

103<sup>D</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 1588

To amend the Internal Revenue Code of 1986 to impose a windfall profit tax on certain drugs for rare diseases or conditions if they become excessively profitable, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 1, 1993

Mr. STARK introduced the following bill; which was referred to the Committee on Ways and Means

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## A BILL

To amend the Internal Revenue Code of 1986 to impose a windfall profit tax on certain drugs for rare diseases or conditions if they become excessively profitable, and for other purposes.

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. WINDFALL PROFIT TAX ON PROFITS FROM**  
4 **DRUGS FOR RARE DISEASES OR CONDITIONS.**

5 (a) IN GENERAL.—Section 28 of the Internal Reve-  
6 nue Code of 1986 is amended by redesignating subsection  
7 (e) as subsection (f) and by inserting after subsection (d)  
8 the following new subsection:

1 “(e) WINDFALL PROFIT TAX.—

2 “(1) IN GENERAL.—If—

3 “(A) there is a windfall profit on any or-  
4 phan drug for any taxable year, and

5 “(B) any portion of such taxable year is  
6 within the exclusivity period for such drug,

7 the tax imposed by this chapter for such taxable  
8 year shall be increased by 75 percent of such wind-  
9 fall profit for such taxable year.

10 “(2) WINDFALL PROFIT.—For purposes of this  
11 subsection, the term ‘windfall profit’ means, with re-  
12 spect to any orphan drug, the excess of—

13 “(A) the gross revenues from sales during  
14 the taxable year of such drug, over

15 “(B) 125 percent of the sum of—

16 “(i) the cost of producing the drug  
17 sold during such year, and

18 “(ii) such year’s allocable share of the  
19 marketing costs of such drug.

20 “(3) NO TAX UNTIL RECOVERY OF TOTAL IN-  
21 VESTMENT IN DRUG DEVELOPMENT.—The gross rev-  
22 enues from the sale of an orphan drug shall be  
23 taken into account under paragraph (2) for any tax-  
24 able year only to the extent the aggregate of such  
25 revenues for the taxable year and all preceding tax-

1       able years exceed the development costs of such  
2       drug.

3           “(4) OTHER DEFINITIONS.—For purposes of  
4       this subsection—

5           “(A) DEVELOPMENT COSTS.—The term  
6       ‘development costs’ means, with respect to any  
7       orphan drug, the amount equal to the excess  
8       of—

9           “(i) the sum of the qualified clinical  
10       testing expenses and the qualified research  
11       expenses attributable to such drug for the  
12       period before the beginning of the exclusiv-  
13       ity period, over

14          “(ii) the aggregate amount received to  
15       develop such drug from Federal funds.

16          “(B) EXCLUSIVITY PERIOD.—The term  
17       ‘exclusivity period’ means the 7-year period re-  
18       ferred to in section 527(a) of the Federal Food,  
19       Drug, and Cosmetic Act.

20          “(C) ORPHAN DRUG.—The term ‘orphan  
21       drug’ means any drug for which an exclusivity  
22       period is granted.

23          “(5) PRORATION.—If only a portion of a tax-  
24       able year is within the exclusivity period, the wind-  
25       fall profit taken into account under this subsection

1 for such year shall be the amount which bears the  
2 same ratio to such profit for such year as such por-  
3 tion bears to the entire taxable year.

4 “(6) COORDINATION WITH OTHER CREDITS AND  
5 MINIMUM TAX.—Any increase in tax under this sub-  
6 section shall not be treated as a tax imposed by this  
7 chapter for purposes of—

8 “(A) determining the amount of any credit  
9 allowable under this chapter or

10 “(B) determining the amount of the mini-  
11 mum tax imposed by section 55.

12 “(7) 75 PERCENT TAX TO BE EXCLUSIVE  
13 TAX.—Gross income shall not include the amount of  
14 windfall profit taken into account under this sub-  
15 section for any taxable year.”

16 (b) EFFECTIVE DATE.—The amendment made by  
17 this section shall apply to amounts paid or incurred after  
18 December 31, 1992, in taxable years ending after such  
19 date.

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