

105TH CONGRESS
1ST SESSION

S. 1299

To limit the authority of the Administrator of the Environmental Protection Agency and the Food and Drug Administration to ban metered-dose inhalers.

IN THE SENATE OF THE UNITED STATES

OCTOBER 21, 1997

Mr. HUTCHINSON (for himself and Mr. INHOFE) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To limit the authority of the Administrator of the Environmental Protection Agency and the Food and Drug Administration to ban metered-dose inhalers.

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 “Asthma Inhaler Regu-
5 latory Relief Act”.

6 **SEC. 2. LIMITATION ON AUTHORITY TO BAN METERED-**
7 **DOSE INHALERS.**

8 Neither the Administrator of the Environmental Pro-
9 tection Agency nor the Commissioner of the Food and

1 Drug Administration may prohibit the manufacture, dis-
2 tribution, or sale of metered-dose inhalers that use
3 chlorofluorocarbons unless the Administrator of the Envi-
4 ronmental Protection Agency and the Commissioner of the
5 Food and Drug Administration jointly certify to the Con-
6 gress that alternatives to such inhalers are available that,
7 for all populations of users of such inhalers, are com-
8 parable in terms of safety and effectiveness, therapeutic
9 indications, dosage strength, costs, and retail availability.

10 **SEC. 3. MORATORIUM ON FURTHER RULEMAKING.**

11 The Commissioner of the Food and Drug Administra-
12 tion shall withdraw the March 6, 1997, advance notice of
13 proposed rulemaking concerning chlorofluorocarbons in
14 metered-dose inhalers and shall not issue any other pro-
15 posal until after the 10th Meeting of the Parties to the
16 Montreal Protocol on Substances That Deplete the Ozone
17 Layer. Any subsequent proposal shall be in the form of
18 an advance notice of proposed rulemaking and shall be ini-
19 tiated only after extensive consultations with patients,
20 physicians, other health care providers, manufacturers of
21 metered-dose inhalers, and other stakeholders.

22 **SEC. 4. DEVELOPMENT OF STRATEGY.**

23 (a) IN GENERAL.—Following the 10th meeting of
24 Parties to the Montreal Protocol on Substances That De-
25 plete the Ozone Layer, but not later than January 30,

1 1999, the Commissioner of the Food and Drug Adminis-
2 tration shall publish a new advance notice of proposed
3 rulemaking, setting forth the initial strategy for facilitat-
4 ing the transition in the United States to metered-dose
5 inhalers that do not use chlorofluorocarbons.

6 (b) OBLIGATIONS UNDER MONTREAL PROTOCOL.—
7 The initial strategy developed under subsection (a) shall
8 be submitted by the Secretary of State to the Montreal
9 Protocol Secretariat by January 31, 1999, to fulfill United
10 States obligations under the Montreal Protocol decision
11 IX/14.

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