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SENATE

REPORT
No. 91-940

SUSPENSION OF DUTY ON L-DOPA

JUNE 23, 1970.—Ordered to be printed

Mr. LONG of Louisiana, from the Committee on Finance, submitted the following

REPORT

[To accompany H.R. 8512]

The Committee on Finance, to which was referred the bill (H.R. 8512) to suspend for a temporary period the import duty on L-Dopa, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

PURPOSE

H.R. 8512 would amend subpart B of part 1 of the appendix to the Tariff Schedules of the United States by adding a new item 907.45 which would suspend the duty on L-Dopa for a period of 2 years, the period to begin on the day after the bill is enacted.

GENERAL STATEMENT

L-Dopa, generically called dihydroxyphenylalanine, is a new drug used in the treatment of Parkinsonism. It has recently been approved by the Food and Drug Administration (FDA) for general use. The FDA is requiring the continued study and testing of the drug by the firms which manufacture it. To obtain relief, the patient must take the drug in massive doses for the rest of his life. The average maintenance dose is said to be 6 to 8 grams daily.

L-Dopa may be produced synthetically from benzenoid intermediates, it may be produced by extraction from certain species of beans, or it may be produced by chemical modification of tyrosine, a naturally occurring amino acid. It is potentially dutiable under any one of four provisions of the Tariff Schedules. If produced synthetically from benzenoid crudes or intermediates, it would be dutiable at 2.45 cents per pound plus 17-percent ad valorem under TSUS item 407.85 if it is determined by the Bureau of Customs to be a drug, or at 2 cents per

pound plus 17.5-percent ad valorem under item 403.60 if it is determined by customs not to be a drug. If produced from naturally occurring plant or animal materials, it would be dutiable at 7-percent ad valorem under item 439.50 if it is determined to be a drug, or at 8.5-percent ad valorem under item 425.04 if it is determined not to be a drug. These rates represent the third-stage reductions negotiated in the Kennedy Round and will remain in effect throughout 1970. The final stages, effective January 1, 1972, will be 1.7 cents per pound plus 12.5-percent ad valorem for items 403.60 and 407.85, 6-percent ad valorem for item 425-04, and 5-percent ad valorem for item 439.50. The ad valorem part of the rates for items 403.60 and 407.85 are subject to valuation on the basis of the American selling price (ASP). During the past several years, imports of L-Dopa are known to have entered under at least three of the four provisions of the TSUS cited above. At the present time, however, it is believed that the bulk of imported L-Dopa is being classified by customs as a drug and is entered under item 407.85 at 2.45 cents per pound plus 17-percent ad valorem.

There are at least two importers of L-Dopa, both of whom sell it in 500-milligram capsules or tablets. The capsules are reportedly sold at wholesale for 20 to 25 cents each, depending on quantity. Most of the imports have originated in Japan, where one producer is reported to make L-Dopa by chemical modification of tyrosine obtained from fish, and another producer makes it synthetically.

Two large pharmaceutical companies, one located in New York and the other in New Jersey, have recently been approved to market the dosage forms of this drug. One of these companies imports the L-Dopa chemical from Japan under TSUS 407.85 but the other is producing it in the United States by a completely synthetic process. In addition, a small chemical company located in New York has started production with a stated capacity of 10 kilograms per day and expects to increase its capacity to 50 kilograms per day. This company has not received an approval from the FDA to market the drug.

No statistics are available on U.S. consumption, production, or imports of L-Dopa. The eventual U.S. consumption may reach 2 million pounds annually, assuming that half of the estimated 1 million U.S. victims of Parkinsonism use the drug at a dosage level of 6 to 8 grams daily.

Your committee is informed that the wholesale price of a 1-month supply of the drug for a patient receiving 6 grams daily would range from $72 to $90—an amount which may be beyond the means of many, if not most, patients.

Several recent experimental reports indicate that it may eventually be possible to reduce the required maintenance dosage of L-Dopa by concomitant use of another drug having a potentiating or synergistic effect.

At present, there is a shortage of L-Dopa in the United States. Neither of the two firms presently authorized by the FDA to market L-Dopa could alone supply the needs of the estimated 1 million U.S. victims of Parkinsonism. The foreign-owned firm which depends on domestic benzenoid intermediates has publicly announced its limited initial marketing will be sufficient to start about 75,000 patients on treatment. Both of the approved firms have been compelled by the

early shortages to limit L-Dopa distribution to physicians and hospitals currently treating Parkinson's disease patients. The American market will not be adequately served until all physicians may prescribe for their patients to purchase L-Dopa through the usual pharmaceutical wholesale and retail drugstores, and there is sufficient inventories to replenish this accustomed pipeline. This is not presently the case.

The Americans afflicted with Parkinson's disease require at least both of the presently authorized sources of L-Dopa. If the company which depends on an imported L-Dopa chemical (presently entering at a duty of 2.45 cents per pound plus 17 percent) cannot get the relief of the duty suspension, it may have to market L-Dopa at a price substantially higher than its foreign-owned competitor. This could create a serious cost disadvantage to the American company which might be forced to suspend production of L-Dopa, thus leaving the entire market solely to the foreign-owned company which has been approved by the FDA and which depends on domestic benzenoid production.

The foreign company presently does not have capacity to supply more than enough of the drug to take care of 75,000 patients, or 7.5 percent of the estimated 1 million Americans suffering from Parkinson's disease. Moreover, once authorized by the FDA, a source of supply may not be switched until the biological equivalence of the alternative supply is established. Establishing such biological equivalence is an extensive and expensive procedure for which guidelines have not yet been established for L-Dopa by the FDA. The patients currently being supplied by the American firm importing L-Dopa may be without this drug if that firm is forced to withdraw from the market because of competition from the foreign firm.

In view of these circumstances, your committee is convinced of the need to provide duty-free treatment of L-Dopa for a 2-year period.

Your committee has received favorable reports on H.R. 8512 from the Departments of Treasury, Commerce, Agriculture, State, and the special representative for trade negotiations as well as an informative report from the U.S. Tariff Commission.

Your committee believes that under the circumstances, suspension of the duty for a temporary period could result in a reduction in the cost of L-Dopa to patients.

Changes in Existing Law

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman).

TARIFF SCHEDULES OF THE UNITED STATES

APPENDIX TO THE TARIFF SCHEDULES

PART 1.—TEMPORARY LEGISLATION

Item	Articles	Rates of Duty		Effective period
		1	2	
*	* * *	*	*	*
	SUBPART B —TEMPORARY PROVISIONS AMENDING THE TARIFF SCHEDULES			
*	* * *	*	*	*
903.90	Istle, processed (provided for in item 192.70, part 15G, schedule 1)	Free	Free	On or before 9/5/72.
	Yarns, wholly of noncontinuous silk fibers (provided for in part 1D, schedule 3):			
905.30	Singles, not bleached and not colored, measuring over 58,800 yards per pound (item 308.40)	Free	Free	On or before 11/7/71.
905.31	Plied, not bleached and not colored, measuring over 29,400 yards per pound (item 308.50 and item 308.51)	Free	Free	On or before 11/7/71.
907.15	Aluminum oxide (alumina) (provided for in item 417.12, part 2C, schedule 4) when imported for use in producing aluminum	Free	Free	On or before 7/15/71.
907.30	Heptanoic acid (provided for in item 425.98, part 2D, schedule 4)	Free	Free	On or before 12/31/70.
907.45	*L-Dopa, however provided for in schedule 4*	*Free*	*No charge*	*The 2-year period beginning day after enactment of this item.*