HARVARD Kennedy School
JOHN F. KENNEDY SCHOOL OF GOVERNMENT

HKS Case 2145.2
February 4, 2019

Funding the FDA: FDA Staffer to Senate Health, Education, Labor, and Pensions Committee Ranking Member (Confidential Information)

Background

You are the lead FDA-policy staffer for the HELP Ranking Member, a Democrat. The Senator is a long-time champion for including cosmetics regulatory review and cosmetics user fees in FDA jurisdiction, and he recently won a significant victory in finally getting those provisions included in this UFA. Thanks to the Senator's efforts, cosmetic products will now be more robustly reviewed and monitored for safety by the FDA. The agency's current authority, while technically on the books, is a bit of a joke and has no "teeth" to enforce any substantial action. The next challenge is making sure the FDA funding situation does not deteriorate to the point of furloughs. The Senator has given you his full confidence in the upcoming negotiations, and you have agency to make decisions on his behalf.

The FDA is based out of the Senator's (and your) home state. An FDA shutdown would result in thousands of his constituents being furloughed, including some of your family members. You wish that the Senator could offer up enough offsets and appropriations cuts to solve this problem, but unfortunately his status and limited resources as Ranking Member of the HELP Committee make this impossible. You see it as the Senator's mission to lead the coalition-building efforts and build the media narrative about Washington politicians furloughing workers due to petty political bargaining. Therefore, immediate passage of the user fee reauthorization is ideal. This will keep the agency open and prevent any workers from being furloughed.

The E&C Chairwoman has been advocating for resources from the HELP Committee to fund the user fee reauthorization. The President has also identified one of the Senator's FDA-related initiatives, increased funding for food safety, as one option for limiting appropriations. Currently, you could allow up to $65 million worth of offsets from the Prevention and Public Health Fund (PPHF) and cut $10 million from additional appropriations the Senator advocated for. While you have full authority from

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the Senator to make these decisions in the UFA negotiations, you know that he wants to protect as much of these offsets and appropriations as possible. You know that the E&C Chairwoman has been holding back on offsets from energy policy that would have a much greater impact on this legislation.

Offsets

The Senator is annoyed that E&C hasn't been contributing to offsets for recent legislation in the shared health care jurisdiction. They seem to think that the PPHF is the best piggybank any time a health issue needs funding. For them, this is a drop in the bucket. For HELP, it is one of the only major offsets available. It's hardly fair to keep digging into this fund, which should be going towards helping Americans get healthier. You are sure that the E&C Chairwoman will want to play leader in these negotiations, which will look good on her re-election campaign. However, given her disinterest in contributing to health care legislation from both committees, it doesn't seem right that she will enjoy the benefits of being seen as the "FDA Savior." The offsets issue is really appalling – the fact that the E&C Chairwoman allows her committee to hoard offsets from large programs like the Strategic Petroleum Reserve (SPR) at the expense of American health care, and now people's livelihoods, is unacceptable under any circumstances. Instead, you should be leading this conversation, as someone whose home state and family will be most affected by furloughs.

You also must consider the delicate balance among supporters of the Senator. Environmental groups and safety advocates have long stood behind the Senator in his effort to increase regulation of cosmetics under the FDA's jurisdiction. In order to make the cosmetics user fees and relevant policies from the UFA meaningful, the Senator is planning to introduce another piece of legislation to fund regulatory and enforcement of the UFA cosmetics provisions. The Senator expects to use $65 million in offsets from the PPHF for this legislation. The Senator expects that the bill currently has 70% support; however, most people are indifferent to this issue and will renege their support if it can't easily be funded. As a result, you must minimize use of those offsets in the user fee reauthorization. You expect that every **$5 million** in Prevention and Public Health Fund offsets you provide for the user fee reauthorization will lead to a **decrease of 3** percentage points in overall support for the cosmetics enforcement legislation. In other words, if you provide no offsets for the user fee reauthorization, support for the upcoming cosmetics enforcement legislation remain at 70%; conversely, if you provide all of you offsets ($65 million), support for the bill will fall to 31%.

