HARVARD Kennedy School
JOHN F. KENNEDY SCHOOL OF GOVERNMENT

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Funding the FDA: Teaching Plan and Debrief

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Exercise Overview

In *Funding the FDA*, staffers for Congressional leadership in the House Energy and Commerce (E&C) and Senate Health, Education, Labor, and Pensions (HELP) committees must negotiate how to meet funding needs and presidential demands that prevent passage of the User Fee Act (UFA). Republicans control both the House and Senate, and the President is a Republican.

UFAs are up for reauthorization every five years. Without user fees, the FDA is unable to collect fees from industry to fund relevant responsibilities. If the current UFA expires without reauthorization, the FDA has some reserve user fees to carry over from the previous year. However, the FDA will have to begin furloughing staff. After five days, the reserve user fees run out, and the FDA will have to accelerate furloughing. Ten days after the current UFA expires, the FDA will have to furlough 80% of staff.

All details of the UFA have been decided, and it is up to the staffers at this negotiation to finalize where funding will come from**. Each party can offer a specific amount in offsets and proposed appropriations to meet the target; however, each party also has individual interests that make them hesitant to offer much.** Policy within the UFA cannot change without jeopardizing votes in either chamber; therefore, committee leadership is not able to change the amount of funding required to reach a deal. The President has also insisted that leadership must reduce the amount of proposed appropriations related to FDA programs in an effort to decrease government spending. To encourage those reductions, the President has identified four FDA-related programs that could have proposed additional appropriations reduced or cut. As the exercise progresses, each round intensifies the time urgency of reaching a deal, as Food and Drug Administration (FDA) workers begin to be furloughed without the UFA's passage.

This exercise highlights a bi-partisan, bi-cameral negotiation between leadership of two committees that each have jurisdiction over the FDA. Possible coalitions exist between members of the same party and members of the same committee. E&C committee members can offer more in offsets, since that committee has jurisdiction over large programs such as the Strategic Petroleum Reserve (SPR) and Medicare/Medicaid. Republicans can offer more in proposed appropriations cuts since they have more influence with members of their own party to get increased funding for programs they care about. There is tension between HELP and E&C over which committee is responsible for solving this problem and how to fairly allocate resources.

Any successful deal must include $650 million in offsets and $100 million in cuts to proposed FDA-related appropriations. It is important to clarify that offsets and appropriations are two separate and unrelated buckets of money; therefore, participants cannot move money between these two categories. For example, if a role has $25 million in appropriations and $500 million in offsets, that person cannot move $75 million from offsets to appropriations to cover the difference.

Mechanics

Time required: 45-60 minutes: preparation (preferable outside of class)
Up to 90 minutes: negotiation (three rounds of 30 minutes each)
45-60 minutes: debrief

Group size: 4 people

Materials: General Instructions (all parties) (separate document, HKS Case 2145.0)
Confidential Instructions for E&C Chairwoman
Confidential Instructions for HELP Chairwoman
Confidential Instructions for E&C Ranking Member
Confidential Instructions for HELP Ranking Member
Press Release for HELP Ranking Member
Results Sheet for HELP Ranking Member
Role Matrix (all parties)

Details of exercise rounds:

Round 1 (Sept 25-Sept 30)	Round 2 (Oct 1-Oct 5)	Round 3 (Oct 6-Oct 10)
• Press release in the first 10 minutes • Negotiate how to fund the FDA in the next 20 minutes **If a deal is reached in Round 1, there are no furloughs.**	• Every 6 minutes (1 day), 800 FDA employees are furloughed	• Every 6 minutes (1 day), 1600 FDA employees are furloughed **If no deal is reached by the end of Round 3, 80% of FDA employees have been furloughed.**

	Offsets ($, millions)	Additional Appropriations ($, millions)	Support (%)	Tradeoffs
E&C Chair	650	100	90% support for energy bill	Minus 4 pp per $50 million (offsets)
HELP Chair	160	75	53% approval rating	Minus 1 pp per $10 million (offsets)
E&C Ranking Member	480	25	95% support for community health centers bill	Minus 3 pp per $40 million (offsets)

HELP Ranking Member	65	10	70% support for cosmetics regulation enforcement bill	Minus 3 pp per $5 million (offsets)
Total Needed	**$650**	**$100**		

	Timing of Deal	Total Furloughs
Round 1	Day 0 (0:00 – 29:59)	0
Round 2	Day 1 (0:00 - 5:59)	800
	Day 2 (6:00 - 11:59)	1600
	Day 3 (12:00 - 17:59)	2400
	Day 4 (18:00 - 23:59)	3200
	Day 5 (24:00 - 29:59)	4000
Round 3	Day 6 (0:00 - 5:59)	5600
	Day 7 (6:00 - 11:59)	7200
	Day 8 (12:00 - 17:59)	8800
	Day 9 (18:00 - 23:59)	10400
	Day 10 (24:00 - 29:59)	12000

Funding the FDA Spreadsheet

An exercise tracker in Excel (HKS case 2145.4) accompanies this teaching package that will aid the instructor in entering and calculating results. The tracker has step-by-step instructions for instructors who may want to display their results to the entire class. Because of the calculations required for determining the support each party has at the end of the exercise for their respective interest, the tracker may be useful and save the instructor time.

