

MEDICARE MODERNIZATION AND PRESCRIPTION DRUG
ACT OF 2002 (SECTION 911: INTERNET PHARMACIES)

JUNE 26, 2002.—Committed to the Committee of the Whole House on the State of
the Union and ordered to be printed

Mr. TAUZIN, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany H.R. 4990]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4990) to amend the Federal Food, Drug, and Cosmetic Act to establish requirements with respect to the sale of, or the offer to sell, prescription drugs through the Internet, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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PURPOSE AND SUMMARY

The purpose of H.R. 4990 is to amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to establish requirements with respect to the sale of, or the offer to sell, prescription drugs through the Internet. The objective is to improve the ability of Federal and state oversight officials to eliminate “rogue” Internet websites illegally selling prescription drugs and provide integrity and disclosure for those who properly sell such drugs on the Internet. The bill provides for the disclosure of certain information on websites and to State licensing officials.

BACKGROUND AND NEED FOR LEGISLATION

The Internet holds great promise to help improve the delivery of health care, including the sale of prescription drugs. Proper use of this new tool may increase convenience, provide valuable information, reduce consumer costs, and provide for more personalized services. However, the Committee has found instances of, and potential for, adverse risks to consumers from unscrupulous parties selling prescription drugs over the Internet. Policing these sales is all the more difficult since websites can be created and removed quickly and the location of the seller is not always clear to the consumer. The problem is most acute with Internet sellers who operate across state boundaries. In the 106th Congress, after two Committee hearings then Chairman Tom Bliley, and other bipartisan cosponsors, introduced H.R. 5476, the Internet Prescription Drug Consumer Protection Act of 2000, during the 106th Congress. H.R. 4990 contains provisions from H.R. 5476.

The legislation would amend the FFDCA to require interstate Internet sellers of prescription drugs to post certain disclosure information. Where the interstate Internet seller is making referrals or solicitations on behalf of a prescriber, the seller would need to post certain information about the prescriber as well. Finally, the Internet seller would need to make certain disclosures to State licensing boards. Violations of these requirements would be enforceable under the FFDCA. The bill also provides for a public education program and further study.

HEARINGS

The Committee on Energy and Commerce has not held hearings on this legislation.

COMMITTEE CONSIDERATION

On Friday, June 21, 2002, the Full Committee met in open markup session and favorably ordered reported a Committee Print on Internet Pharmacies, by voice vote, a quorum being present. Chairman Tauzin then introduced H.R. 4990 to reflect the Committee’s action.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 4990 reported.

A motion by Mr. Tauzin to order H.R. 4990 reported to the House, without amendment, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The purpose of H.R. 4990 is to amend the Federal Food, Drug, and Cosmetic Act to establish requirements with respect to the sale of, or the offer to sell, prescription drugs through the Internet. The objective is to improve the ability of Federal and state oversight officials to eliminate “rogue” interstate Internet websites illegally selling prescription drugs and provide integrity and disclosure for those who properly sell such drugs on the Internet.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 4990, to amend the Federal Food, Drug, and Cosmetic Act to establish requirements with respect to the sale of, or the offer to sell, prescription drugs through the Internet, and for other purposes, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974, which is included in the report to accompany H.R. 4984.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 is included in the report to accompany H.R. 4984.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act. The estimate is included in the report to accompany H.R. 4984.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 911. Findings

Section 911 contains findings concerning both the benefits of Internet prescription drug sales and the potential for abuse of consumers by unlawful or unscrupulous parties through Internet prescription drug sales.

Section 912. Amendments to the Federal Food, Drug, and Cosmetic Act

Section 912 requires interstate Internet sellers of prescription drugs to disclose important information on their websites and to State licensing boards to improve the reliability of consumer transactions and make it easier for State and Federal enforcement officials to patrol for rogue sellers. The failure to post information or for knowingly making a false statement when posting information is prohibited.

Section 913. Public Education

Section 913 requires the Secretary to engage in activities to educate the public about the dangers of purchasing medications from Internet prescription drug sellers who fail to follow the law. The Secretary is also directed to educate the public about effective public and private sector consumer protection efforts, as appropriate.

Section 914. Study Regarding Coordination of Regulatory Activities

Section 914 requires that within 180 days of enactment, and after consultation with the Attorney General, the Secretary is required to submit to Congress a report providing recommendations for coordinating (1) the activities of federal agencies regarding interstate Internet sellers that operate from foreign countries, and (2) the activities of the Federal government with the activities of government of foreign countries regarding such interstate Internet sellers.

Section 915. Effective Date

Section 915 states that the sections in this subtitle shall take effect 1 year after enactment, except that the authority of the Secretary to commence rulemaking is effective on the date of enactment.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

* * * * *

(bb) *The failure to post information required under section 503B(b)(2) or for knowingly making a materially false statement when posting such information as required under such section or violating section 503B(b)(4).*

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CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

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SEC. 503B. INTERNET PRESCRIPTION DRUG SALES.

