

June 11, 1998

UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, DC 20436

MEMORANDUM TO THE COMMITTEE ON FINANCE OF THE UNITED STATES  
SENATE ON PROPOSED TARIFF LEGISLATION<sup>1</sup>

Bill no., sponsor, and sponsor's state: S. 1810 (105th Congress), Senator Roth (DE).

Companion bill: H. R. 3328 (105th Congress), Congressmen Neal & Meehan (MA).<sup>2</sup>

Title as introduced: To suspend temporarily the duty on a certain anti-HIV and anti-AIDS drug.

Summary of bill:<sup>3</sup>

This bill would temporarily suspend the duty on the active ingredient in the HIV drug SUSTIVA<sup>TM</sup> (efavirenz), or 6-Chloro-4-(cyclopropylethynyl)-1, 4-Dihydro-4-(trifluoromethyl)-2H-3, 1-benzoxazin-2-one (CAS No. 154598-52-4), provided for in HTS subheading 2934.90.30 through Dec. 31, 2000.

Effective date: The 15th day after enactment.

Retroactive effect: None.

Statement of purpose:

The sponsor stated in the *Congressional Record* that the active ingredient subject to this bill as found in the anti-HIV and anti-AIDS drug Sustiva<sup>TM</sup>, is a "breakthrough drug" for treating people with HIV and AIDS. He said that passage of the bill would help pharmaceutical firms like DuPont Merck lower its cost of production, and improve its competitiveness in assisting the nation's war against HIV and AIDS. He said that there is no production of this active drug ingredient in the United States other than small laboratory batch synthesis conducted by DuPont Merck for research.<sup>4</sup>

Background information was also provided by the petitioner, DuPont Merck Pharmaceuticals, through the firm's Federal Government Affairs office.<sup>5</sup>

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<sup>1</sup> Industry analyst: Raymond Cantrell (205-3362); attorney: Leo Webb (205-2599).

<sup>2</sup> *Congressional Record*, H. R. 3431, Mar. 10, 1998, p. H1021.

<sup>3</sup> See appendix A for definitions of tariff and trade agreement terms.

<sup>4</sup> *Congressional Record*, S. 1810, Mar. 23, 1998, p. S2429.

<sup>5</sup> Ms. Lynne O'Brien, DuPont Merck Pharmaceuticals, Federal Government Affairs Office, McLean, VA. The petitioner requested attachment of public information provided to the Commission in Appendix C.

Product description and uses:

6-Chloro-4-(cyclopropylethynyl)-  
1,4-dihydro-4-(trifluoro-methyl)-  
2H-3, 1-benzoxazin-2-one:

This chemical is the active pharmaceutical ingredient in the anti-viral drug, Sustiva™, or efavirenz. Sustiva is currently undergoing clinical trials designed to test its effectiveness in treating individuals infected with HIV-1. Sustiva has been shown to significantly inhibit HIV-1 reproduction in infected individuals when used in combination therapy with other anti-viral drugs. DuPont Merck, the discoverers of the anti-HIV pharmacological characteristics of this drug, are actively planning to introduce Sustiva on a commercial basis pending final FDA approval. In the interim, DuPont Merck is dispensing the drug free-of-charge to an estimated 3,000 infected patients in the United States, Canada and European Union (EU), under the provisions of the Sustiva Expanded Access Program.<sup>6</sup>

Tariff treatment:<sup>7</sup>

<u>Product</u>	<u>Col. 1-general</u>	
	<u>HTS subheading</u>	<u>rate of duty</u>
6-Chloro-4-(cyclopropylethynyl)- 1,4-dihydro-4-(trifluoro-methyl)- 2H-3, 1-benzoxazin-2-one.....	2934.90.30	6.6% ad valorem.

Structure of domestic industry (including competing products):

6-Chloro-4-(cyclopropylethynyl)-  
1,4-dihydro-4-(trifluoro-methyl)-  
2H-3, 1-benzoxazin-2-one:

During 1995-97, there was no known production of this chemical in the United States other than small laboratory quantities. The petitioner is not aware of any direct competitors to this product, which is used in treating patients infected with HIV-I. However, there are two drugs in the U.S. marketplace having similar anti-viral mechanisms to that of Sustiva: Viracept (Aouron Pharmaceuticals), and Viramune (Roxane Laboratories). The chemical synthesis of the final product consists of a complex multistep production process requiring specialized equipment and skills. Development of the process to make this product was performed through cooperative arrangements by DuPont Merck

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<sup>6</sup>Expanded access programs are a joint effort between the FDA, the Canadian Health Protection Branch and the U.S. pharmaceutical industry to provide investigational drugs prior to their approval for seriously ill patients with limited therapeutic options.

<sup>7</sup>See appendix B for column 1-special and column 2 duty rates.

with suppliers in Belgium, the United Kingdom, and Switzerland.

