HARVARD Kennedy School
JOHN F. KENNEDY SCHOOL OF GOVERNMENT

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Funding the FDA: FDA Staffer to House Energy and Commerce Committee Chairwoman (Confidential Information)

Background

As Chairwoman of the House Energy and Commerce Committee, your boss is one of the most powerful players in Washington. As her lead staffer on FDA policy, you are responsible for representing the Congresswoman in the upcoming negotiations on the user fee reauthorization bill. She has given you full authority and agency to make decisions in these negotiations. You have never done a user fee bill before, but you are broadly experienced on Capitol Hill and hope that success in this negotiation will position you to become the Congresswoman's Deputy Staff Director on the Committee.

Democrats have been advocating for selling off part of the Strategic Petroleum Reserve (SPR) to fund the additional policies in the UFA legislation. The SPR fall within the jurisdiction of the E&C Committee but does not fall under the jurisdiction of the HELP Committee. The President has also identified one of the Congresswoman's favorite FDA initiatives, a new medical data enterprise, as one option for limiting additional appropriations. Currently, you could approve the sale of up to $650 million worth of crude oil from the SPR and cut $100 million from spending that the Congresswoman has prioritized in her agriculture appropriations bill. You realize that you could intervene alone in funding this User Fee Act and meeting the President's appropriations demand; however, it would not be in your boss's interest to carry this load alone.

Offsets

In nine months, the Speaker of the House, who is a close friend and ally of the Congresswoman, plans to propose a major energy bill before Congress. Given her role as E&C Chair, the Speaker expects the Congresswoman will ensure passage of the bill, partially by using offsets from the SPR to fund the bill in a manner that doesn't provide outrage from either side of the aisle. You don't know exactly how

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much the energy bill will cost yet; however, you know that using SPR offsets in the user fee reauthorization will create more difficult political trade-offs for the energy bill – some members are concerned about selling *too much* of the reserve. You expect that every **$50 million** in SPR offsets you provide for the user fee reauthorization will lead to a **decrease of 4** percentage points in overall support for the energy bill. The Speaker's staff currently expects that the bill would have 90% support. In other words, if you provide no offsets for the user fee reauthorization, support for the upcoming energy bill will remain at 90%; conversely, if you provide all your offsets ($650 million), support for the upcoming energy bill will fall to 38%.

E&C also has jurisdiction over the mandatory spending in the Medicare and Medicaid programs, which constitute over 25% of the federal budget. As such, they are commonly used as offsets. You anticipate the E&C Ranking Member will try to protect these programs from cuts. Your boss does not have strong feelings about how much of the needed offsets comes from Medicare/Medicaid; therefore, if the E&C Ranking Member offers any amount of offsets from Medicare/Medicaid, the Congresswoman will be fine with it, and you should support the Ranking Member. Instead, she needs you to protect offsets from the Strategic Petroleum Reserve.

Recently, the Congresswoman's district was severely hit by a large black-out: all residences and businesses in 75% of the district were without power for nearly 24 hours. Her constituents have been demanding action to address these problems, including demonstrations outside the Congresswoman's district office. Polls indicate that passing this energy bill will solidify her re-election next year. Given both her powerful position as Chair of E&C and demand for action from her constituents, failure to pass the energy bill will be a huge embarrassment for the Congresswoman. It would jeopardize her chances for re-election and her relationship with the Speaker.

Furthermore, the Congresswoman has already established a good record for herself in health policy, a large segment of E&C's jurisdiction. The national media praised the Congresswoman for her creativity in negotiating the 21st Century Cures Act and providing offsets through the SPR. However, that deal is why Democrats have been pressuring you to use crude oil sales again for the UFA. Your colleagues in the Congresswoman's personal office and Energy team have urged you to avoid using these offsets at all for health-related legislation given the political pressure to deliver on energy.

Appropriations

The Congresswoman is appalled that the President is demanding changes to Appropriations as part of this user fee reauthorization. If Congress can decide how to pay for changes in the bill using offsets, why should you have to change anything about appropriations? It's ludicrous. Unfortunately, the American system requires that the President sign all legislation, and this president is putting his foot down on spending.

