border to the Oregon State line, some 800 miles away. Of the 5½ billion pounds of grapes harvested each year, half are eaten, dried for raisins, or squeezed into grape juice. The other half goes into wine.

The warm inland valleys, where the grapes develop less acid and more sugar, produce the dessert wines which, with the apéritifs, account for three-fourths of California's wine production; the prestige, if not the profits, of the industry rests on its finer table and sparkling wines, most of which are made within a leisurely hour's motoring from San Francisco Bay. It is the cool, moist air from the bay which provides natural air conditioning for the north-coast vineyards. Santa Clara to the south, Livermore to the east, and, to the north, separated by the Mayacamas Mountains, the Napa, and Sonoma Valleys.

The Indians named the valley "Sonoma," or "many moons," because they believed seven different moons rose above the mountains to the east. Sonoma, since the days of the Spanish padres, has always been a winegrowing region. Gen. Mariano Vallejo, the amiable Mexican commandante, was a discriminating maker of wine. Sonoma is one of the rare tile-and-abode California towns which has managed to preserve much of its pueblo past without lapsing into the self-consciousness of Santa Barbara or the unrelenting quaintness of Carmel. A choice of accommodations is offered between the 20th century (El Pueblo Motel) and the 19th (the Country Inn). A recent visitor from London, a young woman in tweeds and sensible shoes who had picked the Country Inn, could be heard humming in her room, delighted to have discovered a provincial English inn tucked away in the American wilderness of standardized creature comforts.

The Valley of the Moon, as no visitor can escape noticing, is Jack London country. London's ranch is in nearby Glen Ellen, where he settled with his second wife and soon fell victim to the 1909 eucalyptus boom which hit California as a result of a shortage of eastern hardwoods. He planted nearly 150,000 trees, hoping to make a killing which would liberate him from the agonizing necessity of having to write for a living. Before he was through, he managed to drop close to $50,000.

While London was planting his trees, an Italian immigrants, Samuele Sebastiani, was peddling his robust red wines in 5- and 10-gallon kegs to quarry workers hacking at the Sonoma hillsides for cobblestones to

pave the streets of San Francisco. Sebastiani's son, August, now sits in the front office of the family winery, just 10 feet from where he was born 47 years ago. Over a bottle of his excellent Barbera, we got to talking about the old days, when his father had set himself up in business with a 501-gallon stave tank and enough grapes to fill it. Those days, August felt, were long gone.

"I still buy grapes from some of the same farmers who used to sell to my father and they still treat me like a kid," August said, "but the small winegrower is dying off. Unless you operate on a large scale, you can't make a profit, not after you've spent $4,000 on a tractor and another thousand on a diskplow."

August, like many local winemakers, hangs out at a lively Sonoma landmark, the Swiss Hotel, which faces the plaza on West Spain Street. The Swiss Hotel has a $3 bill, issued by the Farmers & Merchants Bank of Memphis, Tenn., on May 1, 1854, framed above its bar. In the dining room, no less rare, Ted and Helen Dunlap serve real bread, a yeasty surprise for palates resigned to presliced loaves of reclaimed cleaning tissue. Much of the conversation of the winemakers and grape farmers these days centers on their wealthy new neighbor, whose hilltop winery was modeled on his own photographs of the famed Clos Vougeot in Bordeaux.

The new neighbor is James D. Zellerbach, former Ambassador to Italy and board chairman of the Crown Zellerbach Corp. At the Hanzell Vineyards (Zellerbach contracted his wife's name, Hana, and his own), the retired diplomat has planted some 16 acres of Chardonnay and Pinot Noir grapes in terraced vineyards. Ivan Schoch, a Napa Valley grower who seems continually amused by the human scene ("The fun of this business is the assorted individualists who cast such gigantic sparks into the atmosphere"), likes to tell of the time he replanted the Hanzell Vineyards after the first young vines had been washed out.

"With newly cleared land, you always have trouble with displaced wildlife, especially the birds. I was called in to do something about them. We set up a series of small carbide containers which could be exploded at intervals. Unfortunately, nobody thought to tell Mrs. Zellerbach about them. She drove up to the house one day just as the heavy artillery cut loose and it scared the life out of her. It scared the birds, too, for a while, but they soon caught on to the idea. Now we have a sort of border patrol of schoolboys stationed around the perimeter with .22 rifles. They're getting the job done."

