

AIRBORNE LEGISLATIVE HISTORY

DRUGS AND DEVICES—LABELING OR PACKAGING

For text of Act see p. 663

Senate Report No. 946, Oct. 12, 1951 [To accompany H.R. 3298]

House Report No. 700, July 16, 1951 [To accompany H.R. 3298]

The Senate Report repeats in substance the House Report.

Senate Report No. 946

THE Committee on Labor and Public Welfare, to whom was referred the bill (H. R. 3298) to amend section 503 (b) of the Federal Food, Drug, and Cosmetic Act, as amended, having considered the same, report favorably thereon with amendments and recommend that the bill, as amended, do pass.

INTRODUCTION

This bill amends the Federal Food, Drug, and Cosmetic Act to deal more directly and realistically with the labeling and dispensing of drugs that may be sold only upon the prescription of licensed practitioners. It has a two-fold objective: (1) to protect the public from abuses in the sale of potent prescription drugs; and (2) to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician. The committee believes that the bill, as amended, will serve to eliminate much confusion and dissatisfaction caused by ambiguities in the present provisions of the act, and will benefit drug manufacturers, retail druggists, medical practitioners, and the public.

In its consideration of this bill, the Committee has had the benefit of careful study of its provisions by its standing Subcommittee on Health. The subcommittee carefully and thoroughly explored the need for such legislation at this time, and examined the manner in which the provisions of the bill are adapted to deal with the serious problems which have been shown to exist in connection with the labeling and dispensing of both "prescription" and "over-the-counter" drugs. Hearings on the bill were held before the subcommittee from September 11 through September 13, 1951. Favorable action on the bill was urged at the hearing by the Federal Security Administrator and by the Food and Drug Administration, the agency of the Government that administers and enforces the Federal Food, Drug, and Cosmetic Act. In addition, virtually all segments of the drug industry, including the principal associations of drug manufactures, the retail druggists, and the licensed pharmacists were represented at the hearing and submitted testimony which clearly shows that this bill is necessary legislation and will do much to make the Act a fairer and more effective instrument for protecting the public against abuses in the labeling and dispensing of drugs. A representative of the American Medical Association testified at the hearing in support of the bill.

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The hearing held before the subcommittee developed the fact that while there was virtually unanimity of opinion of those who testified as to the need for basic changes in the law governing the labeling and dispensing of "prescription" drugs, there were two principal issues in controversy.

1. The first area of controversy was over a proposal to authorize the Federal Security Administrator to list by name or class the "dangerous" drugs that may be sold only on prescription. The subcommittee had before it for consideration at the time of the hearing, not only this bill, which has been passed by the House of Representatives, but also the companion Senate bill (S. 1186), and amendments in the nature of a substitute therefor, introduced by Senator Humphrey. The principal difference between the bill as passed by the House of Representatives and Senator Humphrey's amendments in the nature of a substitute, had to do with the requirement under which, as part of the definition of so-called dangerous drugs, an administrative determination would have been necessary thus to classify a drug. The amendments in the nature of a substitute for S. 1186 also set forth detailed procedures, including administrative hearings to be followed in connection with the making of administrative determinations referred to together with provisions for judicial review of such determinations.

Prior to the hearing, the provisions for administrative listing of so-called dangerous drugs were vigorously supported by the National Association of Retail Druggists, and equally vigorously opposed by the several associations of drug manufacturers, including the American Pharmaceutical Manufacturers' Association, the American Drug Manufacturers Association, and the Proprietary Association. At the hearing, however, a statement was submitted on behalf of all four of these associations, indicating an agreement on their part that the controversial provisions for administrative listing of so-called dangerous drugs might be eliminated. The four associations, at the same time, proposed two new amendments to the bill. This agreement had the effect of eliminating one of the principal areas of controversy, particularly in view of the fact that the subcommittee was assured by the Food and Drug Administration and the Federal Security Administrator that the bill, while not in their view the best solution, would be workable in the form proposed under the agreement. The subcommittee recommended to the Committee on Labor and Public Welfare, therefore, that the provisions of the House bill which omit the administrative listing provisions, rather than the provisions of the amendments in the nature of a substitute for S. 1186 which include such provisions, be favorably reported to the Senate. The subcommittee further recommended, in reporting favorably on the House bill, that the bill be amended to include the two amendments proposed by the associations of retail druggists and drug manufacturers under the agreement referred to above. The intent and effect of these amendments are discussed hereafter in this report.