Private-sector views:

DuPont Merck is the only known global consumer and supplier of this newly discovered and unique pharmacologically active anti-viral synthetic organic material used for the suppression of HIV-I by those infected in the human population. Three organizations familiar with drugs that may potentially compete with Sustiva were contacted. As of this date, no written responses had been received.<sup>8</sup>

U.S. consumption:<sup>1</sup>

6-Chloro-4-(cyclopropylethynyl)-  
1,4-dihydro-4-(trifluoro-methyl)-  
2H-3, 1-benzoxazin-2-one:

	<u>1995</u>	<u>1996</u>	<u>1997</u>
	-----(\$Million)-----		
U.S. production.....	( <sup>1</sup> )	( <sup>1</sup> )	( <sup>1</sup> )
U.S. imports <sup>2</sup> .....	0.3	1.4	8.5
U.S. exports <sup>2</sup> .....	<0.1	<0.1	<0.1
Apparent U.S. consumption <sup>2</sup> ..	0.3	1.4	8.5

<sup>1</sup>Data are considered to be company proprietary information.

<sup>2</sup>Commission estimates.

Principal import sources: Belgium, Switzerland, and United Kingdom.

Principal export sources: Canada and EU countries.

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<sup>8</sup>Whitman-Walker Clinic, Ms. Kathleen McClure, Pharmacist, Washington, DC; Roxane Laboratories, Mr. Jim Heins, Manager Public Affairs; and, Agouron Pharmaceuticals, Ms. Joy Schmidt, Corp. Communications, LaJolla, CA.

Effect on customs revenues:

Future (1998-2000) effect:

<u>Product</u>	Estimated average annual <u>revenue loss</u> <sup>9</sup>		
	<u>1998</u>	<u>1999</u>	<u>2000</u>
	-----(\$1,000)-----		
6-Chloro-4-(cyclopropylethynyl)- 1,4-dihydro-4-(trifluoro-methyl)- 2H-3, 1-benzoxazin-2-one.....	285	>500	>500

Retroactive effect: None.

Technical comments:

The Commission recommends the chemical nomenclature subject to this bill be amended to conform with the official Chemical Abstract Services (CAS) Registry Number 154598-52-4, as follows:

2H-3, 1-Benzoxazin-2-one, 6-chloro-4-(cyclopropylethynyl)-1,4-dihydro-4-(trifluoromethyl)-.

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<sup>9</sup> Values shown are based on the Commission's knowledge of the current situation--FDA approval pending--and petitioner's belief that this drug will be approved for commercial use by FDA circa Jan. 1, 1999. Value shown for 1998 estimated based on petitioner's planned withdrawal of trial shipments from bonded, duty-free warehouse, approximating 5 to 8% of total stockpile. Commission estimates for 1999 and 2000 based on tariff rates currently in effect, 6.5% under provisions of the Uruguay Round GATT. However, the petitioner believes that current USTR/WTO negotiations to grant duty-free status for this product will result in the drug being added to the duty-free pharmaceutical index.

## APPENDIX A

### TARIFF AND TRADE AGREEMENT TERMS

In the **Harmonized Tariff Schedule of the United States** (HTS), chapters 1 through 97 cover all goods in trade and incorporate in the tariff nomenclature the internationally adopted Harmonized Commodity Description and Coding System through the 6-digit level of product description. Subordinate 8-digit product subdivisions, either enacted by Congress or proclaimed by the President, allow more narrowly applicable duty rates; 10-digit administrative statistical reporting numbers provide data of national interest. Chapters 98 and 99 contain special U.S. classifications and temporary rate provisions, respectively. The HTS replaced the **Tariff Schedules of the United States** (TSUS) effective January 1, 1989.

Duty rates in the **general** subcolumn of HTS column 1 are most-favored-nation (MFN) rates, many of which have been eliminated or are being reduced as concessions resulting from the Uruguay Round of Multilateral Trade Negotiations. Column 1-general duty rates apply to all countries except those enumerated in HTS general note 3(b) (Afghanistan, Cuba, Laos, North Korea, and Vietnam), which are subject to the statutory rates set forth in **column 2**. Specified goods from designated MFN-eligible countries may be eligible for reduced rates of duty or for duty-free entry under one or more preferential tariff programs. Such tariff treatment is set forth in the **special** subcolumn of HTS rate of duty column 1 or in the general notes. If eligibility for special tariff rates is not claimed or established, goods are dutiable at column 1-general rates. The HTS does not enumerate those countries as to which a total or partial embargo has been declared.

The **Generalized System of Preferences** (GSP) affords nonreciprocal tariff preferences to developing countries to aid their economic development and to diversify and expand their production and exports. The U.S. GSP, enacted in title V of the Trade Act of 1974 for 10 years and extended several times thereafter, applies to merchandise imported on or after January 1, 1976 and before the close of June 30, 1998. Indicated by the symbol "A", "A\*", or "A+" in the special subcolumn, the GSP provides duty-free entry to eligible articles the product of and imported directly from designated beneficiary developing countries, as set forth in general note 4 to the HTS.