Northwest of Sonoma, Route 12 plunges abruptly into the redwood empire of the Russian River Valley, where sawmills along the road darken the sky with burning waste. It was the fur-trading Russian colonists entrenched in this rugged mountain country who prodded the Spanish into establishing the Sonoma Mission in 1823 to discourage further czarist expansion in California. When Frol R. Kozlov, First Deputy Premier of the Soviet Union, visited the valley a few years ago, he revealed an unexpected familiarity with the workings of providence by remarking, "God must have meant this place especially for vineyards."

The country was opened to winemaking early in the 1880's by the three Korbel brothers, who cleared the land and planted vines around burned-out redwood stumps too formidable to be dislodged. With a long champagnemaking tradition behind them, the three Heck brothers—Adolf, Paul, and Ben—acquired the Korbel Vineyards in Guerneville 7 years ago. The Hecks, a close-knit, good-humored, hard-riding family, have added a Hollywood touch by installing on their ranch a swimming pool in the shape of a champagne bottle.

Visitors are received in the old Korbel depot, built in 1876, or in what used to be the brandy room, now a spacious reception room with a semicircular bar constructed from an old redwood fermenting tank. The winery still specializes in bone-dry champagnes made by the tedious, traditional methods of Epernay. The Hecks have no truck with the controversial plastic cork, which has set off secondary fermentation in California champagne circles.

"Our yeast is the big secret," Dolf Heck told me over a bottle of Korbel champagne brut. "Yeast is the most important thing in making champagne. We got ours in Europe in 1938. That's what makes the difference."

A California champagne is priced according to the process by which it is made. The process must be identified on the label, but to understand the terms it is advisable to visit the Weibel champagne cellars, a mile south of Mission San José on Route 21, where the different processes can be observed. Weibel makes a variety of table wines and a new specialty, Tangor, but is best known as California's largest producer of champagne. For its finest champagnes, made from the Chardonnay grape, Weibel uses the traditional method of bottle fermentation, which simply means that the secondary fermentation (this is what makes the bubbles) takes place in the bottle, as the label must state. Under the bulk process, the fermentation is carried out in tanks lined with glass or stainless steel, a laborsaving method which reduces both the price and the quality.

Napa is the Indian word for plenty, and nowhere in the wine country are so many vineyards huddled so closely together as in the upper reaches of this valley. South on Route 29, from Calistoga to St. Helena, wineries bob up on either side of the road, like resort hotels along the Strip in Las Vegas. Having bedded down in St. Helena at the El Bonita Motel ("Yes," the owner winced when I discreetly brought up the subject of gender, "I know, but it was that way when I bought the place, and I can't afford to change the name"), I had to choose between turning right toward Rutherford and Oakville or left through St. Helena. I turned left, heading for Charles Krug. It was an excellent choice.

Although the old winery still bears the name of the Prussian who pioneered winemaking in the Napa Valley, it is now in the hands of the two Mondavi brothers, Robert and Peter. Bob is the family salesman, Peter the scientist. Both have a warm lively humor; both are dedicated winegrowers. Like so many of the younger men in the industry, they are quick to try new processes, challenge old concepts. On Sunday afternoon guests gather on the lawn beneath towering oaks and, in blind tastings, pit Mondavi wines against comparable foreign ones.

"We do a little better than 50–50," Bob Mondavi said when I asked how the local wines came out in the test. While we were on the subject, he wanted to know if I had ever tried a blind tasting of American soft drinks. I hadn't. "Try it sometime," he said. "You may be surprised."

The sugary carbonated concoctions which confuse the American palate in childhood are of more concern to California winemakers than the cocktails which maul it in later life. The average American, I learned from the Wine Institute, drinks 12 gallons of soft drinks a year compared to only nine-tenths of a gallon of wine. Some of the larger commercial wineries have capitulated to this sweet tooth by offering flavored wines with a high sugar content. Others have sought an honorable compromise, such as Paul Masson with its Emerald Dry and Charles Krug with its not-so-dry Chenin Blanc.

Across the road from Charles Krug, at the Christian Bros., I had a delightful visit with Brother Timothy, admired his corkscrew collection and, when an old friend dropped by, heard about the time Brother Timothy was invited to a black-tie affair in San Francisco and politely wrote back to ask if a reversed white collar would do just as well. At Louis M. Martini, I joined a 45-minute winery tour, which is virtually a seminar on oenology. At Beringer Bros. I drank a glass of Barenblut in a massive stone-and-timber Rhineland mansion built in 1883. At Inglenook, the tasting room turned out to be a handsome museum of carved oak, with stained-glass windows, ancient goblets, German lamps, and Flemish glass. Next door, at Beaulieu, I was enchanted with an arbor of topped, trellised sycamores which led to the magnificent formal gardens landscaped to focus on Mount St. Helena.

