

COUNTERFEIT DRUG PENALTY ENHANCEMENT ACT  
OF 2012

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JUNE 18, 2012.—Committed to the Committee of the Whole House on the State of  
the Union and ordered to be printed

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Mr. SMITH of Texas, from the Committee on the Judiciary,  
submitted the following

R E P O R T

[To accompany H.R. 3668]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill  
(H.R. 3668) to prevent trafficking in counterfeit drugs, having con-  
sidered the same, report favorably thereon with an amendment and  
recommend that the bill as amended do pass.

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**The Amendment**

Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

This Act may be cited as the “Counterfeit Drug Penalty Enhancement Act of  
2012”.

**SEC. 2. COUNTERFEIT DRUG PENALTY ENHANCEMENT.**

- (a) OFFENSE.—Section 2320(a) of title 18, United States Code, is amended—
- (1) by striking “or” at the end of paragraph (2);
  - (2) by inserting “or” at the end of paragraph (3);
  - (3) by inserting after paragraph (3) the following:
 

“(4) imports, exports, or traffics in a counterfeit drug;”, and
  - (4) by striking “through (3)” and inserting “through (4)”.
- (b) PENALTIES.—Section 2320(b)(3) of title 18, United States Code, is amended—
- (1) in the heading, by inserting “AND COUNTERFEIT DRUGS” after “SERVICES”; and
  - (2) by inserting “or counterfeit drug” after “service”.
- (c) DEFINITION.—Section 2320(f) of title 18, United States Code, is amended—
- (1) by striking “and” at the end of paragraph (4);
  - (2) by striking the period at the end of paragraph (5) and inserting “; and”; and
  - (3) by adding at the end the following:
 

“(6) the term ‘counterfeit drug’ has the meaning given that term in section 201 of the Federal Food, Drug, and Cosmetic Act.”
- (d) PRIORITY GIVEN TO CERTAIN INVESTIGATIONS AND PROSECUTIONS.—The Attorney General shall give increased priority to efforts to investigate and prosecute offenses under section 2320 of title 18, United States Code, that involve counterfeit drugs.

**Purpose and Summary**

H.R. 3668 makes certain enhancements to current Federal law, which criminalizes trafficking in counterfeit goods or services and use of a counterfeit mark on or in connection with such goods or services. This legislation expressly identifies the offense of trafficking counterfeit drugs and increases the penalties for persons who traffic in counterfeit drugs. This bill requires the Attorney General to give increased priority to efforts to investigate and prosecute counterfeit drug cases.

**Background and Need for the Legislation**

Current law prohibits trafficking in counterfeit goods. Section 2320 of title 18, United States Code, is primarily concerned with goods that are trafficked using counterfeit marks or labeling. However, counterfeit drugs are more serious. Counterfeit drugs present a real health risk to consumers and are not limited to a financial loss to the manufacturer or mark holder. While current law technically includes counterfeit drugs, the law does not expressly prohibit trafficking in counterfeit drugs and carries a maximum penalty of only 10 years.

In February 2012, drug manufacturer Roche announced that a counterfeit form of the cancer drug Avastin had been imported and distributed to doctors in the U.S. The counterfeit versions of the drug contained a variety of chemicals, ranging from starch and salt to solvent chemicals like acetone, but not the active ingredient found in the genuine drug. Law enforcement authorities in the United States and several foreign countries attempted to locate the source of the counterfeit drugs with limited success. It is unknown how many patients in the U.S. may have received useless cancer treatments when they were administered these counterfeit drugs.

Even with a 10 year maximum penalty, the actual sentences imposed under the existing counterfeit goods statute are dramatically lower. According to the U.S. Sentencing Commission, between FY 2006 and FY 2010, there were 385 Federal prosecutions for counterfeit goods (18 U.S.C. §2320). The median sentence was 17 months; the mean sentence was only 10 months.

### **Hearings**

The Committee on the Judiciary held a hearing on H.R. 3668 on March 28, 2012.

### **Committee Consideration**

On June 6, 2012, the Committee met in open session and ordered the bill H.R. 3668 favorably reported with an amendment, by voice vote, a quorum being present.

### **Committee Votes**

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the Committee advises that there were no recorded votes during the Committee's consideration of H.R. 3668.

### **Committee Oversight Findings**

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee advises that the findings and recommendations of the Committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

### **New Budget Authority and Tax Expenditures**

Clause 3(c)(2) of rule XIII of the Rules of the House of Representatives is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

### **Congressional Budget Office Cost Estimate**

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the Committee sets forth, with respect to the bill, H.R. 3668, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,  
CONGRESSIONAL BUDGET OFFICE,  
*Washington, DC, June 14, 2012.*

Hon. LAMAR SMITH, CHAIRMAN,  
*Committee on the Judiciary,  
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 3668, the "Counterfeit Drug Penalty Enhancement Act of 2012."