2. The other principal area of controversy which developed at the hearing arose with respect to certain language of the bill which was objected to by the representative of a firm engaged in selling through the

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mail to epileptic patients living throughout the United States a medication comprised principally of phenobarbital. Although the language in question was included in the legislation as originally introduced in both the House of Representatives and the Senate, in the bill as reported to the House of Representatives by the House Interstate and Foreign Commerce Committee and in the bill as passed in the House of Representatives, no issue had been raised concerning this language prior to the hearing before the subcommittee. The subcommittee, however, felt that the language might safely be omitted from the bill. Accordingly, it proposed, and the committee recommends, that this language be stricken. The effect of this amendment is discussed elsewhere in this report.

WHAT THE BILL DOES

As has been pointed out, the bill amends the Federal Food, Drug, and Cosmetic Act so that its provisions will be better adapted to deal realistically with the labeling and dispensing of drugs that may be sold only upon the prescription of licensed practitioners. Its provisions are remedial in the sense that they are intended to protect the public from abuses in the sale of potent prescription medicines. They will also relieve retail pharmacists of unnecessary restrictions on the dispensing of drugs that are safe for use without medical supervision.

Prescription drugs

The bill provides a statutory definition of prescription drugs; it expressly forbids their sale without a prescription; it specifies how they are to be labeled both at the time of interstate shipment and at the time of ultimate dispensing; and it prohibits unauthorized refilling of prescriptions for them.

There are three classes of drugs covered by the statutory definition. The first includes the habit-forming drugs subject to section 502 (d) of the present statute. These are such drugs as the barbiturates. The third class includes all new drugs restricted to prescription sale by effective new-drug applications under section 505 of the present statute. There is no controversy whatever about these two classes. The second class includes any drug which "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs."

This definition of so-called dangerous drugs is contained in paragraph (b) (1) (B) of the bill. It is substantially the same as the administrative definition now contained in the regulations issued by the Federal Security Administrator under the provisions of the Federal Food, Drug, and Cosmetic Act. The proposed definition, however, omits the reference to "efficacious" for use, as well as "safe" for use, without the supervision of a medical practitioner in order to be eligible for over-the-counter sale. This omission is not intended to mean that the only matter to be considered in applying the definition is whether or not a particular drug is poisonous.

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The word "safe," as used in the definition, is intended to have its ordinary meaning. For example, nontoxic drugs like quinidine sulfate, intended for heart disease, or penicillin, for infections, are not safe for self-medication because their unsupervised use may indirectly cause injury or death. The language of the definition clearly shows that toxicity is only one factor, to be considered by the courts in determining whether a particular drug is safe for use without medical supervision. The definition requires the court to consider also other potentialities for harmful effect, the method by which the drug is used, and the collateral measures that may be necessary in order to use the drug safely. When this language is given judicial interpretation consistent with the over-all purpose of the Federal Food, Drug, and Cosmetic Act to protect the public health it will effectively restrict to prescription sale all drugs that require professional supervision for their use.

In order to give this general definition a more precise meaning so that it may be applied with greater uniformity by the drug trade the Administrator can exercise the authority he has under section 701 (a) of the Federal Food, Drug, and Cosmetic Act to issue interpretative regulations. It is to be understood that the inclusion of the statutory definition does not, of course, in any way derogate from the Administrator's authority to interpret and enforce the definition through the issuance of any regulations necessary or appropriate to protect the public from indiscriminate dispensing of drugs over the counter when they may be unsafe for use without the supervision of a practitioner licensed by law to administer such drugs.

As previously stated, the committee considered S. 1186 together with H. R. 3298. S. 1186 would have authorized the Federal Security Administrator to list by name or class the drugs which he considered within the statutory definition. The grant of such administrative authority was objected to as an unnecessary regulation of the drug industry, and the committee concluded that administrative listing is not necessary at this time. It was felt that the statutory definition, together with the authority to make interpretative regulations, could bring an end to the existing confusion in drug labeling and that uniformity can be achieved through cooperative efforts of the drug industry and the Food and Drug Administration working under the statutory plan. If the present confusion is not ended by this legislation it will then be time enough to consider the need for the administrative listing approach.