The contrasting cultures of the California wine country are nowhere so strikingly highlighted as in the Napa Valley. John Daniel, Jr., of Inglenook is the great-nephew of a seafaring Finn. André Tchelistcheff, Beaulieu's production manager, is a French-trained Russian. Louis M. Martini, a towering figure in the industry, is an Italian peasant-philosopher, rooted in the soil from which he sprang. Hanns Kornell, whose champagnes are among California's finest, is a German refugee who arrived in the United States with $2 in his pocket. Jack Taylor, at the Mayacamas Vineyards, is a quietly humorous Englishman. "Please don't give up now! You're almost there," a sign warns approaching visitors as their feeling of being lost in the Mayacamas Mountains begins to crystallize into certainty.

The Napa growers meet once a month at the Miramonte in St. Helena, where Signora Basilio Lucchesi prepares their luncheon, but their daily meeting place is El Real, a Rutherford restaurant where they sit around a long table with a red-checkered cloth. This is their club, coffeehouse, and forum. To understand what is going on in the California wine country, it is not enough to tour the wineries and taste the wines. The picture must be filled in with a visit to El Real.

"Ninety percent of all wine, American and foreign, is ruined in this country by mishandling," I heard André Tchelistcheff contend, starting a discussion which ended with most of his colleagues in agreement but inclined to scale the figure down. All of them have had cases returned, the wine spoiled from storage in an overheated warehouse or from standing upright on the shelves of a package store, the corks dried and shrunk, the wine oxidized.

"We have no wine merchants in America," Tchelistcheff pointed out, "That is the missing link in our chain. It is a tragedy."

A French maitre de chai, who produces a distinguished, perhaps a great, red wine, can safely assume the bottle will be placed on its side in a cool, dark place and, on achieving maturity, will be decanted with care and drunk with respect. The California winemaker must assume his wine may be left standing on a retailer's shelf, possibly for years. If the wine finds its way to a sophisticated palate, it will be dismissed as "vinegar" and the blame fixed not on the seller but on the maker.

When the subject of inexpensive California wines, many of which are sold in half-gallon jugs, was tossed into play, Tchelistcheff suddenly became enthusiastic. He spoke of Gallo's remarkable technical resources,

which reminded me of the impressive research and development department I had recently visited at Italian Swiss Colony in Asti. "Our vin ordinaire," Tchelistcheff said, "is incomparably superior to that of any other country." Louis M. Martini agreed. "It's true," he said. "The vin ordinaire here is made by master winemakers with modern equipment. In Europe it is made by anybody, anywhere, under any conditions."

As I left St. Helena, I notices two signs, one welcoming visitors to "this world famous winegrowing region," the other advertising "new homes, home sites, and large walnut orchard lots—liberal financing." I remembered the latter sign as I drove southeast into Livermore, then southwest to Santa Clara Valley, where burgeoning subdivisions and shopping centers pose a new and serious threat to the north coast vineyards.

"We survived phylloxera and prohibition," an alliterative grape farmer told me, "but I don't know whether we're going to survive people."

The tract-home blight is threatening Sonoma and Napa valley; it is well advanced in Livermore, where new housing has crept to the edges of vineyards first planted in the early 1880's by James Concannon, of County Galway, and Carl Wente, of Hanover, Germany. Their grandchildren now run the vineyards.

Livermore, is a saucerlike basin in the heart of the coast range, some 40 miles east of San Francisco. Hemmed in by high, rolling hills, its gravelly soil was for years a rich, sheltered source of tomatoes, sugarbeets, grain and grapes. The quiet, horsy city of Livermore, where Haraszthy used to buy his pacers, is now a bustling center of nuclear research. Its population in the last 10 years has shot up from 4,300 to 16,000. The figure will top 70,000 by 1980, the chamber of commerce predicts, thus dooming vineyards which produce what many regard, as California's finest white wines.

"We have a low water table here," Karl L. Wente told me, "so this population explosion is draining us dry."

Karl, like John Daniel, Jr., the Mondavi brothers and the Concannon brothers, James and Joseph, just across the road from Wente Bros., is a third-generation winemaker, typical of the college-trained farmer-scientists who are now coming into control of the north coast vineyards. The late Herman Wente, Karl's uncle, was for years the industry's elder statesman. Herman was the winemaker, his brother Ernest, Karl's father, the grape farmer. Karl is both, equally at home in the cellar and in the fields.

