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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Asthma Inhaler Regulatory Relief Act''.

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

Neither the Administrator of the Environmental Protection Agency nor the Commissioner of the Food and

Drug Administration may prohibit the manufacture, distribution, or sale of metered-dose inhalers that use chlorofluorocarbons unless the Administrator of the Environmental Protection Agency and the Commissioner of the Food and Drug Administration jointly certify to the Congress that alternatives to such inhalers are available that, for all populations of users of such inhalers, are comparable in terms of safety and effectiveness, therapeutic indications, dosage strength, costs, and retail availability.

SEC. 3. MORATORIUM ON FURTHER RULEMAKING.

The Commissioner of the Food and Drug Administration shall withdraw the March 6, 1997, advance notice of proposed rulemaking concerning chlorofluorocarbons in metered-dose inhalers and shall not issue any other proposal until after the 10th Meeting of the Parties to the Montreal Protocol on Substances That Deplete the Ozone Layer. Any subsequent proposal shall be in the form of an advance notice of proposed rulemaking and shall be initiated only after extensive consultations with patients, physicians, other health care providers, manufacturers of metered-dose inhalers, and other stakeholders.

SEC. 4. DEVELOPMENT OF STRATEGY.

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

1999, the Commissioner of the Food and Drug Administration shall publish a new advance notice of proposed rulemaking, setting forth the initial strategy for facilitating the transition in the United States to metered-dose inhalers that do not use chlorofluorocarbons.

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

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