CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

October 1, 2014

S. 2141
Sunscreen Innovation Act

As passed by the Senate on September 17, 2014

SUMMARY

S. 2141 would modify the review process that allows the marketing of certain new ingredients in non-prescription sunscreen based on a determination by the Food and Drug Administration (FDA) that they are generally recognized as safe and effective (GRASE). The bill would also require the agency to establish timelines for the review process that permits the marketing of other types of non-prescription drugs based on a GRASE determination. CBO estimates that implementing S. 2141 would cost $35 million for FDA expenses over the 2015-2019 period, assuming appropriation of the necessary amounts.

S. 2141 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

S. 2141 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA).

The bill would impose private-sector mandates, as defined in UMRA, because it would allow FDA to require that marketing applications for certain sunscreen ingredients be submitted in a new standardized format. CBO estimates that the direct cost of complying with those requirements would not exceed the annual threshold established by UMRA for private-sector mandates ($152 million in 2014, adjusted annually for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary effect of S. 2141 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2015	2016	2017	2018	2019	2015-2019
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Estimated Authorization Level	5	6	8	9	11	39
Estimated Outlays	4	6	7	8	10	35

BASIS OF ESTIMATE

For this estimate, CBO assumes that S. 2141 will be enacted early in fiscal year 2015, that the necessary amounts will be appropriated for each year, and that outlays will follow historical spending patterns for similar activities.

Drugs marketed in the United States generally must be tested for safety and efficacy and approved by FDA through an application process. However, certain products currently are marketed under a determination by FDA that they are generally recognized as safe and effective and have been marketed for a specific time and extent under the conditions of their labeling. Under current law, non-prescription sunscreen products are marketed under such a determination and are subject to a multistep process that involves scientific review and notice-and-comment rulemaking by FDA.

Section 2 of S. 2141 would modify FDA's review process that determines if certain ingredients in non-prescription sunscreens are generally recognized as safe and effective. The bill would require that the agency adhere to specific timelines and issue orders relating to such ingredients in sunscreen products. Those timelines would not apply to requests submitted six years after enactment of the bill. S. 2141 also would direct the Secretary of the Department of Health and Human Services (HHS) to issue final regulations governing non-prescription sunscreens within five years after the date of enactment.

Section 3 would amend FDA's review process for marketing certain non-prescription drugs (other than sunscreen products) that determines if they are generally recognized as safe and effective. The bill would direct the Secretary of HHS to establish timelines for review of new applications for such determinations. Sponsors of pending applications could choose to be reviewed under the existing regulatory process or they could elect a framework similar to the review process established by the bill for certain non-prescription sunscreen ingredients. Based on information provided by FDA and assuming appropriation of the necessary amounts, CBO estimates that implementing the bill would cost $35 million over the 2015-2019 period to cover administrative expenses.

PAY-AS-YOU-GO CONSIDERATIONS: None.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

S. 2141 contains no intergovernmental mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

S. 2141 would impose a private-sector mandate, as defined in UMRA, on firms seeking to market certain new active ingredients for sunscreen by giving FDA the authority to modify the format of marketing applications. Under current law, FDA can refuse to allow marketing of a sunscreen product if the agency finds that the sponsor does not provide sufficient data to demonstrate that the ingredients are generally recognized as safe and effective. However, FDA currently cannot require that applicants submit their applications in a standardized format. Such lack of uniformity can slow down the review process. Under S. 2141, FDA would have the authority to impose and enforce a standard format on such applications. The number of applications for new sunscreen ingredients is low in any given year, and the additional cost to each sponsor of complying with the new requirements would be low as well. Therefore, CBO expects that the cost of complying with this new requirement would not exceed the threshold defined in UMRA ($152 million in 2014, adjusted annually for inflation) in any of the first five years following enactment.

PREVIOUS CBO ESTIMATE

On July 23, 2014, CBO transmitted a cost estimate for H.R. 4250, the Sunscreen Innovation Act, as ordered reported by the House Committee on Energy and Commerce on July 15, 2014. The bills would change the FDA review process for marketing certain ingredients in non-prescription sunscreen using slightly different processes. However, S. 2141 also would make changes to the review process for certain non-prescription drugs (other than non-prescription sunscreen products) that determines if such products are generally recognized as safe and effective. S. 2141 also would direct the Secretary of HHS to finalize sunscreen regulations and contains additional reporting requirements. The differences in the cost estimates reflect those differences in the two bills.

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