"The wind, that wicked wind," he muttered under his breath as we stepped outside the old frame winery and stood shivering in a cold gust of wind. "It's sucking all the moisture from the ground." He shook his head, his attention suddenly caught by the cattle grazing on the range behind the winery. "My father keeps telling me, 'Never sell the cattle. Prohibition may come back, but the Americans will never give up their steaks.'" He laughted and the conversation turned to the pomace, the fermented pulp left in the tank after a new wine has been drawn off. Some wine growers use pomace for fertilizer, others sell it or feed it to the livestock.

"We feed ours to the cattle," Karl said. "They come running in the fall when they spot that pomace truck. Some of the old girls have developed quite a taste for the stuff. They get a little high, flop down and snore. Sometimes they forget to cough up their cud and it keeps fermenting. Gives them heartburn. Best beef you've ever tasted, though. Marinated on the hoof."

The Livermore no downpayment virus, which has hit Wente Bros. and Concannon, is mild when compared to the outbreak in the lovely fertile Santa Clara Valley, southwest on Route 21.

"They always take the best farmland," Ed Mirassou said when I visited him in Evergreen, where his family has been farming for 100 years. He and his brother, Norbert, are fourth-generation wine growers, caught now in the squeeze between the bulldozer and the tax assessor. "You can sell the land, put the money in stocks and make more money," Mirassou said, "but you'd rather go broke in the business than make money in another."

To the north and east of San Francisco Bay, the wine country appears predominantly Italian and German. South, in the prune and apricot country of the Santa Clara Valley, the vineyard tradition is French. Almadén, near Los Gatos, was founded by Etienne Thée, who planted his first vines in 1852 and built the house where Louis Benoist, the wealthy present-day owner, carries on the same prodigal hospitality, raising his own partridges and pheasants and serving them with his own champagnes. Once, so the story goes, Benoist was entertaining Louis Martini, who sipped his champagne, and exclaimed, "This is the best California champagne I've ever tasted." As Benoist beamed, Martini paused, frowned, and added quickly, "but maybe I've got a cold."

In setting out the first Almadén vines imported from Bordeaux, Burgundy, the Rhone Valley and the Champagne District, Thée enlisted the help of Charles Lefranc, who married Thée's daughter, then had the good luck to hire a stout, amiable Burgundian, Paul Masson, whose name dominated the California wine industry for a generation. Masson, following the practical precedent set by his employer, married Lefranc's daughter, then formed a partnership with his father-in-law. Later, in the hills above Saratoga, where the present owners have recently built the most strikingly modern winery in California, Paul Masson established his own vineyards. Every summer a series of concerts, "Music at the Vineyards," is given in this natural amphitheater, with champagne served during intermission.

While the wineries woo visitors with tours and tastings the wine country has been slow to promote wine drinking itself. With the exception of the Swiss Hotel in Sonoma and El Real in Rutherford, I was somewhat taken aback by the prevailing apathy toward wine in a major wine-growing district. In many restaurants there were no wine lists. "Which do you want, red or white?" waitresses asked me. When wine lists were available, few were representative of the region's finest wines, although they might be growing a mile away. Most startling of all, however, was the abuse of wine through ignorance.

Bob Mondavi told me he once sent back a bottle of his Charles Krug Pinot Noir, which had been served chilled. His waiter took the bottle to the kitchen and ran it under a hot-water faucet. John Daniel told of being served a warm bottle of French sauterne. When he complained, the waitress tagged him for a square and explained, "It's supposed to be hot." She pointed triumphantly to the label, which identified the wine as an "Haut-Sauterne." "You see," she said, "hot sauterne."

Inevitably, as you wander through the wine country, you discover your own winery, as in Europe you discover your own city. It may be a small winery like Hallcrest, in the Santa Cruz Mountains, where Chaffee Hall steals time from his San Francisco law practice to tend his vineyards; or Souverain, on the slopes of the Howell Mountain above the old Silverado trail, where Lee Stewart makes Green Hungarian. It may be an estate operation, like Beaulieu or Inglenook; a local landmark like Buena Vista, Charles Krug, or Cresta Blanca; a larger winery like Almaden or Paul Masson. Be it small or large, you come away with a proprietary feeling. It becomes your winery, as Rome or Paris or Copenhagen becomes your city, because you discovered it. And when you spot its label, it evokes a picture of a pleasant place where charming people are indulging the harmless lunacy of crushing alien grapes for what they hope will someday become a native beverage.

