I

108TH CONGRESS
1ST SESSION

H. R. 2921

To prohibit the open-air cultivation of genetically engineered pharmaceutical and industrial crops, to prohibit the use of common human food or animal feed as the host plant for a genetically engineered pharmaceutical or industrial chemical, to establish a tracking system to regulate the growing, handling, transportation, and disposal of pharmaceutical and industrial crops and their byproducts to prevent human, animal, and general environmental exposure to genetically engineered pharmaceutical and industrial crops and their byproducts, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 25, 2003

Mr. KUCINICH (for himself, Mr. DEFAZIO, Mr. SANDERS, Ms. LEE, Mr. CONYERS, Mr. GUTIERREZ, Mr. NADLER, Mr. OWENS, Ms. VELÁZQUEZ, Ms. WATERS, Ms. WATSON, and Ms. WOOLSEY) introduced the following bill; which was referred to the Committee on Agriculture

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A BILL

To prohibit the open-air cultivation of genetically engineered pharmaceutical and industrial crops, to prohibit the use of common human food or animal feed as the host plant for a genetically engineered pharmaceutical or industrial chemical, to establish a tracking system to regulate the growing, handling, transportation, and disposal of pharmaceutical and industrial crops and their byproducts to prevent human, animal, and general environmental exposure to genetically engineered pharmaceutical and industrial crops and their byproducts, and for other purposes.

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 ''Genetically Engineered Pharmaceutical and Industrial Crop Safety Act of 2003''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) A pharmaceutical crop or industrial crop is a plant that has been genetically engineered to produce a medical or industrial product, including a human or veterinary drug, biologic, industrial, or research chemical, or enzyme.

(2) The Department of Agriculture has issued ''split approval'' permits to allow the cultivation of 10 food crops genetically engineered to produce biopharmaceuticals or chemicals that are not approved for human consumption. As of January 1, 2003, more than 300 field trials have been conducted in the United States. In nearly 70 percent of these tests, corn has been the crop used, but other crops tested include soybean, tobacco, rice, alfalfa, barley, rapeseed (canola), wheat, tomato, safflower, and sugercane.

(3) Many of the novel substances produced in pharmaceutical crops and industrial crops exhibit

high levels of biological activity and are intended to be used for particular medical or industrial purposes, under very controlled circumstances. None of these substances is intended to be incorporated in food or to be spread into the environment.

(4) The magnitude of the risks posed by pharmaceutical crops and industrial crops depends on many factors, including the chemicals involved, the organisms or environments exposed, and the level and duration of the exposure. Humans, animals, and the environment at large could be at risk from contamination, a major concern of which is that bioactive nonfood substances, which have not been tested, will contaminate or otherwise adversely affect the food supply. Substances intended for use as human drugs are especially problematic because they are intended to be biologically active in people.

(5) Pharmaceutical crops and industrial crops also pose substantial liability and other economic risks to farmers, grain handlers, food companies, and other persons in the food and feed supply chain. These risks include liability for contamination episodes, costly food recalls, losses in export markets, reduced prices for a contaminated food or feed crop, and loss of confidence in the safety of the American

food supply among foreign importers and consumers of American agricultural commodities.

(6) These risks necessitate a zero tolerance standard for the presence of pharmaceutical crops and industrial crops and their byproducts in crops used to produce human food or animal feed.

(7) While there presently exists a pro forma zero tolerance standard, the Department of Agriculture and experts in the field acknowledge that contamination of human food and animal feed is inevitable due to the inherent imprecision of biological and agricultural systems, as well as the laxity of the regulatory regime. This is illustrated, for example, in the Department of Agriculture's regulations, which aim not for prevention (recognized as unattainable), but rather mitigation of the gene flow that results in contamination of food/feed crops with these substances. Some experts in the field are calling for establishment of tolerances, despite the potential risks involved.

(8) Therefore, appropriate regulatory controls, as established by this Act, are urgently needed to ensure that pharmaceutical crops and industrial crops and their byproducts do not enter human food or animal feed crops at any level.

SEC. 3. DEFINITIONS.

In this Act:

(1) The term ''genetically engineered plant'' means a plant that contains a genetically engineered material or was produced from a genetically engineered seed. A plant shall be considered to contain a genetically engineered material if the plant has been injected or otherwise treated with a genetically engineered material (except that the use of manure as a fertilizer for the plant may not be construed to mean that the plant is produced with a genetically engineered material).

