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108TH CONGRESS
2D SESSION

# H. R. 5155

To establish the National Institute for Biomedical Research and Development.

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IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2004

Mr. KUCINICH (for himself, Mr. OWENS, Mr. GRIJALVA, Mr. CONYERS, Ms. LEE, Mr. SERRANO, Mr. DAVIS of Illinois, and Mr. JACKSON of Illinois) introduced the following bill; which was referred to the Committee on Energy and Commerce

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# A BILL

To establish the National Institute for Biomedical Research and Development.

*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 ''Free Market Drug Act''.

**SEC. 2. FINDINGS.**

The Congress finds as follows:

(1) Prescription drugs are increasingly expensive and unaffordable for the patients that need them. The Congressional Budget Office estimates

that drug costs have risen at a 19.1 percent annual rate over the last eight years and projects that they will rise at a 10.1 percent rate annual over the next decade. Drug prices are far higher in the United States than in any other developed country because it is the only country that grants pharmaceutical companies a monopoly in the market, based on patent protection, without any corresponding restriction on prices.

(2) New pharmaceuticals are decreasing in number and quality. In 2002, 17 new drugs classified as new compounds were approved by the Food and Drug Administration (''FDA''), down from 24 in 2001 and 27 in 2000. The vast majority of new drugs are not breakthrough cures, but rather copycat drugs. According to the FDA, more than 70 percent of new drugs approved in the last decade do not constitute qualitative improvements over existing treatments.

(3) Pharmaceutical manufacturers have distorted the quality of drug research in many instances, such as with the drug Celebrex. Often due to the influence of the funding source, drug research has been shown to suffer from concealed and dis-

torted findings, bias, conflicts of interest, and secrecy.

**SEC. 3. ESTABLISHMENT OF NATIONAL INSTITUTE FOR BIOMEDICAL RESEARCH AND DEVELOPMENT.**

Part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end the following subpart:

''Subpart 19—National Institute for Biomedical Research and Development

''PURPOSE OF THE INSTITUTE

''SEC. 464z–1. (a) IN GENERAL.—The general purpose of the National Institute for Biomedical Research and Development (in this section referred to as the 'Institute') is to provide in accordance with this section for the development of drugs, biological products, and devices, including through Federal laboratories under subsection (f), in a manner that will foster an increase in the number and medical efficacy of drugs, biological products, and devices on the market and will make the drugs, biological products, and devices available to the public at reasonable prices.

''(b) IDENTIFICATION OF CANDIDATE DISCOVERIES.—The Director shall monitor the results of research conducted or supported by the National Institutes of Health, and by other appropriate public or private entities,

in order to identify discoveries that, if subjected to appropriate research and development activities, may be suitable for the submission of applications for approval by the Food and Drug Administration as drugs, biological products, or devices for use in humans (referred to in this section as 'candidate discoveries').

''(c) RESEARCH AND OTHER ACTIVITIES REGARDING CANDIDATE DISCOVERIES.—

''(1) IN GENERAL.—The Director of the Institute shall conduct and support research, training, the dissemination of information, and other programs toward identifying candidate discoveries and carrying out appropriate research and development activities regarding such discoveries.

''(2) ANNUAL PLAN.—The Director of the Institute shall establish, and annually review and as appropriate revise, a plan for the development, testing, and manufacture of candidate discoveries through the Institute.

''(3) AWARDS REGARDING RESEARCH AND DEVELOPMENT.—Each award of financial assistance under paragraph (1) for research and development activities shall be an award of a cooperative agreement or a contract.

''(4) PRIORITIES.—In allocating the resources of the Institute, the Director of the Institute shall establish priorities among candidate discoveries.

''(5) INTERNET SITE.—The Director of the Institute shall maintain an Internet site to make available to the public information on activities under this section, including activities carried out by the Director and activities carried out under cooperative agreements or contracts under paragraph (1). Information posted on such site shall be updated quarterly, or on such more frequent intervals as the Director determines to be appropriate. Such information shall include the following:

''(A) An identification of candidate discoveries that are receiving priority under paragraph (4).

''(B) All raw data developed under paragraph (1) in carrying out research and development activities.

''(C) Findings made in carrying out such activities.

''(d) PATENTS.—

''(1) IN GENERAL.—The Director may identify a discovery as a candidate discovery only if the Federal Government holds, or can reasonably be ex-

pected to obtain, a patent on the discovery. The Director may not transfer ownership of such patent to any non-Federal entity, notwithstanding any conflicting provision of chapter 18 of title 35, United States Code.

''(2) CITIZENS' SUITS FOR PROTECTION OF FEDERAL OWNERSHIP OF PATENTS.—

''(A) IN GENERAL.—Except as provided in subparagraph (C), any person may on his or her behalf commence a civil action in an appropriate district court of the United States against—

''(i) any person in order to protect Federal ownership of patents on candidate discoveries; or

''(ii) the Secretary where there is alleged a failure of the Secretary to protect Federal ownership of such patents.