All drugs covered by the three classifications of prescription drugs must bear a label containing the statement "Federal law prohibits dispensing without prescription." This gives the retail druggist clear notice that he will be in violation of the Federal Food, Drug, and Cosmetic Act if he dispenses any drug so labeled without a prescription. This bill also specifies what information must be contained upon the label of the package dispensed to the patient. That label must contain the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the

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name of the patient, and the directions for use and cautionary statements, if any, contained in the prescription.

This bill strengthens the controls over the habit-forming barbiturates. The problems of misuse of these drugs to the detriment of the public—especially of young people—are growing and must be controlled in the public interest. The bill requires that they be sold only on prescription and forbids unauthorized refills of prescriptions for them. In this, it is a definite and clear step forward. It is felt, however, that these drugs pose a special problem not common to all drugs because they are desired by addicts for nonmedical use. This will call for their special treatment, and the committee wishes it understood that in recommending the passage of this bill, as amended, it does so with the knowledge that further legislative consideration must be given to adequate barbiturate controls.

The bill does not relieve any person from any requirements of law, now existing or hereafter adopted, with respect to drugs covered by the narcotic control laws. Paragraph (5) of section 1 makes this clear.

Oral prescriptions

The present law does not recognize the practice of dispensing drugs on oral prescriptions. The committee feels that in this respect the law needs modification and clarification for the convenience of the public, the retail druggist, and the physician. The filling and refilling of prescriptions upon oral or telephone orders with proper safeguards should be permitted, and this bill gives statutory recognition to the practice of telephone dispensing. It permits oral prescriptions for all drugs. However, in the case of habit-forming drugs, dangerous drugs, and new drugs limited to prescription sale, an oral prescription would have to be reduced promptly to writing and kept on file by the pharmacist. The oral order may be communicated to the dispenser by the prescriber himself or under his express authority.

Oral prescriptions for habit-forming drugs

The committee believes that the term "oral prescription," as used in the bill in connection with habit-forming drugs to which section 502 (d) of the act applies, should be given a construction which will assure that these drugs are used only upon the express order of a practitioner licensed by law to administer them. In fact, certain of these drugs, such as narcotics subject to the Harrison Narcotics Act may be dispensed only on a written prescription of a licensed practitioner, and this requirement is expressly preserved by the bill. (See par. (5) of the new sec. 503(b).) The public interest clearly requires that other habit-forming drugs be dispensed and used only under the close and immediate supervision of a licensed practitioner. Accordingly, it is the intention of the committee that the term "oral prescription" as applied to these drugs, means an order communicated orally to the pharmacist by a practitioner licensed by law to administer such drugs, expressly prescribing such a drug, which is reduced promptly to writing and filed by the pharmacist. The Food and Drug Ad-

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ministration, within the limitations of its staffing, can check pharmacists' records to make sure that all habit-forming drugs sold are accounted for by prescriptions on file. The pharmacist, before he dispenses any such drug on oral order, must obtain satisfactory evidence, on the basis of consultation with the licensed practitioner or otherwise, that the order has been expressly authorized in each case by such practitioner.

The Federal Security Agency may adopt regulations needed for the efficient enforcement of this provision, and may find it desirable to require special records for any habit-forming drugs dispensed so that pharmacists and enforcement officials alike can readily detect any possible abuses of the oral prescription privilege extended for such drugs.

Refilling prescriptions

The bill, as amended, deals expressly with the troublesome problem of refilling prescriptions. Under the present law a drug dispensed by refilling a prescription without the knowledge or consent of the prescriber is misbranded and the dispenser is liable to criminal prosecution. The committee concluded that these provisions are too stringent and should be modified. There is no reason why the law should prohibit the refilling of prescriptions for drugs that are not dangerous and are suitable for use by a layman without medical supervision. The bill provides that prescriptions for such drugs may be freely refilled. But, here again, as to drugs which are habit-forming, or which are dangerous, or which are restricted by new drug applications to use under medical supervision, the bill requires that prescriptions may be refilled only with the prescriber's express authorization. This authorization may be either written or oral, but if it is given orally the dispenser must promptly reduce it to writing and keep it on file.

