By any measure, the Orphan Drug Act has been a tremendous success. A total of 49 new drugs for rare diseases have been approved under this program, and 370 others are in the development stage. These drugs have provided lifesaving treatments for such terrible disease as enzyme deficiency, which affects adversely the immune system of about 40 children nationwide. Until the orphan drug was developed to treat these children, they had to spend their entire lives in the protection of an isolation bubble. One of the first orphan drugs is another example of a triumph. The most difficult form of leprosy affects only 4,000 people. A drug known for over 14 years to be effective in treating this condition was not being marketed by any drug company, because it was considered unprofitable—until the Orphan Drug Act provided the marketing incentive. In a similar manner, orphan drugs provide treatment for terrible diseases for which there is usually no alternative therapy.

I have serious concerns about the effect the H.R. 4638 would have upon the incentive of drug companies to develop orphan drugs. I believe we must not endanger the success of this program, which is due to large measure to the existence of the "market exclusivity" provision in the Orphan Drug Act that allows companies to have exclusive marketing rights to an orphan drug for 7 years. Weakening the current 7-year exclusivity provision would certainly discourage development of desperately needed new orphan drugs.

Under current law, firms may apply to develop the same orphan drug, but only the first firm to have its drug approved receives market exclusivity. The certainty of this 7-year period is the basis of the economic incentive to attract drug firms to invest in orphan drugs.

The bill would make two major changes to the market exclusivity provisions of the Orphan Drug Act. First, the bill provides for "shared exclusivity." Firms that can demonstrate that they have developed the orphan drug simultaneously would be allowed to share the market with the firm initially awarded the market exclusivity. Second, the bill requires the Food and Drug Administration to withdraw the marketing exclusivity as soon as the patient population exceeds a 200,000 patient limit. Both of these changes have the effect of weakening the marketing incentives provided by the Act. Under the bill, the length of the market exclusivity period will depend on how quickly the patient population grows and whether other firms file claims for simultaneous development.

In addition, as currently constructed, the 200,000 patient population limit would be applied to orphan drugs approved prior to the enactment of the bill as well as to those approved in the future. This retroactive rule change would send a troublesome signal to all those who might wish to develop orphan drugs that the Federal Government may change unilaterally the rules for firms that made investment decisions based on the expectation of 7 years of market exclusivity.

I am aware that this bill was passed after a number of compromises among Members of Congress. I am extremely concerned, however, that individuals with rare diseases may suffer because of changes that this bill would make in the incentives to develop new drug treatment. Accordingly, I am withholding my approval of H.R. 4638.

GEORGE BUSH.

THE WHITE HOUSE, *November 8, 1990.*

H.R. 4653—MEMORANDUM OF DISAPPROVAL

I am withholding my approval of H.R. 4653, the "Omnibus Export Amendments Act of 1990." Although this legislation contains constructive provisions, it would severely constrain Presidential authority in carrying out foreign policy.

I agree with the principal goals of this bill, which include improved export controls for, and sanctions against the use of, chemical and biological weapons; sanctions on Iraq; missile technology sanctions; and reauthorization of the Export Administration Act. Indeed, I have recently signed into law provisions on missile technology sanctions and sanctions against Iraq comparable to those contained in this bill. H.R. 4653, however, contains elements that I believe would undermine these objectives and our ability to act quickly, decisively, and multilaterally at a time when we must be able to do so. These provisions unduly interfere with the President's constitutional responsibilities for carrying out foreign policy. Rather than signing the bill, I am directing action under existing authorities to accomplish the bill's principal goals.

I am pleased that the Congress endorses my goal of stemming the dangerous proliferation of chemical and biological weapons. The Administration has worked closely with the Congress to design appropriate and effective legislation to improve our ability to impose sanctions on the nations that use such weapons and any companies that contribute to their spread. Indeed, the Administration supported the House version of the sanctions provision. Throughout discussions with the Congress, my Administration insisted that any such legislation should not harm cooperation with our partners and should respect the President's constitutional responsibilities. Unfortunately, as reported from conference, H.R. 4653 does not safeguard those responsibilities, nor does it meet our broader foreign policy goals.

