I

108TH CONGRESS
1ST SESSION

H. R. 2544

To improve the quality, availability, diversity, personal privacy, and innovation of health care in the United States.

IN THE HOUSE OF REPRESENTATIVES

JUNE 19, 2003

Mr. ROHRABACHER introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committees on Energy and Commerce, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To improve the quality, availability, diversity, personal privacy, and innovation of health care in the United States.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medical Independence, Privacy, and Innovation Act of 2003''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—TAX-RELATED PROVISIONS

SEC. 101. FINDINGS.

The Congress finds the following:

(1) Current law confers tax benefits for health insurance provided as an employee fringe benefit, but no similar tax benefit for health insurance purchased by individuals thus creating an unfair bias toward employer provided medical insurance plans and an unfair discrimination against individuals who seek marketplace alternatives to health insurance.

(2) Current law confers a tax benefits for third party payment of medical expenses but no similar tax benefits for direct individual payment of medical expenses. This has promoted employer-provided

third party payment systems and discouraged direct doctor-patient relationships.

(3) The current tax treatment of medical expenses has resulted in a greatly distorted marketplace in medical insurance where decreased opportunities for private personal health insurance has reduced competition both for medical insurance and health care services. This has resulted in an increased costs of both health insurance and health care services and fostered over use of low high premium health insurance plans.

(4) The current tax treatment of medical expenses has restricted the freedom of individuals to exercise direct control over their health care dollars. The exclusion from gross income for employer-provided health care with no corresponding tax benefit for health insurance and health care costs bourn by individuals represents a strong incentive toward employers group plans.

(5) The tax codes preferment of employer-provided group plans has triggered a marketplace response reflected in the significant increases in large health care delivery, and the creation of a relative few health care conglomerates in lieu of thousands of competitive providers of medical insurance and

services. This has increasingly placed medical decisions in the hands of health care bureaucracies and has eroded doctor-patient relationships.

(6) The role of the marketplace in both medical insurance and medical services should be strengthened. The discriminatory tax policies in the area of health insurance and health care should be ended. Private individuals should be able to contract for their health insurance and health care delivery in atmosphere free of discriminatory tax pressures. High deductible low premium as well as catastrophic alternatives in health insurance should be viable options for all Americans.

SEC. 102. DEDUCTION OF MEDICAL EXPENSES FOR INDIVIDUALS.

(a) IN GENERAL.—Subsection (a) of section 213 of the Internal Revenue Code of 1986 (relating to treatment of medical, dental, etc., expenses) is amended to read as follows:

''(a) ALLOWANCE OF DEDUCTION.—There shall be allowed as a deduction the expenses paid during the taxable year, not compensated for by insurance or otherwise, for medical care of the taxpayer, his spouse, or a dependent (as defined by section 152).''.

(b) DEDUCTION ALLOWED IN COMPUTING ADJUSTED GROSS INCOME.—Subsection (a) of section 62 of such Code is amended by inserting after paragraph (18) the following new paragraph:

''(19) MEDICAL CARE.—The deduction allowed by section 213.''.

(c) CONFORMING AMENDMENTS.—

(1) Section 56(b)(1) of such Code is amended by striking subparagraph (B).

(2) Section 67(b) is amended by striking paragraph (5).

(3) Section 72(t)(B) of such Code is amended by striking ''to the extent such distributions do not exceed the amount'' and inserting ''which are''.

(4) Sections 104(a) and 105(b) of such Code are both amended by striking ''(and not in excess of)''.

(d) EFFECTIVE DATE.— The amendments made by this section shall apply to taxable years beginning after December 31, 2003.

SEC. 103. MEDICAL CHECKING ACCOUNTS.

(a) IN GENERAL.—Subchapter F of chapter 1 of the Internal Revenue Code of 1986 (relating to exempt organizations) is amended by adding at the end the following:

"PART IX—MEDICAL CHECKING ACCOUNTS

"Sec. 530A. Medical checking accounts.

"SEC. 530A. MEDICAL CHECKING ACCOUNTS.

