111TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
1st Session } { 111–49

DEXTROMETHORPHAN DISTRIBUTION ACT OF 2009

MARCH 24, 2009.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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

R E P O R T

[To accompany H.R. 1259]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1259) to amend the Federal Food, Drug, and Cosmetic Act with respect to the distribution of the drug dextromethorphan, 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. 1259, the "Dextromethorphan Distribution Act of 2009", is to prohibit a person from: (1) possessing or receiving unfinished dextromethorphan (DXM) unless the person is registered with the Secretary of Health and Human Services (HHS) as a producer of a drug or device or otherwise registered, licensed, or approved under federal or state law to engage in specified pharmaceutical activities; or (2) distributing unfinished DXM to any person other than a registered person or person otherwise registered, licensed, or approved under federal or state law to engage in specified pharmaceutical activities.

BACKGROUND AND NEED FOR LEGISLATION

Dextromethorphan is an over-the-counter (OTC) cough suppressant commonly found in more than 120 OTC cold medications either alone or in combination with other drugs such as analgesics, antihistamines, decongestants, or expectorants. When taken as directed, side effects are rarely observed.

However, DXM is abused by individuals of all ages, and its abuse by teenagers and young adults is of particular concern. The typical clinical presentation of DXM intoxication involves hyperexcitability, lethargy, ataxia, slurred speech, sweating, and hypertension. Abuse of combination DXM products also causes health complications that result from other active ingredients, such as potential delayed liver damage from acetaminophen, and central nervous system and cardiovascular toxicity from antihistamines. The use of high doses of DXM in combination with alcohol or other drugs is particularly dangerous, and deaths have been reported. This abuse is fueled by DXM's widespread availability and extensive "how to" abuse information on various web sites. The sale of the powdered form of DXM over the Internet poses additional risks due to the uncertainty of composition and dose.

The Food and Drug Administration (FDA) is particularly concerned about the abuse of dextromethorphan. In 2005, FDA issued an "FDA Talk Paper" warning against the abuse of DXM.

HEARINGS

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

COMMITTEE CONSIDERATION

The Committee on Energy and Commerce met in open markup session on Wednesday, March 4, 2009, and, pursuant to a motion by Mr. Waxman, agreed by unanimous consent to consider and approve H.R. 1259 and several other bills en bloc. H.R. 1259 was ordered favorably reported to the House by a voice vote. No amendments were offered during full Committee consideration of H.R. 1259.

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 re-

corded votes taken during consideration or ordering H.R. 1257 reported to the House.

COMMITTEE OVERSIGHT FINDINGS

Regarding clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the oversight findings of the Committee are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The purpose of H.R. 1259 is to restrict the distribution, possession, or receipt of the drug DXM to any person other than HHS-registered producers of drugs and devices, or persons registered, licensed, or approved under federal or state law to engage in specified pharmaceutical activities.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of budget authority and revenues regarding H.R. 1259 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. The Committee finds that H.R. 1259 would result in no new or increased entitlement authority or tax expenditures.

EARMARKS AND TAX AND TARIFF BENEFITS

In compliance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 1259 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

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.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, March 20, 2009.

Hon. HENRY A. WAXMAN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1259, the Dextromethorphan Distribution Act of 2009.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Julia Christensen.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 1259—Dextromethorphan Distribution Act of 2009

Summary: H.R. 1259 would restrict the distribution, receipt, and possession of unfinished dextromethorphan to entities registered with the Secretary of Health and Human Services (HHS) or otherwise allowed under certain federal or state laws. It also would deem the product to be adulterated in circumstances that violate the new requirements. Dextromethorphan is an active ingredient commonly found in cough medications available over-the-counter and is subject to abuse by some individuals (particularly teenagers and young adults). "Unfinished" dextromethorphan generally refers to the bulk powdered form of the raw product.

CBO estimates that implementing H.R. 1259 would cost $1 million in 2010 and $11 million over the 2010–2014 period, assuming the appropriation of the necessary amounts. Enacting the bill could affect direct spending and revenues, but we estimate that any such effects would not be significant.

Because those prosecuted and convicted of violating the bill's new requirements involving adulterated dextromethorphan could be subject to criminal fines, the federal government might collect additional fines if the legislation is enacted. Criminal fines are recorded as revenues, then deposited in the Crime Victims Fund and later spent. Such expenditures are classified as direct spending. CBO expects that any additional revenues and direct spending would not be significant because of the small number of cases likely to be affected.

H.R. 1259 would impose a mandate on the private sector as defined in the Unfunded Mandates Reform Act (UMRA) by restricting the distribution, possession, and receipt of unfinished dextromethorphan to entities registered with the Secretary of HHS or otherwise allowed under certain federal or state laws. It would also be the duty of the person selling unfinished dextromethorphan to confirm that the buyer is legally allowed to make the purchase. CBO estimates that the aggregate cost of complying with those mandates would not exceed the threshold established by UMRA for private-sector mandates ($139 million in 2009, adjusted annually for inflation). The bill contains no intergovernmental mandates as defined in UMRA and would not affect the budgets of state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated cost of H.R. 1259 is shown in the following table. The costs of this legislation primarily fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2010	2011	2012	2013	2014	2010–2014
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Estimated Authorization Level	1	2	2	3	4	12
Estimated Outlays	1	2	2	3	3	11

Basis of estimate: For this estimate, CBO assumes that H.R. 1259 will be enacted near the beginning of fiscal year 2010, that the necessary amounts will be appropriated each year, and that outlays will follow historical spending patterns for similar activities of the Food and Drug Administration (FDA). We estimate that implementing the bill would cost $11 million over the 2010–2014 period, assuming the appropriation of the necessary amounts. Enacting the legislation also could affect direct spending and revenues, but CBO estimates that any such effects would not be significant.