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Mark Grabowicz, who can be reached at 226-2860.

Sincerely,

DOUGLAS W. ELMENDORF,  
DIRECTOR.

Enclosure

cc: Honorable John Conyers, Jr.  
Ranking Member

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**H.R. 3668—Counterfeit Drug Penalty Enhancement Act  
of 2012.**

As ordered reported by the House Committee on the Judiciary  
on June 14, 2012.

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CBO estimates that implementing H.R. 3668 would have no significant costs to the Federal Government. Enacting the bill could affect direct spending and revenues; therefore, pay-as-you-go procedures apply. However, CBO estimates that any effects would be insignificant for each year.

H.R. 3668 would establish a new Federal crime for trafficking in counterfeit drugs. As a result, the government might be able to pursue cases that it otherwise would not be able to prosecute. CBO expects that H.R. 3668 would apply to a relatively small number of additional offenders, however, so any increase in costs for law enforcement, court proceedings, or prison operations would not be significant. Any such costs would be subject to the availability of appropriated funds.

Because those prosecuted and convicted under H.R. 3668 would be subject to criminal fines, the Federal Government might collect additional fines if the legislation is enacted. Criminal fines are recorded as revenues, deposited in the Crime Victims Fund, and later spent. CBO expects that any additional revenues and direct spending would not be significant because of the small number of additional cases likely to be affected.

H.R. 3668 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of State, local, or tribal governments.

On January 12, 2012, CBO transmitted a cost estimate for S. 1886, the Counterfeit Drug Penalty Enhancement Act of 2011, as reported by the Senate Committee on the Judiciary on December 8, 2011. The two pieces of legislation are similar and the cost estimates are the same.

The CBO staff contact for this estimate is Mark Grabowicz. The estimate was approved by Theresa Gullo, Deputy Assistant Director for Budget Analysis.

### **Performance Goals and Objectives**

The Committee states that pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, H.R. 3668 makes certain enhancements to Title 18, United States Code, Section 2320 which criminalizes trafficking in counterfeit goods or services and use of a counterfeit mark on or in connection with such goods or services.

### **Advisory on Earmarks**

In accordance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 3668 does not contain any congressional

earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(e), 9(f), or 9(g) of Rule XXI.

### Section-by-Section Analysis

The following discussion describes the bill as reported by the Committee.

#### *Sec. 1: Short Title.*

Section 1 provides that the short title of H.R. 3668 is the “Counterfeit Drug Penalty Enhancement Act of 2012.”

#### *Sec. 2: Counterfeit Drug Penalty Enhancement.*

Section 2 expressly identifies the offense of trafficking counterfeit drugs and increases the penalties for persons who traffic in counterfeit drugs. This section also requires the Attorney General to give increased priority to efforts to investigate and prosecute counterfeit drug cases.

### 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 (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

## SECTION 2320 OF TITLE 18, UNITED STATES CODE

### § 2320. Trafficking in counterfeit goods or services

(a) OFFENSES.—Whoever intentionally—

(1) \* \* \*

(2) traffics in labels, patches, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation, or packaging of any type or nature, knowing that a counterfeit mark has been applied thereto, the use of which is likely to cause confusion, to cause mistake, or to deceive, **[or]**

(3) traffics in goods or services knowing that such good or service is a counterfeit military good or service the use, malfunction, or failure of which is likely to cause serious bodily injury or death, the disclosure of classified information, impairment of combat operations, or other significant harm to a combat operation, a member of the Armed Forces, or to national security, *or*

(4) *imports, exports, or traffics in a counterfeit drug,* or attempts or conspires to violate any of paragraphs (1) **[through (3)]** *through (4)* shall be punished as provided in subsection (b).

(b) PENALTIES.—

(1) \* \* \*

\* \* \* \* \*

(3) COUNTERFEIT MILITARY GOODS OR SERVICES *AND COUNTERFEIT DRUGS*.—Whoever commits an offense under sub-

section (a) involving a counterfeit military good or service or counterfeit drug—

(A) \* \* \*

\* \* \* \* \*

(f) DEFINITIONS.—For the purposes of this section—

(1) \* \* \*

\* \* \* \* \*

(4) the term “counterfeit military good or service” means a good or service that uses a counterfeit mark on or in connection with such good or service and that—

(A) \* \* \*

(B) is intended for use in a military or national security application; **[and]**

(5) the term “traffic” means to transport, transfer, or otherwise dispose of, to another, for purposes of commercial advantage or private financial gain, or to make, import, export, obtain control of, or possess, with intent to so transport, transfer, or otherwise dispose of[.]; and

(6) the term “counterfeit drug” has the meaning given that term in section 201 of the Federal Food, Drug, and Cosmetic Act.

\* \* \* \* \*

