CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

March 20, 2009

H.R. 1259
Dextromethorphan Distribution Act of 2009

As ordered reported by the House Committee on Energy and Commerce on March 4, 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

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