The tracker is locked except for certain cells where the instructor should enter the results of each group. These cells are highlighted in blue. If the instructor would like to unlock the tracker to make any changes, you may do so by unprotecting the sheet (simply search “protect sheet” and click the provided link).

An instructor **does not need** to use this tracker to run this exercise. It is only to aid in the displaying of specific outcomes, if the instructor chooses to do so.

Procedure

1. Distribute roles before class and ask participants to prepare individually in advance of the negotiation. (This exercise can be prepared in class in about 45 minutes. However, the shorter the preparation time allowed, the more likely that participants will be confused about the mechanics and structure of the exercise.)
    a. After students have had time to prepare individually, instructors should provide the opportunity for students to prepare with others who share their role. This will allow an opportunity to compare strategy and ask each other questions about the structure of the exercise. This could be especially helpful with participants without experience working in an American legislature.
2. In class, divide participants into teams of four and allow 90 minutes for them to negotiate. Emphasize the importance of time in this negotiation and remind the HELP Ranking Members that they are responsible for keeping time.
3. Collect the press releases and results sheets of the negotiating groups for use in the debriefing (check to ensure no party offered more funding than the role allows). Outcomes will include how much each member is offering for offsets and reduced additional appropriations. All members do not need to sign a deal. If the outcome includes $650 million in offsets and $100 million in cuts to additional appropriations, and no member goes over their allotted amounts, the results are valid.

Synopsis of Roles and Resources

In this exercise, there are principal-agent dynamics with an FDA staffer representing their Member of Congress or Senator in the negotiations. Confidential instructions include information about the principal's interests, priorities, and tradeoffs along with some personal information for the agent.

FDA Staffer to House E&C Committee Chairwoman (Republican)

The Chairwoman of E&C is a powerful player in Washington. She is a close friend and ally of the Speaker, who is expecting her to ensure passage of an upcoming energy bill later in the year. The E&C Chairwoman's district recently had a major black-out, so the energy bill will directly help her district. She can offer $650 million in offsets (which would fully fund offsets in UFA) from the Strategic Petroleum Reserve; however, using these offsets now would reduce support for the energy bill (since offsets for that bill would need to come from somewhere else or dip further into the SPR). Every $50 million in offsets dedicated to UFA will decrease support for the energy bill by 4 percentage points (current support is estimated at 90%).

The E&C Chairwoman is also frustrated by the President's overreach in demanding that Congress reduce proposed appropriations in this legislation. She has an interest in postponing a deal so that the President faces blame for furloughs. She could offer $100 million in additional appropriations, which she advocated go towards a new medical data enterprise for real-time evidence evaluation (which would also fully meet the President's demands), but she's worried that will make her look weak for conceding everything she advocated for.

Overall, the E&C Chairwoman thinks this problem should be solved with funding from Medicare/Medicaid or the HELP Committee. She doesn't want FDA furloughs to start reflecting poorly on Congress or herself, but there isn't much urgency to solve the problem on her own or to get a deal.

The E&C Chairwoman's FDA staffer has plenty of experience on Capitol Hill but has never negotiated an UFA before.

FDA Staffer to Senate HELP Committee Chairwoman (Republican)

The HELP Chairwoman is a long-serving Republican Senator from a large agricultural state. Before running for Senate, she was CEO of a large pharmaceutical company with strong public health programs; therefore, the Senator is familiar with how the FDA operates and its importance to industry. She is expecting to face a tough re-election campaign, including a possible primary challenger.

The HELP Chairwoman can offer up to $160 million in offsets to meet funding requirements in UFA; however, those offsets were being reserved for legislation to expand Pell Grants, which the Senator promised during her last campaign. Using any of these offsets will decrease her approval rating (currently 53%) by 1 percentage point for every $10 million offered.

However, the HELP Chairwoman is the second-highest ranking Republican on the Agricultural Appropriations subcommittee, and she knows that her additional appropriations for the FDA Innovation Fund are large. She can offer up to a $75 million reduction in appropriations to meet the President's demands.