LEAVE OF ABSENCE

By unanimous consent, leave of absence was granted to Mr. INOUYE, for Thursday, September 27, and Friday, September 28, 1962, on account of official business.

SPECIAL ORDERS GRANTED

By unanimous consent, permission to address the House, following the legislative program and any special orders heretofore entered, was granted to:

Mr. ROBERTS of Texas, for 1 hour, today, and to revise and extend his remarks and to include extraneous matter.

Mr. SCHWENGEL (at the request of Mr. NELSEN), for 1 hour, on October 2, 1962.

Mr. RIVERS of South Carolina (at the request of Mr. WAGGONNER), for 1 hour, on Tuesday, October 2, and Wednesday, October 3.

Mr. O'NEILL (at the request of Mr. WAGGONER), for 2 hours, on Wednesday, October 3.

EXTENSION OF REMARKS

By unanimous consent, permission to extend remarks in the CONGRESSIONAL RECORD, or to revise and extend remarks, was granted to:

Mr. HOLIFIELD (at the request of Mr. WAGGONNER) was given permission to revise and extend the remarks he made in his special order today and include extraneous matter.

(The following Member (at the request of Mr. NELSEN) and to include extraneous matter:)

Mr. AVERY.

(The following Members (at the request of Mr. WAGGONNER) and to include extraneous matter:)

Mr. TOLL.

Mr. CELLER.

Mr. MORRIS K. UDALL.

Mr. SLACK.

SENATE BILLS AND JOINT RESOLUTIONS REFERRED

Bills and joint resolutions of the Senate of the following titles were taken from the Speaker's table and, under the rule, referred as follows:

S. 151. An act for the incorporation of the Merchant Marine and Maritime Service Veterans Association; to the Committee on the Judiciary.

S. 2873. An act for the relief of Claude S. Reeder and Reeder Motor Co., Inc.; to the Committee on the Judiciary.

S. 3698. An act to incorporate the McCarran Foundation, and for other purposes; to the Committee on the Judiciary.

S.J. Res. 208. Joint resolution to establish a commission to develop and execute plans

for the celebration of the 150th anniversary of the Battle of Lake Erie, and for other purposes; to the Committee on the Judiciary.

S.J. Res. 213. Joint resolution to provide for the actual participation of the United States in the West Virginia centennial celebration; to the Committee on the Judiciary.

ENROLLED BILLS SIGNED

Mr. BURLESON, from the Committee on House Administration, reported that that committee had examined and found truly enrolled bills of the House of the following titles, which were thereupon signed by the Speaker:

H.R. 4333. An act to amend the act entitled "An act to provide for the registration and protection of trademarks used in commerce, to carry out the provisions of certain international conventions, and for other purposes," approved July 5, 1946, as amended;

H.R. 5144. An act to provide for the acquisition of and the payment for individual Indian and tribal lands of the Lower Brule Sioux Reservation in South Dakota, required by the United States for the Big Bend Dam and Reservoir project on the Missouri River, and for the rehabilitation, social, and economic development of the members of the tribe, and for other purposes;

H.R. 5165. An act to provide for the acquisition of and the payment for individual Indian and tribal lands of the Crow Creek Sioux Reservation in South Dakota, required by the United States for the Big Bend Dam and Reservoir project on the Missouri River, and for the rehabilitation, social, and economic development of the members of the tribe, and for other purposes;

H.R. 7326. An act for the relief of E. La Ree Smoot Carpenter;

H.R. 7708. An act for the relief of Mr. and Mrs. Gerald Beaver and Sergeant and Mrs. Cecil P. Fisher;

H.R. 8134. An act to authorize the sale of the mineral estate in certain lands;

H.R. 8205. An act to provide tax relief to the International Brotherhood of Teamsters, Chauffeurs, Warehousemen, and Helpers of America Local 863 pension fund and the contributors thereto;

H.R. 8738. An act to amend section 1 and 5b of chapter V of the Life Insurance Act for the District of Columbia;

H.R. 8824. An act to modify the application of the personal holding company tax in the case of consumer financed companies;

H.R. 9472. An act for the relief of Janina Tekla Gruszkos;

H.R. 10022. An act to amend section 510 (a)(1), Merchant Marine Act, 1936;