"(a) GENERAL RULE.—A medical checking account shall be exempt from taxation under this subtitle. Notwithstanding the preceding sentence, any medical checking account shall be subject to the taxes imposed by section 511 (relating to imposition of tax on unrelated business income of charitable, etc., organizations). Rules similar to the rules of paragraphs (2) and (4) of section 408(e) shall apply to medical checking accounts, and any amount treated as distributed under such rules shall be treated as not used to pay qualified medical expenses.

"(b) DEDUCTION FOR CONTRIBUTIONS.—

"(1) IN GENERAL.—In the case of an individual, there shall be allowed as a deduction an amount equal to the aggregate amount paid in cash during the taxable year to a medical checking account of the taxpayer.

"(2) LIMITATIONS.—

"(A) MAXIMUM ANNUAL CONTRIBUTION.—The deduction under paragraph (1) for a taxable year shall not exceed $1,000 ($2,000 in the case of a joint return).

"(B) MAXIMUM ALLOWABLE DEDUCTION BASED ON BALANCE IN ACCOUNT.—No deduc-

tion shall be allowed for a taxable year for any amount contributed to a medical checking account if the sum of such amount plus the balance in the account determined as the end of the taxable year would exceed $2,000 ($4,000 in the case of married individuals filing a joint return, a surviving spouse, and a head of household).

''(c) CREDIT FOR CONTRIBUTIONS.—

''(1) IN GENERAL.—In the case of an individual, there shall be allowed as a credit against the tax imposed by this chapter for the taxable year an amount equal to the credit amount with respect to contributions made during the taxable year to the medical checking account of the taxpayer.

''(2) CREDIT AMOUNT.—For purposes of paragraph (1), the credit amount is the lesser of—

''(A) the total amount of contributions to the medical checking account for the taxable year reduced by the amount of contributions allowed as a deduction under subsection (b), and

''(B) $1,000.

''(d) DEFINITIONS AND SPECIAL RULES.—For purposes of this section—

''(1) MEDICAL CHECKING ACCOUNT.—The term 'medical checking account' means a trust created or organized in the United States for the exclusive benefit of a qualified individual or his beneficiaries, but only if the written governing instrument creating the trust meets the following requirements:

''(A) Except in the case of a rollover contribution described in paragraph (4)(C), no contribution will be accepted unless it is in cash, or it exceeds $1,000 ($2,000 in the case of married individuals filing a joint return, a surviving spouse, and a head of household).

''(B) The trustee is a bank (as defined in section 408(n), an insurance company (as defined in section 816), or another person who demonstrates to the satisfaction of the Secretary that the manner in which such person will administer the trust will be consistent with the requirements of this section.

''(C) No part of the trust assets will be invested in life insurance contracts.

''(D) The assets of the trust will not be commingled with other property except in a common trust fund or common investment fund.

''(E) The interest of an individual in the balance in his account is nonforfeitable.

''(2) QUALIFIED MEDICAL EXPENSES.—The term 'qualified medical expenses' means, with respect to an account holder, amounts paid by such holder for medical care (as defined in section 213(d) for such individual, the spouse of such individual, and any dependent (as defined in section 152 of such individual, but only to the extent such amounts are not compensated for by insurance or otherwise (including distributions from an Archer MSA which are not includible in gross income by reason of section 220(f)(1)).

''(3) CHANGE IN FILING STATUS.—In the case of a taxpayer whose filing status changes during the taxable year, the limitation under subparagraph (B) shall be apportioned among the filing statuses of the taxpayer in accordance with regulations prescribed by the Secretary.

''(4) CERTAIN RULES TO APPLY.—Rules similar to the following rules shall apply for purposes of this section:

''(A) Section 219(d)(2) (relating to no deduction for rollovers).

''(B) Section 219(f)(3) (relating to time when contributions deemed made).

''(C) Section 219(f)(5) (relating to employer payments).

''(D) Section 220(f)(5) (relating to rollover contributions).

''(E) Section 220(f)(7) (relating to transfer of account incident to divorce).

''(F) Section 220(f)(8) (relating to treatment after death of account holder).

''(G) Section 408(g) (relating to community property laws).