(a) *DEFINITIONS.—For purposes of this section:*

(1) *CONSUMER.—The term “consumer” means a person (other than an entity licensed or otherwise authorized under Federal or State law as a pharmacy or to dispense or distribute prescription drugs) that purchases or seeks to purchase prescription drugs through the Internet.*

(2) *HOME PAGE.—The term “home page” means the entry point or main web page for an Internet site.*

(3) *INTERNET.—The term “Internet” means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio, including electronic mail.*

(4) *INTERSTATE INTERNET SELLER.—*

(A) *IN GENERAL.*—The term “interstate Internet seller” means a person whether in the United States or abroad, that engages in, offers to engage in, or causes the delivery or sale of a prescription drug through the Internet and has such drug delivered directly to the consumer via the Postal Service, or any private or commercial interstate carrier to a consumer in the United States who is residing in a State other than the State in which the seller’s place of business is located. This definition excludes a person who only delivers a prescription drug to a consumer, such as an interstate carrier service.

(B) *EXEMPTION.*—With respect to the consumer involved, the term “interstate Internet seller” does not include a person described in subparagraph (A) whose place of business is located within 75 miles of the consumer.

(5) *LINK.*—The term “link” means either a textual or graphical marker on a web page that, when clicked on, takes the consumer to another part of the Internet, such as to another web page or a different area on the same web page, or from an electronic message to a web page.

(6) *PHARMACY.*—The term “pharmacy” means any place licensed or otherwise authorized as a pharmacy under State law.

(7) *PRESCRIBER.*—The term “prescriber” means an individual, licensed or otherwise authorized under applicable Federal and State law to issue prescriptions for prescription drugs.

(8) *PRESCRIPTION DRUG.*—The term “prescription drug” means a drug under section 503(b)(1).

(9) *VALID PRESCRIPTION.*—The term “valid prescription” means a prescription that meets the requirements of section 503(b)(1) and other applicable Federal and State law.

(10) *WEB SITE; SITE.*—The terms “web site” and “site” mean a specific location on the Internet that is determined by Internet protocol numbers or by a domain name.

(b) *REQUIREMENTS FOR INTERSTATE INTERNET SELLERS.*—

(1) *IN GENERAL.*—Each interstate Internet seller shall comply with the requirements of this subsection with respect to the sale of, or the offer to sell, prescription drugs through the Internet and shall at all times display on its web site information in accordance with paragraph (2).

(2) *WEB SITE DISCLOSURE INFORMATION.*—An interstate Internet seller shall post in a visible and clear manner (as determined by regulation) on the home page of its web site, or on a page directly linked to such home page—

(A) the street address of the interstate Internet seller’s place of business, and the telephone number of such place of business;

(B) each State in which the interstate Internet seller is licensed or otherwise authorized as a pharmacy, or if the interstate Internet seller is not licensed or otherwise authorized by a State as a pharmacy, each State in which the interstate Internet seller is licensed or otherwise authorized to dispense prescription drugs, and the type of State license or authorization;

(C) in the case of an interstate Internet seller that makes referrals to or solicits on behalf of a prescriber, the name

of each prescriber, the street address of each such prescriber's place of business, the telephone number of such place of business, each State in which each such prescriber is licensed or otherwise authorized to prescribe prescription drugs, and the type of such license or authorization; and

(D) a statement that the interstate Internet seller will dispense prescription drugs only upon a valid prescription.

(3) DATE OF POSTING.—Information required to be posted under paragraph (2) shall be posted by an interstate Internet seller—

(A) not later than 90 days after the effective date of this section if the web site of such seller is in operation as of such date; or

(B) on the date of the first day of operation of such seller's web site if such site goes into operation after such date.

(4) QUALIFYING STATEMENTS.—An interstate Internet seller shall not indicate in any manner that posting disclosure information on its web site signifies that the Federal Government has made any determination on the legitimacy of the interstate Internet seller or its business.

(5) DISCLOSURE TO STATE LICENSING BOARDS.—An interstate Internet seller licensed or otherwise authorized to dispense prescription drugs in accordance with applicable State law shall notify each State entity that granted such licensure or authorization that it is an interstate Internet seller, the name of its business, the Internet address of its business, the street address of its place of business, and the telephone number of such place of business.

(6) REGULATIONS.—The Secretary is authorized to promulgate such regulations as are necessary to carry out the provisions of this subsection. In issuing such regulations, the Secretary—

(A) shall take into consideration disclosure formats used by existing interstate Internet seller certification programs; and

(B) shall in defining the term "place of business" include provisions providing that such place is a single location at which employees of the business perform job functions, and not a post office box or similar locale.

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ADDITIONAL VIEWS

The major focus of this bill is to require that internet pharmacists and doctors make certain disclosures on their websites. The bill does not make irresponsible internet prescribing illegal, which is what state boards of medicine and pharmacy have requested in correspondence with the Secretary of Health and Human Services. The bill also does not provide for national injunctive authority for states, which Kansas Attorney General Carla Stovall has called "the most important tool the Federal government can give the States" on internet pharmacies.

An amendment was offered that would have solved both of these problems. It would have prevented web site operators (whether pharmacists, doctors or others) from arranging for an internet doctor to prescribe medication for a patient unless the doctor actually sees the patient. It would have had negligible impact on the regular practice of medicine, as doctors would only be subject to the law if they accept a payment from a pharmacy in exchange for a prescription or if they run an illicit internet pharmacy themselves. The amendment would also have provided for state enforcement power, including the opportunity to obtain a nationwide injunction.

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