The major flaw in H.R. 4653 is not the requirement of sanctions, but the rigid way in which they are imposed. The mandatory imposition of unilateral sanctions as provided in this bill would harm U.S. economic interests and provoke friendly countries who are essential to our efforts to resist Iraqi aggression. If there is one lesson we have all learned in Operation Desert Shield, it is that multilateral support enhances the effectiveness of sanctions.

Because of my deep concern about the serious threat posed by chemical and biological weapons, I have signed an Executive order directing the imposition of the sanctions contained in this bill and implementing new chemical and biological weapon export controls. This Executive order goes beyond H.R. 4653 in some respects. It sets forth a clear set of stringent sanctions, while encouraging negotiations with our friends and allies. It imposes an economic penalty on companies that contribute to the spread of these weapons and on countries that actually use such weapons or are making preparations to do so. At the same time, it allows the President necessary flexibility in implementing these sanctions and penalties. Furthermore, the Executive order reaffirms my determination to achieve early conclusion of a verifiable global convention to prevent the production and use of chemical weapons.

The Executive order also directs the establishment of enhanced proliferation controls, carefully targeted on exports, projects, and countries of concern. On this issue, as with other important export control matters, my goal is to pursue effective, multilateral export controls that send the clear message that the United States will not tolerate violations of international law.

I am also concerned that other features of H.R. 4653 would hamper our efforts to improve the effectiveness of export controls. In the rapidly changing situation in Eastern Europe, and in bilateral relationships with the Soviet Union, we have demonstrated the ability to adjust, in cooperation with our allies, export controls on high technology to reflect the new strategic relationships. Last May I asked our allies to liberalize dramatically our multilateral export controls. Negotiations designed to liberalize trade to encourage democratic institutions and open market economies will continue. Our multilateral export controls have contributed significantly to the positive changes brought about in West-East relations. The micromanagement of export controls mandated by H.R. 4653 can only damage these ongoing efforts.

In other areas, H.R. 4653 would be harmful to closely linked U.S. economic and foreign policy interests. For example, under section 128 of the bill there would be extraterritorial application of U.S. law that could force foreign subsidiaries of U.S. firms to choose between violating U.S. or host country laws.

Other sections of H.R. 4653 contain useful provisions that will be implemented as soon as possible. However, additional legal authority is not required to make our export control system reflect the economic and national security realities of today's world. In response to recent world events, I am directing Executive departments and agencies to implement the following changes:

—By June 1, 1991, the United States will eliminate all dual-use export licenses under section 5 of the Export Administration Act to members of the export control group known as CoCom, consistent with multilateral arrangements. In addition, all re-export licenses under section 5 to and from CoCom will be eliminated, consisent with multilateral arrangements.

—By June 1, 1991, the United States will remove from the U.S. munitions list all items contained on the CoCom dual-use list unless significant U.S. national security interests would be jeopardized.

—By January 1, 1991, U.S. review of export licenses subject to CoCom Favorable Consideration and National Discretion procedures will be reduced to 30 and 15 days, respectively.

—By January 1, 1991, new interagency procedures will be instituted to make dual-use export license decisions more predictable and timely.

—By January 1, 1991, the Secretary of State will initiate negotiations to ensure that supercomputer export controls are multilateral in nature and not undermined by the policies of other supplier countries.

—By June 1, 1991, in consultation with industry, we will devise and publish a method to index supercomputer license conditions to reflect rapid advances in the industry and changes in strategic concerns.

—By January 1, 1991, we will significantly increase the threshold for Distribution Licenses to free world destinations and ensure that at least annually these thresholds are adjusted to reflect changes in technology and are consistent with international relationships, including changing requirements to stem the proliferation of missile technology and

nuclear, chemical and biological weapons.