''(H) Section 408(h) (relating to custodial accounts).

''(e) TAX TREATMENT OF DISTRIBUTIONS.—

''(1) AMOUNTS USED FOR QUALIFIED MEDICAL EXPENSES.—Any amount paid or distributed out of a medical checking account which is used exclusively to pay qualified medical expenses of any account holder shall not be includible in gross income.

''(2) INCLUSION OF AMOUNTS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—Any amount paid or distributed out of a medical checking account which is not used exclusively to pay the qualified

medical expenses of the account holder shall be included in the gross income of such holder.

''(3) ADDITIONAL TAX ON DISTRIBUTIONS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—For purposes of this section, rules similar to the rules of section 220(f)(4) shall apply.

''(4) COORDINATION WITH MEDICAL EXPENSE DEDUCTION.—For purposes of determining the amount of the deduction under section 213, any payment or distribution out of a medical checking account for qualified medical expenses shall not be treated as an expense paid for medical care.

''(f) REPORTS.—The Secretary may require the trustee of a medical checking account to make such reports regarding such account to the Secretary and to the account holder with respect to contributions, distributions, and such other matters as the Secretary determines appropriate. The reports required by this subsection shall be filed at such time and in such manner and furnished to such individuals at such time and in such manner as may be required by the Secretary.''.

(b) TAX ON EXCESS CONTRIBUTIONS.—Section 4973 of such Code (relating to tax on excess contributions to individual retirement accounts, certain section 403(b) con-

tracts, and certain individual retirement annuities) is amended—

(1) in subsection (a) by striking ''or'' at the end of paragraph (3), by inserting ''or'' at the end of paragraph (4), and by inserting after paragraph (4) the following:

''(5) a medical checking account (within the meaning of section 530A(d)),'', and

(2) by adding at the end the following new subsection:

''(g) EXCESS CONTRIBUTIONS TO MEDICAL CHECKING ACCOUNTS.—For purposes of this section, in the case of medical checking accounts (within the meaning of section 530A(d)), the term 'excess contributions' means the sum of—

''(1) the aggregate amount contributed for the taxable year to the accounts (other than rollover contributions referred to in section 530A(d)(4)(C)) which is neither excludable from gross income under section 106(b) nor allowable as a deduction or credit under section 530A for such year, and

''(2) the amount determined under this subsection for the preceding taxable year, reduced by the sum of—

''(A) the distributions out of the accounts which were included in gross income under section 530A(e)(2), and

''(B) the excess (if any) of—

''(i) the sum of the maximum amount allowable as a deduction or credit under section 530A (determined without regard to section 106(b)) for the taxable year, over

''(ii) the amount contributed to the accounts for the taxable year.

For purposes of this subsection, any contribution which is distributed out of the medical savings account in a distribution to which section 530A(d)(4)(B) applies shall be treated as an amount not contributed.''.

(c) TAX ON PROHIBITED TRANSACTIONS.—

(1) Section 4975 of such Code (relating to tax on prohibited transactions) is amended by adding at the end of subsection (c) the following new paragraph:

''(6) SPECIAL RULE FOR MEDICAL CHECKING ACCOUNTS.—An individual for whose benefit a medical checking account (within the meaning of section 530A(d)) is established shall be exempt from the tax imposed by this section with respect to any trans-

action concerning such account (which would otherwise be taxable under this section) if, with respect to such transaction, the account ceases to be a medical checking account by reason of the application of section 530A(e)(2) to such account.''.

(2) Paragraph (1) of section 4975(e) of such Code is amended by striking ''or'' at the end of subparagraph (E), by redesignating subparagraph (F) as subparagraph (G), and by inserting after subparagraph (E) the following new subparagraph:

''(F) a medical checking account described in section 530A(d), or''.

(d) FAILURE TO PROVIDE REPORTS ON MEDICAL CHECKING ACCOUNTS.—Paragraph (2) of section 6693(a) (relating to general rule on reports) is amended by striking ''and'' at the end of subparagraph (C), by striking the period at the end of subparagraph (D) and inserting '', and'', and by inserting after subparagraph (D) the following new subparagraph:

''(E) section 530A(g) (relating to medical savings accounts).''.