The **Caribbean Basin Economic Recovery Act** (CBERA) affords nonreciprocal tariff preferences to developing countries in the Caribbean Basin area to aid their economic development and to diversify and expand their production and exports. The CBERA, enacted in title II of Public Law 98-67, implemented by Presidential Proclamation 5133 of November 30, 1983, and amended by the Customs and Trade Act of 1990, applies to merchandise entered, or withdrawn from warehouse for consumption, on or after January 1, 1984. Indicated by the symbol "E" or "E\*" in the special subcolumn, the CBERA provides duty-free entry to eligible articles, and reduced-duty treatment to certain other articles, which are the product of and imported directly from designated countries, as set forth in general note 7 to the HTS.

Free rates of duty in the special subcolumn followed by the symbol "IL" are applicable to products of Israel under the **United States-Israel Free Trade Area Implementation Act** of 1985 (IFTA), as provided in general note 8 to the HTS.

Preferential nonreciprocal duty-free or reduced-duty treatment in the special subcolumn followed by the symbol "J" or "J\*" in parentheses is afforded to eligible articles the product of designated beneficiary countries under the **Andean Trade Preference Act** (ATPA), enacted as title II of Public Law 102-182 and implemented by Presidential Proclamation 6455 of July 2, 1992 (effective July 22, 1992), as set forth in general note 11 to the HTS.

Preferential or free rates of duty in the special subcolumn followed by the symbol "CA" are applicable to eligible goods of Canada, and rates followed by the symbol "MX" are applicable to eligible goods of Mexico, under the **North American Free Trade Agreement**, as provided in general note 12 to the HTS and implemented effective January 1, 1994 by Presidential Proclamation 6641 of December 15, 1993. Goods must originate in the NAFTA region under rules set forth in general note 12(t) and meet other requirements of the note and applicable regulations.

Other special tariff treatment applies to particular **products of insular possessions** (general note 3(a)(iv)), **products of the West Bank and Gaza Strip** (general note 3(a)(v)), goods covered by the **Automotive Products Trade Act (APTA)** (general note 5) and the **Agreement on Trade in Civil Aircraft (ATCA)** (general note 6), **articles imported from freely associated states** (general note 10), **pharmaceutical products** (general note 13), and **intermediate chemicals for dyes** (general note 14).

The **General Agreement on Tariffs and Trade 1994** (GATT 1994), pursuant to the Agreement Establishing the World Trade Organization, is based upon the earlier GATT 1947 (61 Stat. (pt. 5) A58; 8 UST (pt. 2) 1786) as the primary multilateral system of disciplines and principles governing international trade. Signatories' obligations under both the 1994 and 1947 agreements focus upon most-favored-nation treatment, the maintenance of scheduled concession rates of duty, and national treatment for imported products; the GATT also provides the legal framework for customs valuation standards, "escape clause" (emergency) actions, antidumping and countervailing duties, dispute settlement, and other measures. The results of the Uruguay Round of multilateral tariff negotiations are set forth by way of separate schedules of concessions for each participating contracting party, with the U.S. schedule designated as Schedule XX.

Pursuant to the **Agreement on Textiles and Clothing (ATC)** of the GATT 1994, member countries are phasing out restrictions on imports under the prior "Arrangement Regarding International Trade in Textiles" (known as the **Multifiber Arrangement (MFA)**). Under the MFA, which was a departure from GATT 1947 provisions, importing and exporting countries negotiated bilateral agreements limiting textile and apparel shipments, and importing countries could take unilateral action in the absence or violation of an agreement. Quantitative limits had been established on imported textiles and apparel of cotton, other vegetable fibers, wool, man-made fibers or silk blends in an effort to prevent or limit market disruption in the importing countries. The ATC establishes notification and safeguard procedures, along with other rules concerning the customs treatment of textile and apparel shipments, and calls for the eventual complete integration of this sector into the GATT 1994 over a ten-year period, or by Jan. 1, 2005.

Rev. 8/12/97

**APPENDIX B**

**SELECTED PORTIONS OF THE  
HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES**

(Appendix not included in the electronic version of this report.)



## **APPENDIX C**

### **OTHER ATTACHMENTS**

(Appendix not included in the electronic version of this report.)

105TH CONGRESS  
2D SESSION

# S. 1810

To suspend temporarily the duty on a certain anti-HIV and anti-AIDS drug.

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IN THE SENATE OF THE UNITED STATES

MARCH 23, 1998

Mr. ROTH introduced the following bill; which was read twice and referred to  
the Committee on Finance

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## A BILL

To suspend temporarily the duty on a certain anti-HIV and  
anti-AIDS drug.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. TEMPORARY SUSPENSION OF DUTY.**

4       (a) IN GENERAL.—Subchapter II of chapter 99 of  
5       the Harmonized Tariff Schedule of the United States is  
6       amended by inserting in numerical sequence the following  
7       new heading:

“	9902.32.56	6-Chloro-4-(cyclopropylethynyl)-1, 4-Dihydro-4-(trifluoro-methyl)-2H-3, 1-benzoxazin-2-one (CAS No. 154598-52-4) (provided for in subheading 2934.90.30) .....	Free	No change	No change	On or before 12/31/2000	”.
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1           (b) **EFFECTIVE DATE.**—The amendment made by  
2 this section applies with respect to goods entered, or with-  
3 drawn from warehouse for consumption, on or after the  
4 15th day after the date of enactment of this Act.

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