The Senator's state is also home to a few medical device manufacturers who would be upset if the FDA stopped reviewing applications for their products. Therefore, the Senator does not want furloughs to happen.

The HELP Chairwoman's FDA staffer for this negotiation is new to the Senator's office but has extensive experience negotiating UFAs for the FDA.

FDA Staffer to House E&C Committee Ranking Member (Democrat)

The E&C Ranking Member is a very senior House Democrat and leader on FDA policy issues. He is concerned that shutting down the FDA could set a precedent for small-government Republicans who want to eliminate agencies they view as unnecessary. He can offer up to $480 million in offsets from Medicare/Medicaid; however, he is worried about opening the door to Republicans demands for decreased federal health care spending, especially for programs that help the elderly and poor. Also, he is worried about an upcoming reauthorization for community health centers that may need offsets from Medicare/Medicaid. There is currently 95% support for the community health centers bill, but every $40 million offered for the UFA reauthorization will decrease support by 3 percentage points. The E&C Ranking Member prefers to use offsets from the SPR instead.

As a Democrat in the Republican-controlled Congress, the Congressman was only able to secure $25 million in additional appropriations to modernize generic drug development and review. He could offer this $25 million to meet the President's demands, but his Chief of Staff believes securing the funding would satisfy more liberal members of the caucus who have been unhappy with the Congressman's inability to stop Republican attacks on federal health programs.

The Congressman is frustrated with the E&C Chairwoman for refusing to use offsets from energy or trade. Instead, she thinks Medicare/Medicaid are always the best option. The Congressman wants the FDA to stay open but does not want to sacrifice Medicare/Medicaid when there are other options from the SPR.

The FDA staff for the Ranking Member on this negotiation has worked for him over the last decade. This is the staffer's third UFA negotiation overall and second with the Congressman as Ranking Member of E&C.

FDA Staffer to House HELP Committee Ranking Member (Democrat)

The HELP Ranking Member is desperate to find a resolution to this problem but does not have much power to change the situation on his own. Not only is the FDA headquartered in his state of Maryland, meaning that furloughs will have huge negative consequences for his constituency, but the UFA reauthorization also includes a significant personal victory. The Ranking Member has been a long-time champion for including cosmetics regulatory review and cosmetics user fees in FDA jurisdiction, and the UFA reauthorization finally includes those provisions.

As a Democrat from HELP, the Ranking Member does not have much to offer as options for funding the FDA. He could allow up to $65 million in offsets from the Prevention and Public Health Fund (PPHF), though he was hoping to save that for future legislation to enforce the cosmetics provisions of the new UFA. He expects that the future legislation currently has 70% support (not many other people care deeply about the issue), but using offsets from PPHF now would reduce that by 3 percentage points per $5 million used in UFA reauthorization.

The Ranking Member successfully advocated for $10 million in increase appropriations for food safety, which could be offered to meet the President's demands if necessary. Given that $10 million doesn't make much of a dent in the demands, the Ranking Member thinks there are other programs with more funding available to cut.

Overall, the stakes are high in this negotiation because the Ranking Member's constituents are at risk of furlough. Therefore, he needs a deal to happen as quickly as possible. Given the urgency, the HELP Ranking Member will be responsible for time keeping, the press release, and the final results form.

The FDA staffer for the HELP Ranking Member is also from Maryland. This staffer has a personal stake in the negotiations with some family members at risk of being furloughed from their FDA jobs.

Debriefing and Case Analysis

Begin the debrief by previewing the issues and then showing results. The results are divided into three categories to briefly discuss: Press Release, Furloughed Workers, Resource Allocation. Following the results, instructors will prompt the students with reflection questions and then discuss specific skills that negotiators can use to navigate dynamics in this exercise.

1. *Press Release:*

Display press release results showing whether each group had a press release, who signed it, and (if desired) quotes from specific press releases that highlight differences in how groups approached it. Press releases could include the following characteristics:

- Commitment to action
- Statement of fact (i.e., negotiations are happening)
- Assign blame to the President
- Assign blame to specific participants(s) without their signature(s) (i.e., "The Chairwoman of Energy and Commerce could solve this problem now, but she is more concerned with partisan battles than American workers."
- No press release

Possible questions:

- What role did the press release play in your negotiation?
- Did any party feel strongly for or against the press release? How did this impact the rest of the negotiation?
- Was the group decision unanimous?

If any groups did not sign a press release, you should ask why they chose not to release one. Possible reasons include: 1) they ran out of time before agreement on what it would say; 2) conscious decision not to release one after discussion; or 3) conscious decision to start negotiation terms immediately to prevent furloughs.