H.R. 10937. An act to amend the act providing for the economic and social development in the Ryukyu Islands;

H.R. 11059. An act relating to the effective date of the qualification of Bricklayers Local 45 (Buffalo, N.Y.) pension fund as a qualified trust under section 401(a) of the Internal Revenue Code of 1954;

H.R. 11217. An act to amend section 6112 of title 10, United States Code;

H.R. 11728. An act to amend section 1208 (a) of the Merchant Marine Act, 1936, to authorize investment of the war risk insurance fund in securities of, or guaranteed by, the United States;

H.R. 12589. An act to amend the Smith-Lever Act of May 8, 1914, as amended;

H.R. 12711. An act making appropriations for sundry independent executive bureaus, boards, commissions, corporations, agencies, and offices, for the fiscal year ending June 30, 1963, and for other purposes; and

H.R. 13067. An act to amend title VIII of the National Housing Act with respect to the authority of the Federal Housing Commissioner to pay certain real property taxes and to make payments in lieu of real property taxes.

SENATE ENROLLED BILL AND JOINT RESOLUTION SIGNED

The SPEAKER announced his signature to an enrolled bill and a joint resolution of the Senate of the following titles:

S. 455. An act to amend the act of July 14, 1955, relating to air pollution control, to authorize appropriations for an additional 2-year period, and for other purposes; and

S.J. Res. 230. Joint resolution expressing the determination of the United States with respect to the situation in Cuba.

BILLS PRESENTED TO THE PRESIDENT

Mr. BURLESON, from the Committee on House Administration, reported that that committee did on this day present to the President, for his approval, bills of the House of the following titles:

H.R. 5144. An act to provide for the acquisition of and the payment for individual Indian and tribal lands of the Lower Brule Sioux Reservation in South Dakota, required by the United States for the Big Bend Dam and Reservoir project on the Missouri River, and for the rehabilitation, social, and economic development of the members of the tribe, and for other purposes;

H.R. 5165. An act to provide for the acquisition of and the payment for individual Indian and tribal lands of the Crow Creek Sioux Reservation in South Dakota, required by the United States for the Big Bend Dam and Reservoir project on the Missouri River, and for the rehabilitation, social, and economic development of the members of the tribe, and for other purposes;

H.R. 12526. An act to amend section 172 of the Internal Revenue Code of 1954 to provide a 7-year net operating loss carryover for certain regulated transportation corporations; and

H.R. 12711. An act making appropriations for sundry independent executive bureaus, boards, commissions, corporations, agencies, and offices, for the fiscal year ending June 30, 1963, and for other purposes.

ADJOURNMENT

Mr. WAGGONNER. Mr. Speaker, I move that the House do now adjourn.

The motion was agreed to; accordingly (at 6 o'clock and 2 minutes p.m.) the House adjourned until tomorrow, Friday, September 28, 1962, at 12 o'clock noon.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 2 of rule XXIV, executive communications were taken from the Speaker's table and referred as follows:

2586. A letter from the Secretary of the Army, transmitting a letter from the Chief of Engineers, Department of the Army, dated July 6, 1962, submitting a report, together with accompanying papers and illustrations, on a review of the reports on the James River, Va., requested by resolutions of the Committees on Public Works, U.S. Senate and House of Representatives, adopted August 13, 1954, and March 30, 1955 (H. Doc. No. 586); to the Committee on Public Works and ordered to be printed with 12 illustrations.

2587. A letter from the Secretary of the Army, transmitting a letter from the Chief of Engineers, Department of the Army, dated September 7, 1962, submitting a report, together with accompanying papers and illustrations, on a survey of the Scioto River Basin, Ohio, authorized by the Flood Control Act, approved August 28, 1937 (H. Doc. No. 587); to the Committee on Public Works and ordered to be printed with illustrations.

REPORTS OF COMMITTEES ON PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XIII, reports of committees were delivered to the Clerk for printing and reference to the proper calendar, as follows:

Mr. HAYS: Committee on House Administration. House Concurrent Resolution 513. Concurrent resolution for printing additional copies of hearings; without amendment (Rept. No. 2488). Ordered to be printed.

Mr. HAYS: Committee on House Administration. Senate Concurrent Resolution 90. Concurrent resolution authorizing the printing for the use of the Joint Economic Committee of additional copies of its hearings entitled "State of the Economy and Policies for Full Employment"; without amendment (Rept. No. 2489). Ordered to be printed.