(e) CLERICAL AMENDMENT.—The table of parts for subchapter F of chapter 1 of such Code is amended by adding at the end the following new item:

''PART IX. MEDICAL CHECKING ACCOUNTS.''.

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2003.

SEC. 104. DECREASE IN MINIMUM ANNUAL DEDUCTIBLES UNDER A HIGH DEDUCTIBLE HEALTH PLAN FOR PURPOSES OF ARCHER MSAS.

(a) IN GENERAL.—Subparagraph (A) of section 220(c)(2) of the Internal Revenue Code of 1986 (defining high deductible health plan) is amended—

(1) in clause (i) by striking ''$1,500'' and inserting ''$1,000'', and

(2) in clause (ii) by striking ''$3,000'' and inserting ''$2,000''.

(b) MINIMUM NOT INCREASED BY INFLATION.—Section 220(g) of such Code is amended by inserting ''(other than the $1,000 amount in subparagraph (A)(i) and the $2,000 amount in subparagraph (A)(ii) thereof)'' after ''subsection (c)(2)''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2003.

TITLE II—MEDICAL PRIVACY

SEC. 201. FINDINGS.

The Congress finds the following:

(1) Medical privacy is an issue that concerns a growing number of people in the United States. The culture of the United States has always strongly favored a close physician-patient relationship. One of the key elements of this relationship is the trust that a patient has that their personal information will be treated as confidential by medical personnel and will not be made public or accessible to other persons without their permission.

(2) In our increasingly complex times, two trends are combining to exert pressure on maintaining the confidentiality of health care information. First, public policy favors an increased ability to provide protection against harmful prescription interactions and for the reporting of medications' serious side effects. Second, health care insurers desire to take advantage of economies of scale in controlling health care costs. These trends have greatly reduced expectations for the privacy of health care information.

(3) For the first time in our Nation's history, serious loopholes have been written into privacy protections that were created to protect the right of individuals. Positive changes in privacy law have been made in recent years to guarantee that patients are

notified regarding the use of their health information, have access to their own medical records, and are able to request corrections of such records. These protections must be maintained and strengthened.

(4) One of the greatest needs in the area of health privacy is to protect individuals against the use of their confidential health information for profit-generating consumer marketing. Patients justifiably have objections to this use of their information without their consent.

(5) There recently have been implemented a series of alarming modifications to the standards previously finalized to protect the privacy of individually identifiable health information. These include changes in important definitions, additions to the category of health care operations for which patient consent for the use of their information is not required, and changes in permitted use of patient information without consent for public health purposes.

(6) Recent rollbacks in health privacy need to be reversed, and the individuals' confidence that their private conversations with medical personnel will remain private needs to be strengthened.

(7) There is also a need to protect the integrity and confidentiality of social security account numbers and to prohibit Federal agencies from imposing national standards for identification of individuals.

SEC. 202. MODIFICATION OF REGULATIONS ON PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.

(a) MARKETING.—

(1) IN GENERAL.—The modifications made by the August 2002 medical privacy rule to the definition of the term ''marketing'' in section 164.501 of title 45, Code of Federal Regulations, shall have no force or effect.

(2) AUTHORIZATIONS FOR MARKETING.—Section 164.508 of title 45, Code of Federal Regulations, shall be construed and applied so as to require that, if an authorization is required for a use or disclosure of protected health information for marketing, the authorization shall be considered invalid unless it—

(A) uses the term ''marketing'';

(B) states that the purpose of the use or disclosure involved is marketing; and

(C) describes the specific marketing uses and disclosures authorized.

(b) CONSENT FOR USES OR DISCLOSURES TO CARRY OUT TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS.—

(1) IN GENERAL.—The modifications made to section 164.506 of title 45, Code of Federal Regulations, by the August 2002 medical privacy rule shall have no force or effect.

(2) USE OR DISCLOSURE WITHOUT CONSENT.—

(A) IN GENERAL.—Section 164.506 of title 45, Code of Federal Regulations, insofar as it permits any use or disclosure of protected health information without consent, shall have no force or effect.