2. *Furloughed Workers:*

Display "Furloughed Workers" table with group number, number of parties in the final deal, round the deal was signed in, minute the deal was signed in, and total number of furloughed workers.

Possible questions:

- If any groups signed a deal in Round 1, how were you able to come to agreement so quickly?
- If any groups did not reach agreement, what prevented a deal from being signed? Did you not feel urgency about the furlough clock?
- How did your group handle the furlough clock?
    - Possible options include regular announcements of how many people have been furloughed, creating urgency (we have three minutes until the end of this round), or ignoring the clock altogether to prevent distraction.

3. *Resource Allocation:*

This exercise includes a few information asymmetries that participants may uncover through inquiry-based questions, in sidebars, or by strategically revealing information. Before revealing what each role had, ask: **How did you and/or your group deal with these asymmetries? What is the risk of revealing too much information?** This can lead into a discussion of the negotiator's dilemma (from Lax and Sebenius) and the tension between creating and claiming value.

After discussing the negotiator's dilemma, reveal the resource allocation. Ask: **Is anyone surprised by these numbers?** Participants may be surprised about HELP Chairwoman's low offsets, E&C Ranking Member's high offsets, and HELP Ranking Member's low offsets and appropriations. Discussion of strategic misrepresentation and credibility may come up.

Next, compare how each role did relative to other people in that role. The table includes group number, final number of offsets and appropriations offered in the deal, starting support percentage, and final support percentage. Show the tables for each role, giving participants time to process each one, then move into conversation on fairness standards. Ask: **How did you think through what would be a fair resolution? Did anyone in your group disagree with your fairness standards? How did your group determine a fair allocation of resources?** Possible responses include:

- Equal share from everyone
- Proportional distribution (dependent on sharing information)
- Needs-based distribution (people who benefit more from the deal should contribute more, though in this exercise the HELP Ranking Member could only contribute 10% of what was needed)

4. *Reflection Questions:*

Once participants have had a chance to see all the results and discuss similarities or differences in how groups approached the negotiation, instructors should use the following questions to prompt reflection:

- What role did ethics play in your negotiation?
- What were the different types of power in the negotiation?
- If you had to do the same negotiation again, what would you do differently? How do you think a different strategy would impact the outcome?

5. *Skills and Takeaways:*

- **Using an interest-based approach:** For some groups, this exercise will devolve into a distributive negotiation where they are "horse-trading" over numbers. This is a common, and intentional, trap of this negotiation. If students feel that way, ask them what accounts for the differences in results between groups: Was it persuasion, framing of arguments, process control? Did the group establish a process that led to creative option generation or did they stay positional? Ask if

students moved beyond positions to take an interest-based approach. Ask what their understanding of their interests and priorities was prior to the negotiation, and what their plan was to articulate these interests. Ask what their understanding of the interests of others was prior to the negotiation and what plan they had for filling in the gaps of missing information. Ask how information was shared within the group and how new information adjusted the creative options the group proposed. Ask groups what their process of creating options was – did they engage in or did they propose sets of packages intended to satisfy the multiple interests represented. Negotiators should have discovered that the "costs of action" are different for each stakeholder and should use this information to shape packages that meet the interests of each member. Being able to negotiate the various shared and opposed interests will help create a deal that can reach the interests of multiple parties.

- **Establishing fairness standards and legitimacy**: Each negotiator will have been operating under their own understanding of what constituted a fair deal. Was it equality (equal share from everyone)? If yes, why? Was it proportional distribution (everyone contributes proportionally to total resources and/or proportionally to total cost of action)? If yes, why? Was it needs-based distribution (those who benefit the most should contribute more)? If yes, why? There is not a judgment to be made for which is *the* fair standard in *Funding the FDA*. However, a good negotiator will be able to identify the standards they are using, articulate why those are fair, and be prepared to identify and negotiate that standard within a group.
- **Separate self-interest from group interest:** How did negotiators manage the conflict between advocating for yourself and your interests, and advocating for the FDA and broader interests? How did you think about framing your interests and priorities in a way that benefit others? As part of preparation, did you think about shared interests? Timing is key here: know when to push for your own needs and when to focus on the group's overall goals.
- **Share and withhold information strategically**: The way negotiators share or withhold information can influence how others perceive their trustworthiness and/or desperation to reach a deal. Sharing information too quickly could lead others to believe the negotiator has more resources. Similarly, negotiators who withhold too much could damage their reputations moving forward, especially when their resources are revealed. How did negotiators manage this tension?

