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

Background

You are the lead FDA policy staffer for the HELP Chairwoman, a long-serving Republican Senator from a large agricultural state. Before she was elected, the Senator was CEO of a large pharmaceutical company with strong public health programs, such as vaccine manufacturing and developing treatments for emerging infectious diseases. While her state used to consistently elect Senators from both parties, due to demographic shifts and changes to the political landscape, it now leans more Democratic. The Senator is now the state's sole Republican holding statewide office. She has remained popular due to her name recognition, connections to the community, and ability to deliver for her constituents; however, indications are that she will face both a primary challenge and strong opponent from the Democratic Party in her next campaign. The most recent election was more competitive than expected, and she narrowly won by only four points.

You are new to the Senator's office but have extensive experience negotiating UFAs from the FDA, where you served in various policy positions for over two decades. Despite not working closely with her before, the Senator has expressed full faith in you and gave you complete authority to make decisions in this negotiation.

You have heard rumors that the E&C Committee wants to fund the policies in the UFA reauthorization with HELP Committee's offsets, even though both have jurisdiction over FDA policy. You know that HELP does not have sufficient offsets to fund the new policies included in UFA, meaning that some offsets must come from E&C. Additionally, the President has

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identified one of the Senator's proposed appropriations, the FDA Innovation Fund, as an option for limiting spending.

Currently, you could allow up to $160 million worth of offsets from the HELP committee and cut $75 million from additional appropriations the Senator wants for the Innovation Fund. However, there are important constraints for each of these items.

Offsets

Fully funding Pell Grants, a program that subsidizes college for low-income students, is a major responsibility of the HELP Committee. Pell Grants are near the end of their current authorization, and if offsets are used from Pell Grants, then the Senator would have to reduce spending in the next reauthorization. While Pell Grant legislation typically has bipartisan support, the Senator is worried that partisanship around the issue this year will be the worst she's ever seen. Therefore, even though both Republicans and Democrats typically avoid touching money from Pell Grants, it is possible that E&C could strong arm the HELP committee into pulling from those funds.

During her last re-election campaign, the Senator committed her unconditional support for low-income students seeking the American dream and promised to expand access to Pell Grants – an unusual position for a Republican Senator but essential to electoral success in her left-leaning state. However, given the President's emphasis on reigning in government spending, there is less support for expanding Pell Grants than the Senator expected. This means HELP Committee offsets are strictly limited if the Senator is going to follow through on her campaign promise.

You know the Senator wants to use all $160 million in available offsets for the upcoming Pell Grant reauthorization. You expect that every **$10 million** in offsets you provide for the user fee reauthorization will lead to a **decrease of 1** percentage point in the Senator's approval rating back home. The most recent polling data shows the Senator has a 53% approval rating in her home state. In other words, if you provide no offsets for the user fee reauthorization, her approval rating will stay at 53%; conversely, if you provide all your offsets ($160 million), her approval rating will fall to 37%. There is still time before her next election to recover; however, a low approval rating could give credibility to potential primary opponents.

HELP also controls offsets from the Prevention and Public Health Fund (PPHF), which you expect the HELP Ranking Member to protect for his next pet project on cosmetics. The Senator doesn't care how much of the needed offsets come from this fund; therefore, if the HELP Ranking Member offers any amount of offsets from the PPHF, the Senator will be fine with it. Instead, she needs you to protect offsets from Pell Grants.

Appropriations

The Senator is the second highest ranking Republican on the Agricultural Appropriations subcommittee in the Senate. She has been on the committee for 25 years and used to be chair of the subcommittee herself. She has good relationships with the current subcommittee and full committee chairs, and other Senators frequently come to her with requests for appropriations. Generally, what she asks for is representative of what other Senators from rural states want – and that means it gets funded.

The Senator knows that her proposed additional appropriation for the FDA Innovation Fund is quite large and that the program has already been funded in previous years through the 21st Century Cures Act. On the other hand, she has previously made large concessions to the E&C Chairwoman and used money from the PPHF to cover spending on other health-related legislation from both committees. These new appropriations would help the FDA promote and support innovative medical products, reduce the regulatory burden, and provide funding to incentivize the development of new devices to help solve the opioid epidemic. Many rural states, like her own, have been impacted by the opioid epidemic, so you would like to avoid using the FDA Innovation Fund proposed appropriations unless it's an absolute necessity, as you know it will cut into this important work. The Senator has made you responsible for protecting funding for this program during the user fee reauthorization negotiations.

Other Considerations

You must balance those concerns with the Senator's sense of responsibility for the FDA and her moral wish to prevent any furloughs from happening, bearing in mind that your resources are limited. Furthermore, the Senator's state has several major device manufacturers who do not want the FDA to stop reviewing their applications. She is receiving considerable political pressure from companies in the state to avoid any furloughs, and you worry that delays in funding the FDA will make it look like the Senator can no longer deliver for her constituents and their interests. Therefore, swift passage of the UFA legislation is the only way to protect the Senator's interests.

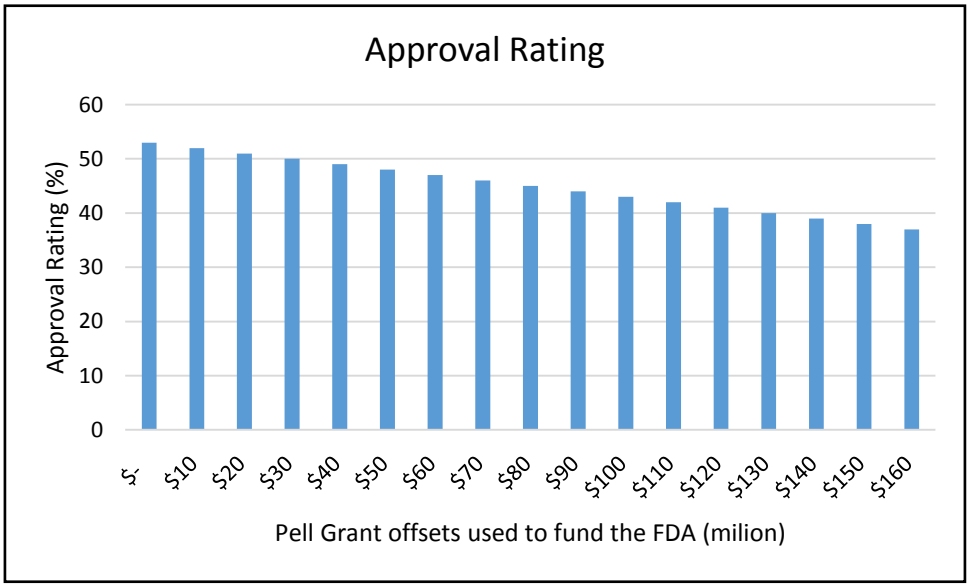
While political and legislative staffers are not sure what the impact of a full shutdown will be, you can expect that it will be significant. The Senator warned you that failure to reach a deal that meets her constraints could jeopardize her chances for re-election, her reputation as a dealmaker, and the well-being of device manufacturers in her state.

Resources:

	Offsets ($, millions)	Additional Appropriations ($, millions)	Support (%)	Cost to Support (decrease percentage point)
E&C Chair				
HELP Chair	$160	$75	53% approval rating	$10 million in offsets/ -1 pp
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