In summary, H.R. 4653 contains serious and unacceptable flaws that would hamper our efforts to prevent the proliferation of weapons of mass destruction and to ease restrictions on the legitimate sale of dual-use goods to acceptable users. Rather than sign this bill, I have chosen to take a series of steps under existing authorities to ensure that mutually shared objectives are met in a timely and effective manner. I will work with the Congress, upon its return, to enact an appropriate extension of the Export Administration Act.

GEORGE BUSH.

THE WHITE HOUSE, *November 16, 1990.*

H.R. 3134—MEMORANDUM OF DISAPPROVAL

In the closing days of the 101st Congress, two bills were passed providing for somewhat different benefits for the surviving spouses of assassinated Federal judges. These survivors have suffered profound and tragic losses, and they have our deepest sympathies. I am pleased that the Congress has passed legislation allowing these individuals to receive additional benefits.

One bill—H.R. 5316, the "Judicial Improvements Act of 1990"—has not yet been presented to me for approval. Upon its presentation to me, I plan to approve H.R. 5316, which contains provisions that would increase the benefits, subject to certain limits, for surviving spouses of all assassinated Federal judges on an equitable basis.

My approval of H.R. 5316 makes the approval of another bill—H.R. 3134—unnecessary. Therefore, I am withholding my approval of H.R. 3134, a bill which would have provided somewhat different benefits for Mrs. Joan R. Daronco. This action, in conjunction with my planned approval of H.R. 5316, will ensure that Mrs. Daronco and all such surviving spouses receive their benefits in an equitable manner.

GEORGE BUSH.

THE WHITE HOUSE, *November 16, 1990.*

S. 321—MEMORANDUM OF DISAPPROVAL

I am withholding my approval of S. 321, the "Indian Preference Act of 1990." S. 321 would establish, among other things, a program to provide preferences to qualifying Indian enterprises in the award of Federal grants or contracts using funds appropriated for the benefit of Indians. The bill would impose new, expensive, and often duplicative program responsibilities on the Secretary of the Interior that would be difficult to implement. It would also likely result in Federal agencies assuming new, unfunded liabilities related to Indian preference enterprises.

My Administration strongly supports the goals of S. 321 and is committed to helping alleviate the widespread unemployment and underemployment on Indian reservations. Moreover, the Administration supports efforts to prevent companies from misusing Federal Indian preference programs. Accordingly, amendments are needed to the "Buy Indian Act" to increase Indian economic self-sufficiency and employment opportunities and to prevent utilization of preference provisions by non-qualifying companies. However, S. 321 is seriously flawed and would create more problems than it would solve.

I am withholding my approval of S. 321 to allow further review of the issues in the 102nd Congress. Many of the issues raised by S. 321 are complex and deserve a full airing in both Houses of Congress. The House passed S. 321 in the final days of the 101st Congress without sufficient consideration of these complex issues.

In the interim, I am directing the Secretary of the Interior to take the necessary steps to address the contracting problems identified in the November 1989 report of the Special Committee on Investigations of the Senate Select Committee on Indian Affairs.

In particular, I am directing the Secretary to issue guidelines that set forth specific procedures to govern Bureau of Indian Affairs field contracting officers in conducting pre-award reviews of grants and contracts. I am also directing the Secretary to develop and submit proposed regulations to implement the "Buy Indian Act" for Executive review within 90 days.

GEORGE BUSH.

THE WHITE HOUSE, *November 16, 1990.*

S. 2834—MEMORANDUM OF DISAPPROVAL

I have withheld my signature from S. 2834, the proposed "Intelligence Authorization Act, Fiscal Year 1991," thereby preventing it from becoming law. I am compelled to take this action due to the bill's treatment of one highly sensitive and important issue that directly affects the Nation's security, although there also are several objectionable elements of the bill that trouble me.

I cannot accept the broad language that was added in Conference to the definition of covert action. Section 602 of the bill defines "covert action" to include any "request" by the United States to a foreign government or a private citizen to conduct a covert action on behalf of the United States. This provision purports to regulate diplomacy by the President and other members of the executive branch by forbidding the expression of certain views to foreign governments and private citizens absent compliance with specified procedures; this could require, in most instances, prior reporting to the Congress of the intent to express those views.