Mr. HAYS: Committee on House Administration. Senate Concurrent Resolution 91. Concurrent resolution authorizing the printing of additional copies of the hearings on Department of Agriculture handling of pooled cotton allotments of Billie Sol Estes; without amendment (Rept. No. 2490). Ordered to be printed.

Mr. ROBERTS of Alabama: Committee on Interstate and Foreign Commerce. H.R. 134. A bill to provide that seat belts sold or shipped in interstate commerce for use in motor vehicles shall meet certain safety standards; with amendment (Rept. No. 2491). Referred to the Committee of the Whole House on the State of the Union.

Mr. DAWSON: Committee on Government Operations. Twenty-eighth report pertaining to Federal Home Loan Bank Board (Rept. No. 2492). Referred to the Committee of the Whole House on the State of the Union.

Mr. DINGELL: Committee of conference. S. 901. An act to advance the marine sciences, to establish a comprehensive 10-year program of oceanographic research and surveys, to promote commerce and navigation, to secure the national defense, to expand ocean, coastal, and Great Lakes resources, to authorize the construction of research and survey ships and laboratory facilities, to expedite oceanographic instrumentation, to assure systematic studies of effects of radioactive materials in marine environments, to enhance the public health and general welfare, and for other purposes (Rept. No. 2493). Ordered to be printed.

Mr. BONNER: Committee on Merchant Marine and Fisheries. H.R. 12968. A bill to amend section 901(b) of the Merchant Marine Act, 1936, to eliminate certain time limitations; with amendment (Rept. No. 2494). Referred to the Committee of the Whole House on the State of the Union.

Mr. BONNER: Committee on Merchant Marine and Fisheries. S. 3396. An act to amend section 511(h) of the Merchant Marine Act, 1936, as amended, in order to extend the time for commitment of construction reserve funds; without amendment (Rept. No. 2495). Referred to the Committee of the Whole House on the State of the Union.

PUBLIC BILLS AND RESOLUTIONS

Under clause 4 of rule XXII, public bills and resolutions were introduced and severally referred as follows:

By Mr. CLEM MILLER:

H.R. 13258. A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to its application to grapes to be used in the making of wine; to the Committee on Interstate and Foreign Commerce.

H.R. 13259. A bill to amend the Federal Food, Drug, and Cosmetic Act to require imported wine to meet the same sanitation standards required of domestic wine; to the Committee on Interstate and Foreign Commerce.

By Mr. SANTANGELO:

H.R. 13260. A bill to establish in the Department of Health, Education, and Welfare a Medical Service Bureau to serve as a center for the worldwide dissemination of current medical information; to the Committee on Interstate and Foreign Commerce.

By Mr. GONZALEZ:

H.R. 13261. A bill to amend the joint resolution of September 10, 1962, to provide that any Reserve ordered to active duty thereunder shall be entitled upon request to be appointed a member of a regular component in the same grade as that held by him at the time he requests such appointment; to the Committee on Armed Services.

By Mr. TOLLEFSON:

H.R. 13262. A bill to exclude cargo which is lumber from certain tariff filing requirements under the Shipping Act, 1916; to the Committee on Merchant Marine and Fisheries.

By Mr. RODINO:

H.J. Res. 896. Joint resolution proposing an amendment to the Constitution of the United States pertaining to the offering of prayers in public schools and other public places in the United States; to the Committee on the Judiciary.

By Mr. MORRIS K. UDALL:

H. Con. Res. 576. Concurrent resolution for a study of the procedures of Congress; to the Committee on Rules.

By Mr. CHAMBERLAIN:

H. Res. 816. Resolution amending the Rules of the House of Representatives relating to the appointment of professional and clerical staffs of the committees of the House; to the Committee on Rules.

By Mr. DAWSON:

H. Res. 817. Resolution to amend the Rules of the House of Representatives with respect to the location of activities of the Committee on Government Operations; to the Committee on Rules.

PRIVATE BILLS AND RESOLUTIONS

Under clause 1 of rule XXII, private bills and resolutions were introduced and severally referred as follows:

By Mr. BOLAND:

H.R. 13263. A bill for the relief of Mrs. Rose D'Arienzo; to the Committee on the Judiciary.

By Mr. FINNEGAN:

H.R. 13264. A bill for the relief of Dr. Mehmet Cemil Alpaslan; to the Committee on the Judiciary.

By Mr. KARTH:

H.R. 13265. A bill for the relief of (Mrs.) Chryssi Kourounis; to the Committee on the Judiciary.