The provisions relating to the refilling of prescriptions are needed to meet a serious public health problem which has arisen from the indiscriminate refilling of prescriptions for dangerous and habit-forming drugs. A witness for the Food and Drug Administration cited cases in which death had occurred as a consequence of unauthorized prescription refills. The use of dangerous and habit-forming drugs must be under the supervision of the prescribing physician. This bill is intended to require that the licensed practitioner, if he has not authorized the refill in writing, be consulted by the pharmacist and the refill be authorized by such practitioner before any prescription for a drug that is limited to prescription sale may be refilled.

EFFECT OF COMMITTEE AMENDMENTS

Amendment (1) was proposed by a firm engaged in selling through the mails to epileptic patients living throughout the United States a medication comprised principally of phenobarbital. Other provisions of the bill, to which the firm did not object, clarify and simplify the provisions of existing law regarding the labeling, sale, and dispensing of habit-forming and other dangerous drugs that should be sold only on prescription. These provisions are adequate to enable the Food and Drug Administration to compel such firms through appropriate court action, if necessary, to op-

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erate in a manner consistent with the public interest. The committee is aware of the obvious dangers to the public interest in the sale of barbiturates, including phenobarbital, without immediate and close medical supervision. The Food and Drug Administration has a responsibility in connection with the elimination of such dangers. This bill greatly strengthens the Administration's hand in discharging that responsibility.

The other two amendments were proposed by the combined drug trade in a statement signed by the National Association of Retail Druggists, the American Pharmaceutical Manufacturers' Association, the American Drug Manufacturers Association, and the Proprietary Association.

Amendment (2) was recommended because the associations felt the language it strikes out was of uncertain meaning and added nothing of importance to the bill. In any event, should a person place a statement on the label of a drug entirely safe for self-medication representing or implying that dispensing it without a prescription is prohibited by Federal law, that drug would be misbranded under the provision of law, section 502 (a), which forbids false or misleading labeling statements. Striking the language objected to does not relieve any manufacturer, regardless of the way in which he does business, from compliance with the requirement of section 502 (f) that all drugs not limited to prescription sale must bear adequate warnings and adequate directions for use telling the purchasing public what the drug is to be used for and how it is to be taken to accomplish the beneficial effects it is intended to have.

Amendment (3) was proposed to emphasize the fact that the responsibility for preparing adequate directions for use and appropriate warnings against misuse in the labeling of drugs that may be sold without a prescription is upon the manufacturer and not the retail druggist. It does nothing more than free the retail druggist of responsibility for supplementing the labeling of some manufacturers' drugs to give the public adequate directions for use and warnings against misuse. The druggist could rely in good faith upon the manufacturers' labeling for compliance with these requirements of the existing law. The amendment offers the druggist no protection against violations which arise if he sells a dangerous drug covered by paragraph (1) of the bill without meeting the prescription requirements.

Amendment (4) is a technical renumbering amendment.

EFFECTIVE DATE

Section 3 of the amended bill provides that its provisions shall take effect 6 months after the date of its enactment. This postponement of the effective date is considered necessary to permit manufacturers to meet the new labeling requirements.

SECTIONAL ANALYSIS

Section 1 of the bill amends the Federal Food, Drug, and Cosmetic Act by substituting for subsection (b) of section 503, relating to the labeling

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and dispensing of prescription drugs, a new subsection defining drugs that may be dispensed only on prescription and specifying the conditions under which such drugs may be dispensed.

Prescription drugs

Under paragraph (1) of the new subsection (b) prescription drugs are defined as drugs intended for use by man which fall within any one of three different categories. In limiting prescription drugs to those intended for use by man this new subsection differs from the present law, which refers to prescription drugs to include not only those dispensed on prescription of physicians and dentists, but also those dispensed on prescription of a veterinarian. Under the committee bill, drugs intended for use under the supervision of a veterinarian will not require a prescription, although it will be possible under section 502 (f) to exempt such drugs from adequate directions for use if they are to be used by or under the supervision of a veterinarian. In the absence of any exempting regulations, these drugs will be subject to the labeling and dispensing requirements of the act applicable to over-the-counter drugs.

