

Amendment 1226: Requires GAO to perform an independent study of FDA's tobacco regulatory activities to determine their effectiveness. Specifically, this amendment would require GAO to assess whether the express goals of this legislation are being accomplished.

Purpose: To require an independent study of federal tobacco regulatory activities effectiveness

This amendment would require the Government Accountability Office (GAO) to develop metrics-based performance measures for the FDA's regulatory activities with respect to tobacco. GAO would also recommend program evaluations that should be conducted for programs and activities related to tobacco that are administered by the FDA.

GAO would specifically be tasked with developing performance measures to:

- Evaluate harm-reduction strategies approved by the Food and Drug Administration;
- Measure whether consumers are better informed relating to health and dependency effects or safety of tobacco;
- Determine if FDA programs make tobacco less accessible to minors; and
- Evaluate whether FDA regulations have encouraged smoking cessation and reduced tobacco-related disease.

Similar language was included in the recent H.R.1388, the Edward M. Kennedy Serve America Act, which recently became public law. The only difference is that this amendment includes additional performance measures that are specific to FDA-regulation of tobacco, which are based on Sec. 3 of this bill, which outlines the intent of this legislation.

Requiring an independent analysis of the performance of FDA's tobacco regulatory activities, based on the express intent of this legislation, is not a partisan issue. This amendment will provide Members of Congress and the Food and Drug Administration with the information necessary to ensure that FDA is successful in fulfilling its charge.

Sen. Burr, in offering his alternative, argues that this FDA tobacco bill will not accomplish its intended goals because it limits the availability of less harmful tobacco products such as smokeless tobacco. If we are not going to adopt Sen. Burr's alternative, we should at least study the programs and activities FDA puts in place to regulate tobacco. We should be pursuing policies that work—which means we must measure effectiveness.

According to the American Association of Public Health Physicians, if we could get all American smokers to switch to one of the lowest risk smokeless tobacco products, the current death toll attributable to cigarette smoking (over 400,000 per year) could be reduced to less than 3,000 deaths per year.

These same physicians contend that adding a harm reduction component to current tobacco control policies could reduce tobacco-related illness and death in the U.S. by 50% to 80% within ten years—with eventual reductions in excess of 90% over the following 10 to 20 years. If we are not going to embrace these strategies today—we should at least study whether or not the path that we are taking will actually reduce death and disease.