In addition to the skills above, instructors can highlight the following key lessons:

- Agreement bias: Did anyone fall below their reservation point? How did you determine your reservation point? Do you think you'd be fired for signing onto this deal?
- Process design: Who took the mantle of process leadership? How did process design impact your group's ability to reach an agreement? Did anyone deliberate use process design to speed up or slow down an agreement?
- Reputational consequences: What role did ethics play? What were your criteria for a "good deal"? What standards were used in decision-making? How were these standards agreed upon?
- Time management: How did multiple rounds influence your strategy for concessions? Did anyone use the furlough-clock to increase urgency or build momentum towards an agreement?
- Coalition mapping and perceptions of power: How did you perceive sources of power during the exercise? How did those perceptions influence coalition building? What was the difference between party-based and committee-based coalitions?

Scenario Notes and FAQs

This exercise is a fictional scenario based on legislative processes and structures of the United States Congress. This section includes basic information for instructors on FDA policy and previous User Fee Act negotiations.

The exercise materials include all relevant information for participants to run the exercise, and this section is intended to give instructors additional context and supplementary background on real-world User Fee Act negotiations.

1. *How much of the FDA do user fees cover?*
    - In April 2017, the FDA estimated that industry user fees pay for about 42.5% of the FDA's budget.[a]
2. *What provisions would be added in a real-world UFA?*
    - The following provisions were added into the 2012 and/or 2017 UFAs[b, c]:
        - Increased use of standardized electronic data in product submissions
        - Increased communication with companies
        - Implemented structure for benefit/risk framework in drug review
        - New regulatory science for assessing safety and effectiveness of products
        - Development of drugs for rare diseases
        - Advanced patient-reported outcomes and assessments for clinical trials
        - Inspection of overseas generic drug making facilities
        - Tools to combat drug shortages
        - Ensured safety and security of supply chain
        - Modernized clinical trial process

3. *What is the real risk if an UFA reauthorization is not passed by Congress before the deadline?*
    - In 2017, Congressional leaders warned that failure to pass the UFA reauthorization would delay review of critical drugs and devices, threaten biomedical industry jobs and American leadership in the industry, and lead to layoff notices for more than 5,000 FDA employees.[d]

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[a] Commissioner, Office of the. "FDA Basics - Fact Sheet: FDA at a Glance." *US Food and Drug Administration Home Page*, Center for Biologics Evaluation and Research, April 2017, www.fda.gov/AboutFDA/Transparency/Basics/ucm553038.htm.

[b] Margaret Hamberg, "User Fees: Ensuring a Stronger and Better FDA," *FDA Voice*, Food and Drug Administration, June 26, 2012, blogs.fda.gov/fdavoice/index.php/2012/06/user-fees-ensuring-a-stronger-and-better-fda.

[c] "House, Senate Health Committee Leaders Release Discussion Draft of FDA User Fees Reauthorization." *Energy and Commerce Committee*, April 14, 2017, energycommerce.house.gov/news/press-release/house-senate-health-committee-leaders-release-discussion-draft-fda-user.

[d] Ibid.

Sample Agreements

Harvard Kennedy School students ran this exercise in November 2018. For illustrative purposes only, the following results were recorded:

	When the Deal Was Signed	Total Furloughed Workers
Group 1	R2 Day 4	3200
Group 2	R2 Day 1	800
Group 3	R3 Day 6	5600
Group 4	R2 Day 2	1600
Group 5	R2 Day 4	3200
Group 8	R3 Day 9	10400

Offsets ($) Spent						
	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6
E&C Chair	150	330	345	650	400	350
HELP Chair	25	50	25	0	0	20
E&C RM	450	222.5	255	0	215	250
HELP RM	25	47.5	25	0	35	30

% Support						
	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6
E&C Chair	78	63.6	62.4	38	58	62
HELP Chair	50.5	48	50.5	53	53	51
E&C RM	61.25	78.3125	75.875	95	78.875	76.25
HELP RM	55	41.5	55	70	49	52

Appropriations ($) Spent						
	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6
E&C Chair	100	0	30	50	50	20
HELP Chair	0	70	50	30	30	50
E&C RM	0	25	20	10	10	20
HELP RM	0	5	0	10	10	10

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HKS Case 2145.2
February 4, 2019

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 much the

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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:

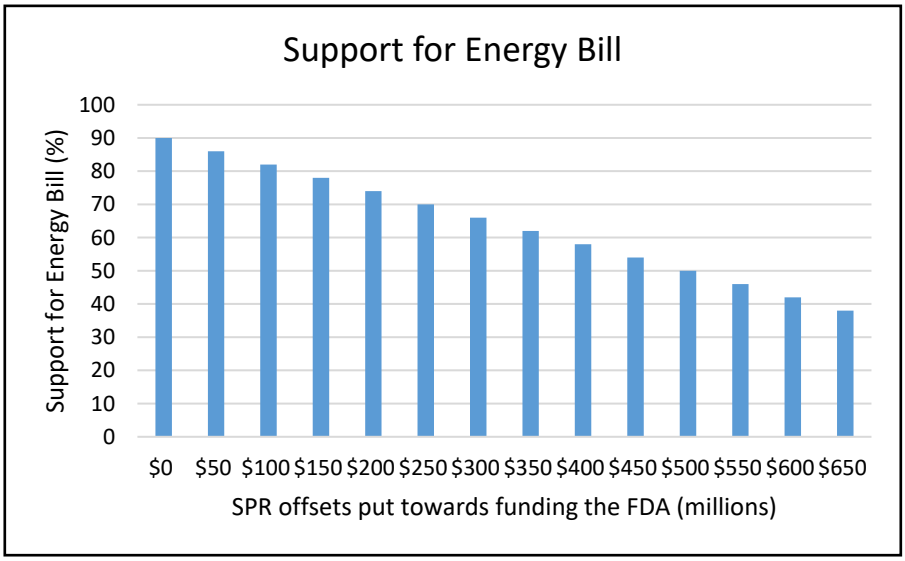
	Offsets ($, millions)	Additional Appropriations ($, millions)	Support (%)	Cost to Support (decrease percentage point)
E&C Chair	$650	$100	90% support for energy bill	$50 million in offsets/ -4 pp
HELP Chair				
E&C Ranking Member				
HELP Ranking Member				
Total Needed	**$650**	**$100**		

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



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 identified

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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:

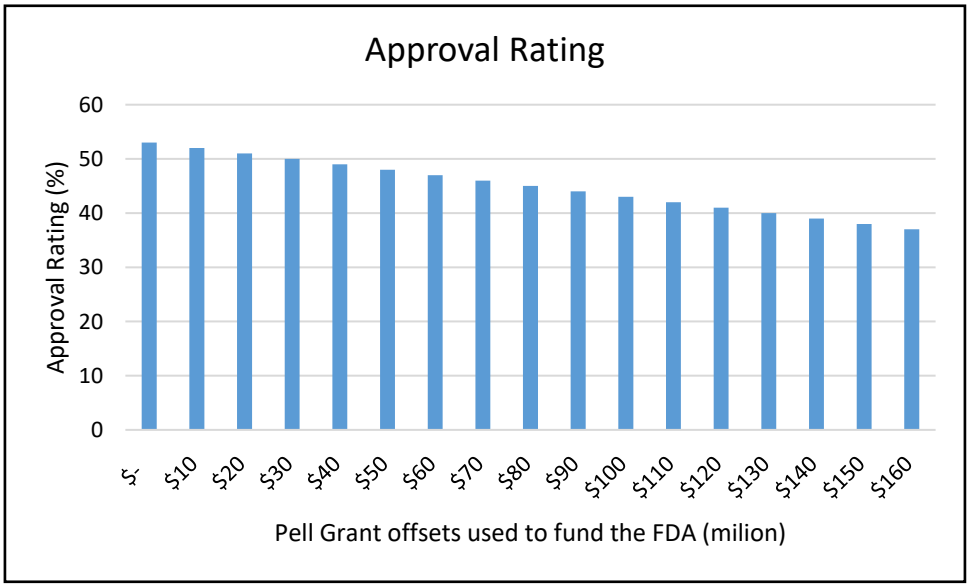
	Offsets ($, millions)	Additional Appropriations ($, millions)	Support (%)	Cost to Support (decrease percentage point)
E&C Chair				
HELP Chair	$160	$75	53% approval rating	$10 million in offsets/ -1 pp
E&C Ranking Member				
HELP Ranking Member				
Total Needed	**$650**	**$100**		

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



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

Background

You are the lead FDA-policy staffer for the E&C Ranking Member, a very senior House Democrat. The Congressman is a long-time leader on FDA policy issues, and you have served as FDA staffer to him for nearly a decade. This is your third UFA bill, and second with the Congressman as Ranking Member of E&C.

The Congressman is very concerned about the current UFA situation. He worries that a shutdown of the FDA could set the precedent for shutting down and then shrinking any government agency that Republicans feel is unnecessary. You've all seen the damage that a few tweets from a Member of Congress or the Cabinet can do in this 24-hour news cycles era. From a different angle, the FDA is an important agency for many medical device manufacturers and pharmaceutical companies in the Congressman's district. Furloughing workers would lead to an administrative backlog and delay in application processing that could negatively impact the Congressman's constituent companies and potentially voters – depending on how long the shutdown lasts.