The three categories of prescription drugs defined as such in the bill are: (a) habit-forming drugs to which section 502 (d) of the act relating to drugs containing any narcotic or hypnotic substance, including barbituric acid, or habit-forming chemical derivatives thereof, is applicable; (b) drugs which, because of their toxicity or other potentiality for harmful effect, or the methods of their use, or the collateral measures necessary to their use, are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs; or (c) drugs which are limited by an effective application under section 505 of the act, relating to new drugs, to use under professional supervision.

Included in the first of these three categories are not only the habit-forming narcotics and chemical derivatives thereof, but also barbituric acid and its habit-forming derivatives, such as amytal, phenobarbital, pentobarbital, and the like. This category includes all of the drugs and derivatives thereof specified in section 502 (d) of the act and the regulations thereunder. Dispensing of these drugs must not only comply with the provisions of the bill, but also must conform to the requirements of that section, and the interstate label must bear the name and quantity or proportion of the habit-forming drug or derivatives and in juxtaposition therewith the statement:

"Warning—May be habit forming."

The second category of prescription drugs, defined in subparagraph (B) of paragraph (1) of the new subsection (b) includes the so-called dangerous drugs. As noted elsewhere in this report, the phrase "not safe," as used in this subparagraph, is intended to have its ordinary meaning. Furthermore, in determining whether a drug is safe for use without medical supervision, there must be taken into consideration not only the drug's toxicity, but also other potentialities for harmful effect, the method by which it is

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used, and the collateral measures necessary to its safe use. The broad language of the definition contained in this subparagraph is intended to comprehend all drugs that in fact should be administered under medical supervision in order to insure their safe use. Such difficult borderline cases as may arise under this definition can be dealt with under the interpretative and rule-making power provided for in section 701 (a) of the act.

The third category of drugs defined as "prescription" drugs includes all new drugs restricted to prescription sale by effective new drug applications under section 505 of the act.

Written and oral prescriptions and refills

Paragraph (1) of the new subsection (b) also provides that a "prescription" drug (any drug falling in any one of the three categories referred to above) shall be dispensed only (1) upon a written prescription of a practitioner licensed by law to administer such drug, or (2) upon an oral prescription of such a practitioner, communicated by him or under his express authority to the pharmacist, if such prescription is promptly reduced to writing and filed by the pharmacist, or (3) by refilling any such written or oral prescription if such refilling is authorized by or under the express authority of the practitioner either in the original prescription or by oral order, which is reduced promptly to writing and filed by the pharmacist. The provisions with respect to oral prescriptions and refills do not apply, however, in the case of narcotics subject to the Internal Revenue Code (Harrison Narcotic Act), since subparagraph (5) of the new subsection (b) expressly safeguards the provisions of that act, and under those provisions and the regulations of the Bureau of Narcotics such drugs may be dispensed only on written prescription. Also, as pointed out elsewhere, with respect to other habit-forming drugs, oral prescriptions and refills are limited to situations in which the pharmacist obtains satisfactory evidence, on the basis of consultation with a licensed practitioner or otherwise, that the prescription or refill has been expressly authorized by such practitioner. A violation of the prescription requirements of paragraph (1) of the new subsection (b) is, under the provisions of this paragraph, deemed to be an act which results in the drug being misbranded while held for sale.

Labeling of prescription drugs

Paragraph (2) of the new subsection (b) provides that a drug dispensed on prescription shall be exempt from the provisions of the act relating to the misbranding of drugs except those which specify that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular (sec. 502 (a)), if it is an imitation of another drug or is offered for sale under the name of another drug (sec. 502 (i) (2) and (3)), if it is, or purports to be, or is represented as a drug composed wholly or partly of insulin or of penicillin or certain other antibiotics except under certain conditions (sec. 502 (k) and (l)). These provisions continue to apply to any drug subject to the act, whether sold over-the-counter or on prescription.