Spending subject to appropriation

H.R. 1259 would restrict the possession, receipt, and distribution of unfinished dextromethorphan to entities registered with the Secretary of HHS or otherwise allowed under certain federal or state laws (with specific exceptions). It also would amend the Federal Food, Drug, and Cosmetic Act to deem unfinished dextromethorphan to be adulterated when it is possessed, received, or distributed in violation of the new restrictions established under the bill.

CBO expects that FDA would be primarily responsible for administering the new registration requirements and related restrictions established under H.R. 1259. Following enactment, we expect that FDA would provide instruction to affected entities (such as chemical manufacturers) concerning how to comply with the bill's new requirements and that it would coordinate with other federal and state agencies that monitor or regulate dextromethorphan sales. We anticipate that ongoing administrative costs (mostly associated with enforcing the new requirements) would be roughly $2 million to $3 million annually. Based on information provided by FDA in 2007, 12 additional agency staff (based on full-time equivalents) might be necessary to administer and enforce the bill's new requirements. However, CBO expects that staffing would build up to such levels over several years.

Direct spending and revenues

Because those prosecuted and convicted of violating the bill's new requirements involving adulterated dextromethorphan could be subject to criminal fines, the federal government might collect additional fines if the legislation is enacted. Criminal fines are recorded as revenues, then deposited in the Crime Victims Fund and later spent. Such expenditures are classified as direct spending. CBO expects that any additional revenues and direct spending would not be significant because of the small number of cases likely to be affected.

Estimated impact on the private sector: H.R. 1259 would impose a private-sector mandate, as defined in UMRA, by restricting the distribution, possession, and receipt of unfinished dextromethorphan to entities registered with the Secretary of HHS or otherwise allowed under certain federal or state laws. However, CBO believes the mandate would affect relatively few entities. Many of them would be exempt from registration, such as pharmacies and non-commercial research institutions, and others would have already registered to deal with other chemical products. H.R. 1259 would also impose a duty on the person selling unfinished dextromethorphan to confirm that the buyer is legally allowed to

make the purchase. This verification process would require additional administrative work for sellers, but this cost would be negligible. CBO estimates that the direct cost of these mandates would be less than the annual threshold established in UMRA ($139 million in 2009, adjusted annually for inflation).

Estimated impact on state, local, and tribal governments: The bill contains no intergovernmental mandates as defined in UMRA and would not affect the budgets of state, local, or tribal governments.

Estimate prepared by: Federal costs: Julia Christensen; Impact on state, local, and tribal governments: Lisa Ramirez-Branum; Impact on the private sector: Keisuke Nakagawa.

Estimate approved by: Peter H. Fontaine, Assistant Director for Budget Analysis.

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.

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 1. Short title

Section 1 establishes the short title of the Act as the "Dextromethorphan Distribution Act of 2009".

Section 2. Restrictions on distribution of bulk dextromethorphan

Section 2 amends section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) to include unfinished DXM that is possessed, received, or distributed in violation of section 506D among the listing of adulterated drugs and devices. It further amends the Act by inserting a new section, 506D, which restricts the possession, receipt, and distribution of DXM.

Section 506D. Restrictions on distribution of bulk dextromethorphan

Section 506D prohibits a person from: (1) possessing or receiving unfinished DXM unless the person is registered with the Secretary

of HHS as a producer of a drug or device or approved pursuant to a federal or state law to engage in specified pharmaceutical activities, or (2) distributing unfinished DXM to any person other than a person registered with the Secretary as a producer of a drug or device or approved pursuant to a federal or state law to engage in specified pharmaceutical activities. Section 2 excludes from such prohibitions common carriers that possess, receive, or distribute unfinished DXM between registered persons.

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 V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—
(a) * * *

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(j) If it is unfinished dextromethorphan and is possessed, received, or distributed in violation of section 506D.

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SEC. 506D. RESTRICTIONS ON DISTRIBUTION OF BULK DEXTROMETHORPHAN.

(a) RESTRICTIONS.—No person shall—

(1) possess or receive unfinished dextromethorphan, unless the person is registered under section 510 or otherwise registered, licensed, or approved pursuant to Federal or State law to engage in the practice of pharmacy, pharmaceutical production, or manufacture or distribution of drug ingredients; or

(2) distribute unfinished dextromethorphan to any person other than a person registered under section 510 or otherwise registered, licensed, or approved pursuant to Federal or State law to engage in the practice of pharmacy, pharmaceutical production, or manufacture or distribution of drug ingredients.

(b) EXCEPTION FOR COMMON CARRIERS.—This section does not apply to a common carrier that possesses, receives, or distributes unfinished dextromethorphan for purposes of distributing such unfinished dextromethorphan between persons described in subsection (a) as registered, licensed, or approved.

(c) DEFINITIONS.—In this section:

(1) The term "common carrier" means any person that holds itself out to the general public as a provider for hire of the transportation by water, land, or air of merchandise, whether or not the person actually operates the vessel, vehicle, or aircraft

by which the transportation is provided, between a port or place and a port or place in the United States.

(2) The term "unfinished dextromethorphan" means dextromethorphan that is not contained in a drug that is in finished dosage form.

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