I am particularly concerned that the vagueness of this provision could seriously impair the effective conduct of our Nation's foreign relations. It is unclear exactly what sort of discussions with foreign governments would constitute reportable "requests" under this provision, and the very possibility of a broad construction of this term could have a chilling effect on the ability of our diplomats to conduct highly sensitive discussions concerning projects that are vital to our national security. Furthermore, the mere existence of this provision could deter foreign governments from discussing certain topics with the United States at all. Such a provision could result in frequent and divisive disputes on whether an activity is covered by the definition and whether individuals in the executive branch have complied with a statutory requirement.

My objections to this provision should not be misinterpreted to mean that executive branch officials can somehow conduct activities otherwise prohibited by law or Executive order. Quite the contrary. It remains Administration policy that our intelligence services will not ask third parties to carry out activities that they are themselves forbidden to undertake under Executive Order No. 12333 on U.S. intelligence activities. I have also directed that the notice to the Congress of covert actions indicate whether a foreign government will participate significantly.

Beyond this issue, I am also concerned by the treatment in the Joint Explanatory Statement accompanying the Conference Report of notification to the Congress of covert actions. I reached an accommodation with the Intelligence Committees on the issues of notifying the Congress of covert actions "in a timely fashion," as required by current law, and have provided letters to the Intelligence Committees outlining how I intend to provide such notice. I was consequently dismayed by the fact that language was inserted in the Joint Explanatory Statement accompanying the Conference Report that could be construed to undercut the agreement reached with the Committees. This language asserts that prior notice may be withheld only in "exigent circumstances" and that notice "in a timely fashion" should now be interpreted to mean "within a few days" without exception. Such as interpretation would unconstitutionally infringe on the authority of the President and impair any Administration's effective implementation of covert action programs. I deeply regret this action.

Additionally, I am concerned that there are several legislatively directed policy determinations restricting programs of vital importance to the United States that I do not believe are helpful to U.S. foreign policy. This bill, like its predecessor last year, also contains language that purports to condition specified actions on the President's obtaining the prior approval of committees of the Congress. This language is clearly unconstitutional under the Presentment clause of the Constitution and the Supreme Court's decision in *INS* v. *Chadha*, 462 U.S. 919 (1983). I again urge the Congress to cease including such unconstitutional provisions in bills presented to me for signature.

This Administration has had a good relationship with the Intelligence Committees. I am willing to work with the Congress to address the primary issue that has prompted my veto as well as other difficulties with the bill. I will also continue to work with the Congress to ensure there is no change in our shared understanding of what constitutes a covert action, particularly with respect to the historic missions of the armed forces. I am confident that these issues can be resolved quickly in the next Congress through mutual trust and a good-faith effort on the part of the Administration and the Congress.

GEORGE BUSH.

THE WHITE HOUSE, *November 30, 1990.*

MESSAGES AND COMMUNICATIONS RECEIVED FOLLOWING THE SINE DIE ADJOURNMENT OF THE 101ST CONGRESS AND FOLLOWING THE PUBLICATION OF THE FINAL ADDITION OF THE CONGRESSIONAL RECORD OF THE 101ST CONGRESS

COMMUNICATION FROM THE CLERK OF THE HOUSE

The text of the communication from the Clerk of the House of Representatives dated November 2, 1990, is as follows:

WASHINGTON, DC,
November 2, 1990.

Hon. THOMAS S. FOLEY,
The Speaker, House of Representatives, Washington, DC.

DEAR MR. SPEAKER: Pursuant to the permission granted in Clause 5 of Rule III of the Rules of the U.S. House of Representatives, the Clerk received the following messages from the Secretary of the Senate:

1. Received at 1:17 a.m. on Sunday, October 28, 1990: That the Senate passed without amendment, H.J. Res. 687;