HELP also controls offsets from Pell Grants, which you typically would want to protect at all costs; however, you know how dire the situation is for funding the FDA and preventing furloughs. The Senator knows that the HELP Chair is in a difficult position with her approval rating and will want to hold off from using more Pell Grant money than is absolutely necessary; therefore, if the HELP Chair offers any amount of offsets from Pell Grants, the Senator will be fine with it. Instead, he needs you to protect offsets from the PPHF for his legislation.

Appropriations

The Senator successfully advocated for an additional $10 million in appropriations to better support the FDA's critical implementation of the FDA Food Safety Modernization Act. You find it frustrating and unbelievable that Congress can't find the motivation to fully fund basic food safety initiatives that protect all Americans. You know that this funding request is smaller than the other programs the President identified and that the potential consequences of not fully funding something like food safety are devastating. There should be plenty of other money available to meet the President's demand, and you are responsible for protecting this funding for food safety during the user fee reauthorization negotiations.

Other Considerations

The stakes for this negotiation are high. You know the Senator will be horrified if the FDA shuts down on his watch, and your community will bear the brunt of furloughs. While the other staffers may be concerned about things like industry reaction or media portrayal, you need to remind them that this negotiation will have real impacts on real people's lives. Whether or not families have enough money to put food on the table depends on this group finding a way to fund the FDA. It is clear that you must reach a deal to fund the FDA before the end of this negotiation.

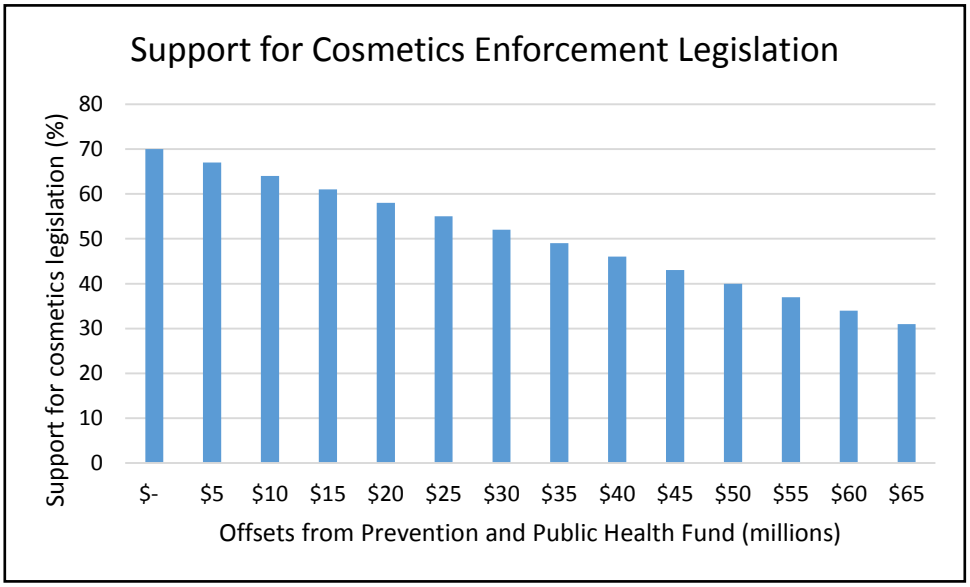
To make sure that people don't lose sight of this fact, you will be responsible for timing during the negotiation.

Resources:

	Offsets ($, millions)	Additional Appropriations ($, millions)	Support (%)	Cost to Support (decrease percentage point)
E&C Chair				
HELP Chair				
E&C Ranking Member				
HELP Ranking Member	$65	$10	70% for cosmetics enforcement legislation	$5 million in offsets/ -3 pp
Total Needed	**$650**	**$100**		

Constraints to a successful deal:

$ millions in offsets	$650
$ millions cut from additional appropriations	$100

Furlough Rate:

Total FDA workers	15,000
Percent of FDA workers furloughed after day 10	80%
FDA reviewers furloughed per day (day 1 to 5)	800
FDA reviewers furloughed per day (day 5 to 10)	1,600