(2) The term ''genetically engineered material'' means material that has been altered at the molecular or cellular level by means that are not possible under natural conditions or processes (including recombinant DNA and RNA techniques, cell fusion, microencapsulation, macroencapsulation, gene deletion and doubling, introducing a foreign gene, and changing the positions of genes), other than a means consisting exclusively of breeding, conjugation, fermentation, hybridization, in vitro fertilization, tissue culture, or mutagenesis.

(3) The term ''genetically engineered seed'' means a seed that contains a genetically engineered material or was produced with a genetically engi-

neered material. A seed shall be considered to contain a genetically engineered material or to have been produced with a genetically engineered material if the seed (or the plant from which the seed is derived) has been injected or otherwise treated with a genetically engineered material (except that the use of manure as a fertilizer for the plant may not be construed to mean that any resulting seeds are produced with a genetically engineered material).

(4) The term ''pharmaceutical crop'' means a genetically engineered plant that is designed to produce medical products, including human and veterinary drugs and biologics. The term includes a crop intentionally treated with genetically engineered material that, in turn, produces a medical substance.

(5) The term ''industrial crop'' means a genetically engineered plant that is designed to produce industrial products, including industrial and research chemicals and enzymes. The term includes a crop intentionally treated with genetically engineered material that, in turn, produces an industrial substance.

SEC. 4. REGULATION OF PRODUCTION OF PHARMACEUTICAL CROPS AND INDUSTRIAL CROPS.

(a) TEMPORARY MORATORIUM PENDING REGULATIONS.—No pharmaceutical crop or industrial crop may

be grown, raised, or otherwise cultivated until the final regulations and tracking system required by this section are in effect.

(b) PROHIBITION ON OPEN-AIR CULTIVATION.—No person may grow, raise or otherwise cultivate a pharmaceutical crop or industrial crop in an open air environment.

(c) PROHIBITION ON USE OF COMMON HUMAN FOODS OR ANIMAL FEEDS.—No person may grow, raise, or otherwise cultivate a pharmaceutical crop or industrial crop in a food commonly used for human food or domestic animal feed.

(d) BIOTECH TRACKING SYSTEM.—The United States Department of Agriculture shall establish a tracking system to regulate the growing, handling, transportation, and disposal of all pharmaceutical and industrial crops and their byproducts to prevent contamination.

(e) REGULATIONS.—The Secretary of Agriculture shall issue regulations—

(1) to enforce the prohibitions imposed by subsections (b) and (c);

(2) to designate the common foods whose use as a source of a pharmaceutical crop or industrial crop is prohibited by subsection (c); and

(3) to establish the tracking system required by subsection (d).

SEC. 5. CIVIL PENALTIES FOR VIOLATION.

(a) AUTHORITY TO ACCESS PENALTIES.—The Secretary of Agriculture may assess, by written order, a civil penalty against a person that violates a provision of section 5, including a regulation promulgated or order issued under such section. Each violation, and each day during which a violation continues, shall be a separate offense.

(b) AMOUNT AND FACTORS IN ACCESSING PENALTIES.—The maximum amount that may be accessed under this section for a violation may not exceed $1,000,000. In determining the amount of the civil penalty, the Secretary shall take into account—

(1) the gravity of the violation;

(2) the degree of culpability;

(3) the size and type of the business; and

(4) any history of prior offenses under such section or other laws administered by the Secretary.

(c) NOTICE AND OPPORTUNITY FOR HEARING.—The Secretary shall not assess a civil penalty under this section against a person unless the company is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code.

(d) JUDICIAL REVIEW.—(1) An order assessing a civil penalty against a person under subsection (a) may be reviewed only in accordance with this subsection. The order shall be final and conclusive unless the person—

(A) not later than 30 days after the effective date of the order, files a petition for judicial review in the United States court of appeals for the circuit in which the person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia; and

(B) simultaneously sends a copy of the petition by certified mail to the Secretary.

(2) The Secretary shall promptly file in the court a certified copy of the record on which the violation was found and the civil penalty assessed.

(e) COLLECTION ACTION FOR FAILURE TO PAY ASSESSMENT.—If a person fails to pay a civil penalty after the order assessing the civil penalty has become final and unappealable, the Secretary shall refer the matter to the Attorney General, who shall bring a civil action to recover the amount of the civil penalty in United States district court. In the collection action, the validity and appropriateness of the order of the Secretary imposing the civil penalty shall not be subject to review.

SEC. 6. REPORT TO CONGRESS ON ALTERNATIVE METHODS TO PRODUCE PHARMACEUTICAL AND INDUSTRIAL CROPS.

The National Academy of Sciences shall submit to Congress a report that explores alternative methods to produce pharmaceuticals or industrial chemicals that have the advantage of being conducted in controlled production facilities and do not present the risk of contamination.

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