CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

October 12, 2007

H.R. 970
Dextromethorphan Distribution Act of 2007

As ordered reported by the House Committee on Energy and Commerce on September 27, 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

unfinished 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.

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