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Similarly, the packaging requirements set forth in section 502 (g) and (h) apply to all such drugs. Prescription drugs must, however, bear at the time of dispensing a label containing the name and address of the dispenser, the serial number and the date of the prescription or of its filling, the name of the practitioner, if stated in the prescription the name of the patient, and the directions for use and cautionary statements, if any, stated in the prescription. The exemption provided for by this paragraph does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of the subsection.

Exempt narcotics and similar drugs

Under paragraph (3) of the new subsection (b) the Administrator may by regulation remove habit-forming drugs, as defined in section 502 (d), and new drugs, from the prescription requirements contained in paragraph (1) of the subsection when these requirements are not necessary for the protection of the public health.

Prescription legend

Paragraph (4) of the new subsection requires that, in addition to the labeling requirements in the case of prescription drugs specified in paragraph (2) of the subsection, the interstate label on such drugs must bear the statement "Caution: Federal law prohibits dispensing without prescription." On the other hand, over-the-counter drugs are forbidden to bear a label containing this caution statement. A prescription drug, label on which does not bear the specified caution statement, is deemed to be misbranded. So, too, is an over-the-counter drug, the label on which bears this or a substantially similar statement.

Narcotics and marihuana

Paragraph (5) of the new subsection provides that compliance with the requirements of the bill does not relieve any person from any other requirement prescribed by or under authority of law with respect to drugs now or hereafter within the classifications defined in the Harrison Narcotic Act (sec. 3220 of the Internal Revenue Code, 26 U. S. C. 3220), or marihuana, as defined in section 3238 (b) of the Internal Revenue Code (26 U. S. C. 3238 (b)).

Good faith defense for retail druggists

Section 2 of the bill amends section 303 of the act, which specifies the penalties applicable to violations of the act. It adds to the several defenses available under subsection (c) of section 303 a new defense which has the effect of relieving from liability because of misbranding under section 502 (f) of the act any dispenser who makes delivery or proffers delivery of a drug in good faith if the labeling on such drug at the time of such delivery or proffered delivery contained the same directions for use and warning statements as were contained in the labeling at the time of receipt of the drug by such dispenser. This defense, however, is not appli-

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cable in the case of a drug which, in accordance with the practice of the trade, is to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, and is not applicable to a prescription drug.

Effective date

Section 3 contains an effective date provision. In order to enable the drug industry to adapt its operations to the requirements specified in the bill, and to give the Food and Drug Administration time in which to develop procedures necessary to implement administration of the bill, it is provided that the provisions of the bill will not go into effect until 6 months have elapsed after the date of its enactment.

UNIFORMED SERVICES—REENLISTMENT BONUS

For text of Act see p. 667

Senate Report No. 935, Oct. 11, 1951 [To accompany H.R. 5405]

House Report No. 1078, Sept. 27, 1951 [To accompany H.R. 5405]

The Senate Report repeats in substance the House Report.

Senate Report No. 935

THE Committee on Armed Services, to whom was referred the bill (H. R. 5405) to amend section 207 (a) of Public Law 351, Eighty-first Congress, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

PURPOSE OF THE BILL

The purpose of the bill is to amend the law with respect to reenlistment bonuses so as to correct an injustice that has been done to several thousand men in the Army and Air Force who reenlisted for an indefinite period prior to October 1, 1949.

DISCUSSION OF THE BILL

Under present law, men who reenlist following an original enlistment are entitled to a reenlistment bonus of \$40, \$90, \$160, \$250, or \$360, depending upon whether the reenlistment is for a period of 2, 3, 4, 5, or 6 years. Upon an enlistment for an unspecified period of time amounting to more than 6 years, a lump sum of \$360 is authorized, and \$60 each year thereafter subject to the limitation that the total amount paid shall not exceed \$1,440.

The Comptroller General has ruled that Public Law 351 of the Eighty-first Congress only permits a reenlistment bonus to be paid after a person has been discharged or separated and then reenlists. Men who reenlisted for an indefinite period prior to October 1, 1949, are still serving in their indefinite enlistment periods and have not been discharged or separated and, therefore, there is no way they can become eligible for a reenlistment