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H.R. 2725, the *FDA "S.O.S." Act of 2013*

Summary:
H.R. 2725, the *Food and Drug Administration (FDA) Safety Over Sequestration (S.O.S.) Act of 2013,* would protect industry user fees paid to FDA from sequestration or other across-the-board spending cuts in fiscal year 2014 and beyond.

The Problem:
User fees are negotiated periodically with input from industry, the Agency, patient groups and other stakeholders, and are intended to support FDA's drug, biologic, biosimilar, medical device and diagnostic product review activities. FDA relies heavily on user fees to supplement congressional appropriations for its product review activities: industry user fees fund approximately 60-65% of the cost of FDA human drug and biologics review activities, and approximately one-third of the cost of FDA device and diagnostics review activities.

Under sequestration, FDA's FY13 budget is slashed by approximately 5%. The U.S. Office of Management and Budget (OMB) late last year determined that industry-financed user fees to FDA would also be sequestered alongside congressionally appropriated monies.

Why This is Important:
User fees for drugs were implemented in 1992 after industry, consumer groups, and FDA agreed the length of time from submission to a final review decision was taking far too long; user fees were extended to medical devices in 2002, and have more recently been implemented for generic drugs, biologics, biosimilars, animal drugs, and other product review activities. The agreements negotiated between industry and FDA aim to ensure faster, more predictable approval times, and specify that user fees are intended to supplement rather than replace congressionally appropriated funding to FDA.

Last year, passage of the *FDA Safety and Innovation Act* (FDASIA) renewed FDA's authority to collect user fees and provided much-needed improvements to regulatory review processes. In fact, industry agreed to pay *increased* user fees in order to facilitate the needed system and process improvements under the renewed FDA user fee law. In FY13 alone, sequestration prevents FDA from accessing and using nearly $85 million in industry-paid user fees to conduct review activities and make the necessary regulatory process improvements.

The Solution:
User fees are private monies – not federal taxpayer dollars – and should not be subject to sequestration. The *FDA S.O.S. Act* would exempt industry user fees paid to FDA from any across-the-board cuts due to sequestration in FY14 or subsequent fiscal years. (The bill does not address the $85 million sequestered in FY13.)

Cost:
CBO has not scored the bill, and cannot score the bill for FY14 until OMB determines whether or not FDA user fees will be sequestered in the next fiscal year.

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**Cosponsors and endorsements updated 10/11/13*