The Congresswoman is also upset that the President has identified the creation of a new medical data enterprise as one of the programs that could have its funding reduced. She advocated for and ultimately proposed an additional $100 million in appropriations for this program, which would establish

a new capability for near-real-time evidence evaluation. This program would support pre- and post-market evaluation of FDA-approved products, provide cost savings for industry, and improve use of life-saving technologies. The Congresswoman used her position as Chair of Agricultural Appropriations subcommittee to ensure this program would get fully funded, and it would hurt her reputation as a power-broker if funding were cut through this unconventional deal.

Other Considerations

Your team expects that the ultimatum from the President that is part of the holdup will backfire on him – it seems clear that he has unreasonable demands regarding appropriations, not the Chairwoman. Because the Congresswoman has a positive relationship with the media, her communications director suggested that it will play in her favor to let the FDA's funding lapse, which means holding off on making a deal until after the FDA runs out of reserve user fees. However, anything much more than a week of furloughs would likely reflect poorly on Congress. However, it will be important to make sure that your boss is not seen as the roadblock to a deal.

If you decide to contribute to funding the FDA, you could still retain funds for the Congresswoman's programs and interests: many see E&C as the easy option for offsets given your broad jurisdiction, but other committees and programs should carry the burden as well. Someone like the E&C Ranking Member, for example, who is trying to protect even small offsets from gargantuan programs like Medicare and Medicaid, should put in their fair share of the burden instead of just pointing fingers and making value judgments. The HELP Ranking Member could also decide to act instead of wailing. With the FDA in his district, he should be taking the lead on this conversation and developing a solution.

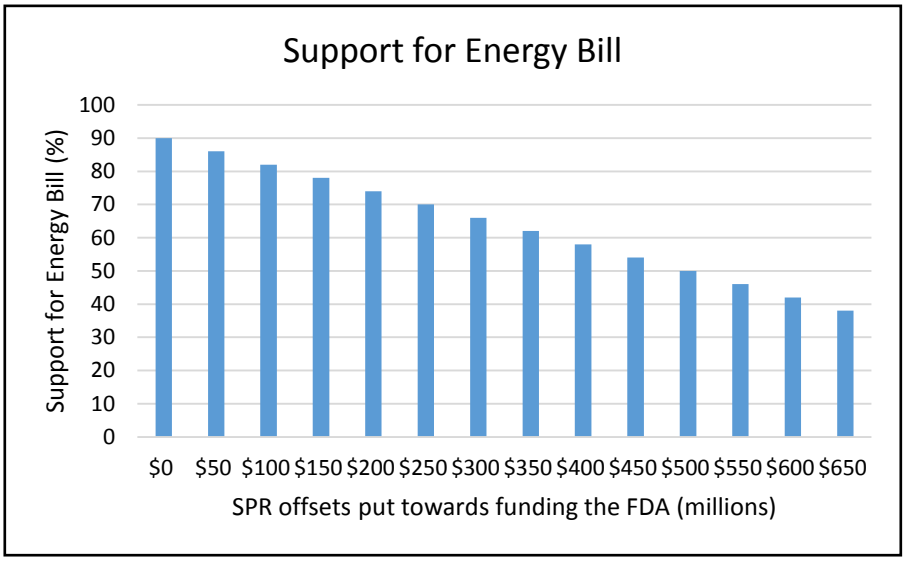
While political and legislative staffers are not sure what the impact of a full shutdown will be, you know that it will be significant. The Congresswoman warned you that failure to reach a deal that meets her constraints could jeopardize her relationship with the Speaker, approval rating, and reputation.

Resources:

	Offsets ($, millions)	Additional Appropriations ($, millions)	Support (%)	Cost to Support (decrease percentage point)
E&C Chair	$650	$100	90% support for energy bill	$50 million in offsets/ -4 pp
HELP Chair				
E&C Ranking Member				
HELP Ranking Member				
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