By Mr. NIX:

H.R. 13266. A bill for the relief of Masis Bedian; to the Committee on the Judiciary.

By Mr. O'BRIEN of New York:

H.R. 13267. A bill for the relief of Richard H. Marshall; to the Committee on the Judiciary.

By Mr. O'NEILL:

H.R. 13268. A bill for the relief of Chin Tau Sun; to the Committee on the Judiciary.

H.R. 13269. A bill for the relief of Wong Shee Heung; to the Committee on the Judiciary.

H.R. 13270. A bill for the relief of Tam Suey Kin and Tam Lai Ping; to the Committee on the Judiciary.

By Mr. ROGERS of Colorado:

H.R. 13271. A bill for the relief of Dr. René A. Arcilla; to the Committee on the Judiciary.

By Mr. MATHIAS:

H.R. 13272. A bill for the relief of Dr. Arturo Marinay Riego; to the Committee on the Judiciary.

EXTENSIONS OF REMARKS

Young Democratic Clubs of America Announce Their National Observance Day on Saturday, September 29: Thirty Years' Service for Party and Country—1932–62

EXTENSION OF REMARKS
OF
HON. MORRIS K. UDALL
OF ARIZONA
IN THE HOUSE OF REPRESENTATIVES
Thursday, September 27, 1962

Mr. MORRIS K. UDALL. Mr. Speaker, young Democratic groups had existed in various States and localities for many years prior to the founding of the Young Democratic Clubs of America in 1932, but no national organization existed to coordinate and stimulate the work of these groups. In January of 1930 serious efforts were begun toward the creation of a national organization.

The Honorable Jouett Shouse, chairman of the Democratic National Committee, wrote to party leaders in August 1931, suggesting that they encourage increased activity among the younger members of the party. The 1932 meeting of the national committee adopted a resolution approving the idea. The committee, however, strictly adhered to the position that the young Democrats, if they wished to form a national organization, must do so on their own initiative. The committee felt that it could do no more than properly welcome such an organization and cooperate with it after it was formed.

The Young Democratic Clubs of America will this Saturday celebrate the 30th anniversary of the forming of their national organization. These young people did have the initiative to create their own national group, and I believe we should on this occasion commend the Young Democratic Clubs of America for their organization work and support of their party throughout the last 30 years.

Elected ASCS Farmer Committeemen Administer Farm Programs

EXTENSION OF REMARKS
OF
HON. JOHN M. SLACK, JR.
OF WEST VIRGINIA
IN THE HOUSE OF REPRESENTATIVES
Thursday, September 27, 1962

Mr. SLACK. Mr. Speaker, although the farm bill we recently passed was not all we would have liked to have had, I do hope that this legislation will achieve a reduction in our farm commodity surpluses and prevent a further reduction in our farm income. In fact, I would hope that this bill might achieve an increase in farm income.

When the ayes and nays are taken and the final vote counted, our work is then done. There is nothing more we can do to make it work or to make it help the people for which it is intended. Who does make it work? Who does see that it helps the people for whom it is intended? Who does explain it to each of the farmers who might take advantage of its provisions? Yes, there is much more to be done after the bill leaves this Chamber that we never see and often never realize. The men who make it work are our farmer ASCS committeemen who are elected by the fellow farmers to administer and carry out our farm programs at the local level. The farmer ASCS committeemen meet at specified or regular intervals which is determined by the amount and size of the program they have to administer in their individual county.

On such occasions, they keep minutes of their deliberations which are a matter of record in the county office. These meetings are presided over by the chairman of the committee and regular motions are made and passed on and majority rule prevails. Good county committeemen cannot let personal prejudices or favoritism creep into the decisions of the committee. They know they must be willing and prepared to defend their decisions to their fellow farmers.

They approve and disapprove such matters as allotments, yields for farms, agricultural conservation program practices, facility loans, appeals, and many other matters which may come before them. They may be called upon to get into a number of other matters which may come before them.

They may be called upon to get into a number of other assignments, including disaster area plans, emergency drought area designations, and civil defense activity. They have been known to be instrumental in many cases in assisting and recruiting voluntary labor for a resident of their county stricken by sickness or other misfortune.

In addition to the county committeemen there are individual community committees. These are the men who carry out the person-to-person, farmer-to-farmer contact which makes the program work.

I would like to ask that each Member of this body look seriously at the tremendous job being done by the ASCS farmer-elected committeemen in each of the counties of his district. I am sure that, if you do not already know, you will be