(B) CIRCUMSTANCES WHERE CONSENT NOT REQUIRED.—A health care provider may use or disclose an individual's protected health information without obtaining the prior consent of the individual only in the following circumstances:

(i) To fill or dispense a prescription, and to search for drug interactions related to that prescription, if the health care provider obtains written consent from the individual as soon as practicable.

(ii) To carry out treatment of that individual if—

(I) the individual has not executed a Universal Health Privacy Declaration promulgated under subparagraph (C);

(II) the individual and the health care provider have not had in-person communication regarding such treatment; and

(III) obtaining consent would be impracticable.

(C) UNIVERSAL HEALTH PRIVACY DECLARATION.—

(i) IN GENERAL.—The Secretary of Health and Human Services shall promulgate a document which shall be known as the ''Universal Health Privacy Declaration''.

(ii) ELIGIBILITY.—A Universal Health Privacy Declaration may be executed by any individual who is a citizen of the United States or an alien lawfully admitted to the United States for permanent residence.

(iii) PURPOSE.—A Universal Health Privacy Declaration, once executed by an individual described in clause (ii) and not revoked, shall be considered to prohibit, as provided under subparagraph (B), a health care provider from using or disclosing the individual's protected health information for treatment without obtaining the prior consent of the individual.

(iv) ENFORCEMENT.—There is established in the Department of Health and Human Services an Office of the Health Privacy Ombudsman, which shall be headed by an individual known as the ''Health Privacy Ombudsman''. The Health Privacy Ombudsman shall be charged with investigating complaints submitted by individuals described in clause (ii) regarding a use or disclosure of protected health information in violation of their Universal Health Privacy Declaration.

(c) DISCLOSURES FOR LAW ENFORCEMENT PURPOSES.—Subparagraph (C) of section 164.506(f)(1)(ii) of title 45, Code of Federal Regulations shall have no force or effect.

(d) DEFINITIONS.—

(1) IN GENERAL.—For purposes of this section:

(A) DECEMBER 2000 MEDICAL PRIVACY RULE.—The term ''December 2000 medical privacy rule'' means the final rule on standards for privacy of individually identifiable health information published on December 28, 2000, in the Federal Register (65 Fed. Reg. 82462), including the provisions of title 45, Code of Federal Regulations, revised or added by such rule.

(B) AUGUST 2002 MEDICAL PRIVACY RULE.—The term ''August 2002 medical privacy rule'' means the final rule, published on August 14, 2002, in the Federal Register (67 Fed. Reg. 53182), that modified the December 2000 medical privacy rule.

(2) OTHER TERMS DEFINED.—For purposes of this section:

(A) HEALTH CARE PROVIDER.—The term ''health care provider'' shall have the meaning given such term in section 160.103 of title 45, Code of Federal Regulations, as contained in the December 2000 medical privacy rule.

(B) DISCLOSURE; INDIVIDUAL; PROTECTED HEALTH INFORMATION; TREATMENT; USE.—

The terms ''disclosure'', ''individual'', ''protected health information'', ''treatment'', and ''use'' shall have the meaning given such terms in section 164.501 of title 45, Code of Federal Regulations, as contained in the December 2000 medical privacy rule.

TITLE III—MODIFICATIONS REGARDING REGULATION OF DRUGS UNDER FEDERAL FOOD, DRUG, AND COSMETIC ACT

SEC. 301. DEFINITION OF DRUG.

Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)) is amended in the first sentence by striking ''and (B) articles intended'' and all that follows and inserting the following: ''and (B) articles intended for use in the diagnosis, cure, or treatment (but not mitigation or prevention) of disease in man or other animals.''.

SEC. 302. STRIKING OF EFFECTIVENESS REQUIREMENT; MODIFICATIONS REGARDING PATENT LISTINGS, PATENT CERTIFICATIONS, AND THIRTY-MONTH RULE.