Republicans have been pushing for offsets from Medicare and Medicaid, which are both controlled by the E&C Committee. The President has also identified one of the Congressman's favorite FDA initiatives, modernizing generic drug development, as one option for limiting appropriations. Currently, you could allow up to $480 million worth of offsets from Medicare and Medicaid (total) and cut $25 million from FDA appropriations the Congressman advocated for. While you have full authority from the Congressman to make these decisions in the UFA negotiation, you know that he wants to protect as much of these offsets and appropriations as possible.

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Offsets

Recent national controversy over access to health care has put the Congressman in a difficult position. The Republican Party, which controls both chambers of Congress, has tried to gut federal health care programs through defunding landmark legislation from the previous administration, and now it seems that Medicare and Medicaid funding could be next. While the Congressman has been successful in defending the programs thus far, the left-wing media bashes him again and again for not doing more to advance these programs (like supporting single payer). This negative attention is starting to take a toll, and there are rumors of a more liberal candidate challenging him in the upcoming primary.

There is a lot of pressure on your office to deliver a legislative win on health care access. While the Congressman is very concerned with the user fee reauthorization developments, he is struggling to balance it with the other policy priorities before the Committee. There is a "must do" reauthorization of community health centers coming up, and failure to pass that legislation would be devastating to your boss. Members of Congress rarely want to vote against community health centers; however, they have come to expect that offsets will come from Medicare/Medicaid. As a result, you must minimize use of those offsets in the user fee reauthorization. You expect that every **$40 million** in Medicare/Medicaid offsets you provide for the user fee reauthorization will lead to a **decrease of 3** percentage points in overall support for the community health centers bill. The Congressman's Staff Director expects that the bill currently has 95% support. In other words, if you provide no offsets for the user fee reauthorization, support for the upcoming community health centers bill will remain at 95%; conversely, if you provide all your offsets ($480 million), support for the upcoming community health centers bill will fall to 59%.

E&C also controls offsets from the Strategic Petroleum Reserve (SPR), which you anticipate the E&C Chairwoman will be protecting. The Congressman does not care how much of the needed offsets comes from the SPR; therefore, if the E&C Chair offers any amount of offsets from SPR, the Congressman will be fine with it. Similarly, he would agree to using the Prevention and Public Health Fund (PPHF). You know the HELP Committee has been frustrated with using the PPHF, but it is an easy and painless way to pay for bipartisan initiatives. Overall, the Congressman needs you to protect Medicare and Medicaid, which impact millions of people.

Appropriations

In another effort to decrease health care costs for the American people, the Congressman advocated for and proposed $25 million in appropriations for the FDA to modernize generic drug development and review. This funding request is likely smaller than some of the other programs the President identified; however, it could have a significant positive impact on consumer access to affordable prescription drugs. Your boss has been a leader in this area, and his Chief of Staff believes that securing this funding could get some of the more liberal parts of the party off his back. There should be plenty of other money available in other programs to meet the President's demand, and you are responsible for protecting funding for this program during the user fee reauthorization negotiations.

Other Considerations

The Congressman has been getting frustrated with the E&C Chairwoman for refusing to use offsets from other areas of E&C jurisdiction that meet her Republican interests. For example, she rarely offers offsets from telecommunications, energy, or trade. You feel that the Chairwoman tries to milk every penny out of Medicare and Medicaid (at least, that's what you've noticed in your last two UFA negotiations). Why don't they understand that Democrats can't make all the concessions for financing these things? You are sure that the Chairwoman's staff will approach you and ask for support on providing offsets. You want the FDA to stay open, yet you can't sacrifice the Congressman's chances of passing the community health center bill. Those offsets could be used more strategically to win popularity and support for your Congressman.

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 Congressman warned you that failure to reach a deal that meets his constraints could jeopardize his approval rating and reputation in the House.

Resources:

