110TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPORT
110–377

DEXTROMETHORPHAN DISTRIBUTION ACT OF 2007

OCTOBER 15, 2007.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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

R E P O R T

[To accompany H.R. 970]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 970) 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 with an amendment and recommend that the bill as amended do pass.

CONTENTS

PURPOSE AND SUMMARY

The purpose of H.R. 970, the Dextromethorphan Distribution Act of 2007, is to prohibit a person from: (1) possessing or receiving un-

finished dextromethorphan unless the person is registered with the Secretary of Health and Human Services as a producer of a drug or device; or (2) distributing unfinished dextromethorphan to any person other than a registered person.

BACKGROUND AND NEED FOR LEGISLATION

Dextromethorphan (DXM) 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 (e.g., acetaminophen), antihistamines (e.g., chlorpheniramine), decongestants (e.g., pseudoephedrine) and/or expectorants (e.g., guaifenesin). The typical antitussive adult dose is 15 or 30 mg taken 3 to 4 times daily. The anticoughing effects of DXM persist for 5 to 6 hours after oral administration. When taken as directed, side effects are rarely observed.

DXM is abused by individuals of all ages, but its abuse by teenagers and young adults is of particular concern. 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.

DXM abusers report a heightened sense of perceptual awareness, altered time perception, and visual hallucinations. The typical clinical presentation of DXM intoxication involves hyperexcitability, lethargy, ataxia, slurred speech, sweating, hypertension, and nystagmus. Abuse of combination DXM products also causes health complications—increased blood pressure from pseudoephedrine, potential delayed liver damage from acetaminophen, and central nervous system, cardiovascular, and anticholinergic toxicity from antihistamines—that result from other active ingredients. The use of high doses of DXM in combination with alcohol or other drugs is particularly dangerous and deaths have been reported.

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. The agency is working with other health and law enforcement authorities to address this serious issue and to warn the public of potential harm, after five recently reported deaths of teenagers that may be associated with the consumption of powdered DXM sold in capsules.

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 Thursday, September 27, 2007, and ordered H.R. 970 favorably reported to the House by a voice vote. No amendments were offered during full Committee consideration. Pursuant to a unanimous consent request by Mr. Dingell, a technical correction to the bill was made, which is shown in the text reported by the Committee.

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 recorded votes taken during consideration or ordering H.R. 970 reported to the House. A motion by Mr. Dingell to order H.R. 970 favorably reported to the House was agreed to by a voice vote.

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. 970 is to restrict the distribution of the drug dextromethorphan to any person other than FDA-registered producers of drugs and devices.

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. 970 would result in no new or increased budget authority, 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. 970 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, October 12, 2007.

Hon. JOHN D. DINGELL,
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. 970, the Dextromethorphan Distribution Act of 2007.

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

Sincerely,

ROBERT A. SUNSHINE
(For Peter R. Orszag, Director).

Enclosure.

H.R. 970—Dextromethorphan Distribution Act of 2007

Summary: H.R. 970 would restrict the distribution, receipt, and possession of unfinished dextromethorphan to certain entities registered with the Secretary of Health and Human Services. 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. 970 would cost less than $500,000 in 2008 and about $11 million over the 2008–2012 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. 970 would impose a mandate on the private sector as defined in the Unfunded Mandates Reform Act (UMRA) by requiring people receiving, possessing, or distributing unfinished dextromethorphan to register with the Secretary of Health and Human Services. It would also be the duty of the person selling unfinished dextromethorphan to confirm that the buyer is also registered or exempt from registration. CBO estimates that the aggregate cost of complying with those mandates would not exceed the threshold established by UMRA for private-sector mandates ($131 million in 2007, 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. 970 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—				
	2008	2009	2010	2011	2012
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Estimated Authorization Level	1	2	2	3	4
Estimated Outlays	*	2	2	3	4

Note: * = less than $500,000.

Basis of estimate: For this estimate, CBO assumes that H.R. 970 will be enacted near the beginning of fiscal year 2008, 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 about $11 million over the 2008–2012 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. 970 would restrict the possession, receipt, and distribution of unfinished dextromethorphan to certain entities registered with the Secretary of Health and Human Services (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 registration requirements 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. 970. 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 might coordinate with other federal and state agencies that monitor or regulate dextromethorphan sales. We also anticipate that ongoing administrative costs (mostly associated with enforcing the new requirements) would be roughly $2 million to $4 million annually. Based on information provided by FDA, 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. Taken together, CBO estimates that such activities would cost less than $500,000 in 2008 and about $11 million over the 2008–2012 period.

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.

Intergovernmental and private-sector impact: H.R. 970 would impose a private-sector mandate, as defined in UMRA, on people that receive, possess, or distribute unfinished dextromethorphan by requiring them to register with the Secretary of Health and Human Services. CBO believes the mandate would affect relatively few people. 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. 970 would also impose a duty on the person selling un-

finished dextromethorphan to confirm that the buyer is registered or exempt from registration. This verification process would require additional administrative work for sellers, such as chemical manufacturers, to confirm the buying party's registration, but this cost would be negligible. CBO estimates that the direct cost of these mandates would be less than the threshold of $131 million in 2007 adjusted for inflation.

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: Keith J. Fontenot, Deputy Assistant Director for Health and Human Resources, Budget Analysis Division.

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 2007".

Section 2. Restrictions on distribution of bulk dextromethorphan.

Section 2 prohibits a person from: (1) possessing or receiving unfinished dextromethorphan unless the person is registered with the Secretary of Health and Human Services as a producer of a drug or device, or (2) distributing unfinished dextromethorphan to any person other than a registered person. Section 2 excludes from such prohibitions common carriers that possess, receive, or distribute unfinished dextromethorphan 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

* * * * * * *

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) * * *

* * * * * * *

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

* * * * * * *

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

(2) distribute unfinished dextromethorphan to any person other than a person registered under section 510.

(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 registered under section 510.

(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.

* * * * * * *

○