(a) STRIKING OF EFFECTIVENESS REQUIREMENT; PROHIBITION AGAINST LISTING OF CERTAIN PATENTS.—

(1) IN GENERAL.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by striking ''(b)(1)'' and all that follows through ''clinical trials required by clause (A).'' and inserting the following:

''(b) APPLICATION.—

''(1) CONTENTS.—

''(A) IN GENERAL.—Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application—

''(i) full reports of investigations which have been made to show whether or not such drug is safe for use;

''(ii) a full list of the articles used as components of such drug;

''(iii) a full statement of the composition of such drug;

''(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

"(v) such samples of such drug and of the articles used as components thereof as the Secretary may require; and

"(vi) specimens of the labeling proposed to be used for such drug.

"(B) PATENT INFORMATION.—

"(i) REQUIREMENT.—The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture use, or sale of the drug.

"(ii) TYPES OF PATENTS.—

"(I) PATENTS SUBJECT TO REQUIREMENT.—The patents for which information under clause (i) is required to be filed with the Secretary are drug substance (ingredient) patents, drug product (formulation and composition) patents, product by proc-

ess patents, and method of use patents.

"(II) PROHIBITION REGARDING CERTAIN PATENTS.—Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not patents described in subclause (I), and information on such patents may not be filed with the Secretary.

"(III) PATENT REGARDING DRUG SUBSTANCE.—For patents that claim the drug substance, the applicant shall submit information only on patents that claim the drug substance that is the subject of the pending or approved application or that claim a drug substance that is the same as the active ingredient that is the subject of an approved or pending application within the meaning of subsection (j)(2)(A)(ii).

"(IV) PATENT REGARDING DRUG PRODUCT.—For patents that claim a drug product, the applicant shall sub-

mit information only on those patents that claim a drug product that is the subject of a pending or approved application.

"(V) PATENT REGARDING METHOD OF USE.—For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use that are the subject of a pending or approved application. For approved applications, the applicant shall identify the indication or other condition of use in the approved labeling that corresponds to the listed patent and claim identified.

"(iii) FILING OF PATENT AFTER SUBMISSION OF APPLICATION.—If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by clauses (i) and (ii).

''(iv) PUBLICATION OF PATENT INFORMATION.—Upon approval of the application, the Secretary shall publish information submitted under clauses (i) through (iii).

''(C) GUIDANCE REGARDING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL TRIALS.—The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by subparagraph (A)(i).''.

(2) CONFORMING AMENDMENTS.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(A) in section 201(p)—

(i) by striking ''safety and effectiveness of'' and inserting ''safety of''; and

(ii) by striking ''safe and effective for use'' and inserting ''safe for use''; and

(B) in section 505—

(i) by striking ''safety and effectiveness'' each place such term appears and inserting ''safety'';

(ii) by striking ''safety or effectiveness'' each place such term appears and inserting ''safety''; and

(iii) in subsection (i)(1)(D), by striking ''pediatric safety and efficacy'' and inserting ''pediatric safety''.

(b) ABBREVIATED APPLICATIONS; SINGLE CERTIFICATION REGARDING PATENT INVALIDITY OR NONINFRINGEMENT; SINGLE THIRTY-MONTH DELAY IN APPROVAL.—Section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)) is amended in the matter after and below clause (viii) by adding at the end the following sentence: ''With respect to a certification under clause (vii)(IV), an abbreviated application (whether or not amended) may not contain more than one such certification, without regard to patents filed after the date of the certification.''.

SEC. 303. GRANTING OF EXCLUSIVE OR PARTIALLY EXCLUSIVE LICENSES REGARDING INVENTIONS MADE WITH FEDERAL ASSISTANCE.

No grant of an exclusive or partially exclusive license pursuant to chapter 18 of title 35, United States Code,

may be made, except in accordance with section 209 of such title (relating to the availability to the public of an invention and its benefits on reasonable terms).

SEC. 304. IMPORTATION OF CERTAIN DRUGS.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:

''IMPORTATION OF CERTAIN DRUGS

''SEC. 804. (a) REGULATIONS.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from foreign nations.

''(b) LIMITATION.—The regulations under subsection (a) shall require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 (including being safe for the intended use of the prescription drug) with sections 501 and 502 and with other applicable requirements of this Act.''.

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