''(B) RELIEF.—In a civil action under subparagraph (A), the district court involved may, as the case may be—

''(i) enforce the compliance of a person with provisions relating to Federal ownership of patents; or

"(ii) order the Secretary to perform an act or duty relating to such ownership.

"(C) LIMITATIONS.—

"(i) NOTICE TO SECRETARY.—A civil action may not be commenced under subparagraph (A)(i) prior to 60 days after the plaintiff has provided to the Secretary notice of the violation involved.

"(ii) RELATION TO ACTIONS OF SECRETARY.—A civil action may not be commenced under subparagraph (A)(ii) if the Secretary has commenced and is diligently prosecuting a civil action in a district court of the United States to protect the Federal ownership of the patent involved.

"(D) RIGHT OF SECRETARY TO INTERVENE.—In any civil action under subparagraph (A), the Secretary, if not a party, may intervene as a matter of right.

"(E) AWARD OF COSTS; FILING OF BOND.—In a civil action under subparagraph (A), the district court involved may award costs of litigation (including reasonable attorney and expert witness fees) to any party whenever the court determines such an award is appropriate.

The court may, if a temporary restraining order or preliminary injunction is sought, require the filing of a bond or equivalent security in accordance with the Federal Rules of Civil Procedure.

''(F) SAVINGS PROVISION.—This paragraph does not restrict any right that a person (or class of persons) may have under any statute or common law to seek enforcement of provisions relating to Federal ownership of patents on candidate discoveries, or to seek any other relief (including relief against the Secretary).

''(e) APPLICATION FOR APPROVAL BY FOOD AND DRUG ADMINISTRATION.—

''(1) IN GENERAL.—Each application submitted to the Food and Drug Administration for the approval of a candidate discovery, or for authorization to engage in investigational uses of the discovery, shall be submitted by the Director of the Institute or by a private entity. In the case of a private entity, such application shall be submitted pursuant to—

''(A) a cooperative agreement or contract between the Director of the Institute and the private entity; and

''(B) a nonexclusive license granted by the Director to the private entity for the commer-

cial marketing of the discovery, notwithstanding any conflicting provision of chapter 18 of title 35, United States Code.

''(2) INSTITUTE AS HOLDER OF APPROVED APPLICATION.—In the case of an application referred to in paragraph (1) that is submitted by the Director of the Institute and approved by the Food and Drug Administration, the Director, promptly after such approval, shall seek to provide to one or more appropriate private entities nonexclusive licenses for the commercial marketing of the candidate discovery involved, notwithstanding any conflicting provision of chapter 18 of title 35, United States Code.

''(f) FEDERAL LABORATORY SYSTEM.—

''(1) IN GENERAL.—The Director of the Institute shall carry out this section directly and through Federal laboratories established by the Director in accordance with paragraph (2).

''(2) CERTAIN REQUIREMENTS.—Subject to the extent of amounts made available in appropriations Acts, the Director shall establish 10 laboratories under paragraph (1). Each such laboratory shall be established within the National Institutes of Health, and shall be headed by an Associate Director, who shall be appointed by the Director of the Institute.

With respect to the location of the laboratories, the laboratories shall be equitably distributed among the various regions of the United States.

''(3) TEN-YEAR PERFORMANCE REVIEW.—Promptly after the expiration of the ten-year period beginning on the date on which a Federal laboratory under paragraph (2) becomes operational (as determined by the Director), and every ten years thereafter, the Director of the Institute shall provide for a comprehensive review of the performance of the laboratory. The Director may, for good cause found pursuant to such a review, terminate the laboratory. If the laboratory is terminated, the Director of the Institute shall transfer the duties of the laboratory, and the funds and other assets of the laboratory, to the remaining laboratories under paragraph (2), and shall transfer within the Institute the officers and employees of the laboratory, or otherwise provide for the disposition of such officers and employees in accordance with applicable law.

''(g) REWARDS FOR SIGNIFICANT ADVANCES.—The Director of the Institute shall establish a fund, consisting of amounts reserved under subsection (i)(2), from which the Director may provide cash awards to individuals or organizations that, in carrying out research and develop-

ment activities under subsection (c), make significant advances in knowledge regarding a disease, disorder, or other health condition, including new treatments or diagnostic techniques.

''(h) DEFINITIONS.—For purposes of this section:

''(1) The term 'biological product' has the meaning that applies under section 351.

''(2) The terms 'drug' and 'device' have the meanings given such terms under section 201 of the Federal Food, Drug, and Cosmetic Act.

''(i) FUNDING.—

''(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $19,930,000,000 for fiscal year 2004, $20,400,000,000 for fiscal year 2005, $20,910,000,000 for fiscal year 2006, $21,430,000,000 for fiscal year 2007, and $21,970,000,000 for fiscal year 2008.

''(2) REWARDS FOR SIGNIFICANT ADVANCES.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Director of the Institute shall reserve $50,000,000 for the fund under subsection (g).''.

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