## H. R. 626

To require persons who undertake federally funded research and development of drugs to enter into reasonable pricing agreements with the Secretary of Health and Human Services, and for other purposes.

## IN THE HOUSE OF REPRESENTATIVES

February 8, 1999

Mr. Sanders (for himself, Mr. DeFazio, Mr. Rohrabacher, Mr. Campbell, Mr. Allen, Mr. Nadler, Mr. Berry, Mrs. Thurman, Mrs. Jones of Ohio, Mr. Stark, Mr. Olver, Mr. Boucher, Mr. Kucinich, Mr. Luther, Mr. Waxman, Ms. Schakowsky, and Ms. Ros-Lehtinen) introduced the following bill; which was referred to the Committee on Commerce

## A BILL

To require persons who undertake federally funded research and development of drugs to enter into reasonable pricing agreements with the Secretary of Health and Human Services, 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. SHORT TITLE.
- 4 This Act may be cited as the "Health Care Research
- 5 and Development and Taxpayer Protection Act".

## 1 SEC. 2. REASONABLE PRICE AGREEMENT.

2	(a) In General.—If any Federal agency or any non-
3	profit entity undertakes federally funded health care re-
4	search and development and is to convey or provide a pat-
5	ent or other exclusive right to use such research and devel-
6	opment for a drug or other health care technology, such
7	agency or entity shall not make such conveyance or pro-
8	vide such patent or other right until the person who will
9	receive such conveyance or patent or other right first
10	agrees to a reasonable pricing agreement with the Sec-
11	retary of Health and Human Services or the Secretary
12	makes a determination that the public interest is served
13	by a waiver of the reasonable pricing agreement provided
14	in accordance with subsection (c).
15	(b) Consideration of Competitive Bidding.—In
16	cases where the Federal Government conveys or licenses
17	exclusive rights to federally funded research under sub-
	exclusive rights to federally funded research under sub- section (a), consideration shall be given to mechanisms for
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18	section (a), consideration shall be given to mechanisms for
18 19 20	section (a), consideration shall be given to mechanisms for determining reasonable prices which are based upon a
18 19	section (a), consideration shall be given to mechanisms for determining reasonable prices which are based upon a competitive bidding process. When appropriate, the mech-
18 19 20 21	section (a), consideration shall be given to mechanisms for determining reasonable prices which are based upon a competitive bidding process. When appropriate, the mechanisms should be considered where—
18 19 20 21 22	section (a), consideration shall be given to mechanisms for determining reasonable prices which are based upon a competitive bidding process. When appropriate, the mechanisms should be considered where—  (1) qualified bidders compete on the basis of

1	accordance with a cost based reasonable pricing for-
2	mula;

- 3 (3) qualified bidders compete on the basis of 4 the least period of time before prices are adjusted in 5 accordance with a cost based reasonable pricing for-6 mula;
- 7 (4) qualified bidders compete on the basis of 8 the shortest period of exclusivity; or
- 9 (5) qualified bidders compete under other com-10 petitive bidding systems.
- 11 Such competitive bidding process may incorporate require-
- 12 ments for minimum levels of expenditures on research,
- 13 marketing, maximum price, or other factors.
- 14 (c) Waiver shall take effect under sub-
- 15 section (a) before the public is given notice of the proposed
- 16 waiver and provided a reasonable opportunity to comment
- 17 on the proposed waiver. A decision to grant a waiver shall
- 18 set out the Secretary's finding that such a waiver is in
- 19 the public interest.

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