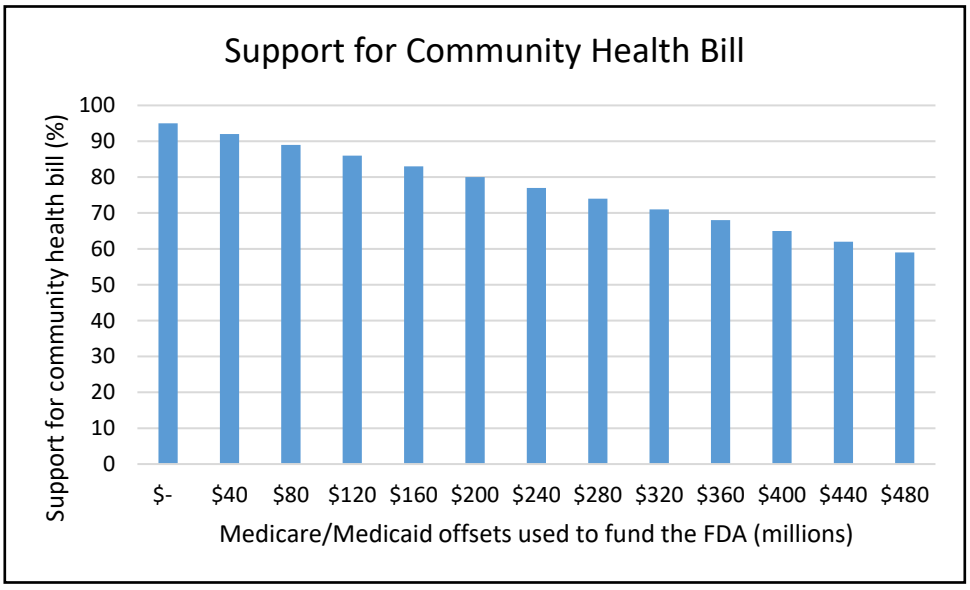
	Offsets ($, millions)	Additional Appropriations ($, millions)	Support (%)	Cost to Support (decrease percentage point)
E&C Chair				
HELP Chair				
E&C Ranking Member	$480	$25	95% for community health centers bill	$40 million in offsets/ -3 pp
HELP Ranking Member				
Total Needed	**$650**	**$100**		

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



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 the Senator

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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:

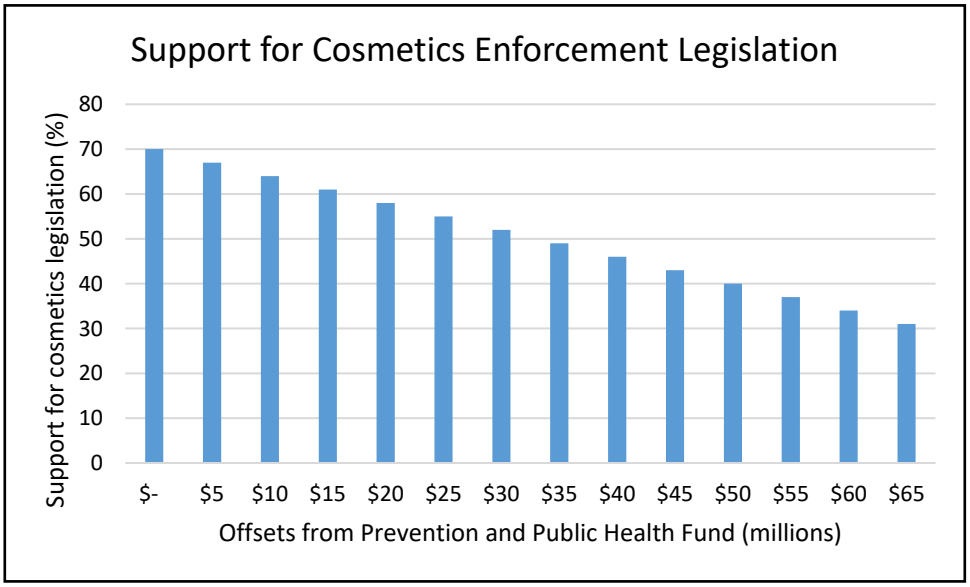
	Offsets ($, millions)	Additional Appropriations ($, millions)	Support (%)	Cost to Support (decrease percentage point)
E&C Chair				
HELP Chair				
E&C Ranking Member				
HELP Ranking Member	$65	$10	70% for cosmetics enforcement legislation	$5 million in offsets/ -3 pp
Total Needed	**$650**	**$100**		

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



Funding the FDA:

Press Release

You may choose to issue a brief press release on your intention to Fund the FDA. If you choose to do so, this must be completed during the first ten minutes of Round I. You may hand this form in at the end of the negotiation.

Press Release:

Signatures:

_____ _____

E&C Chairwoman HELP Chairwoman

_____ _____

E&C Ranking Member HELP Ranking Member

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Funding the FDA:

Results Form

Group number: _____

Who signed the press release?

E&C Chair HELP Chair E&C RM HELP RM

Did you sign a deal?

Yes / No

In what round did you sign a deal? _____

If you signed a deal in Rounds 2 or 3, in what day did you sign a deal? _____
(Round 2 = Days 1 – 5; Round 3 = Days 6 – 10)

Who signed the final deal?

E&C Chair HELP Chair E&C RM HELP RM

How were resources allocated?

Actor	Offsets ($, millions)	Appropriations ($, millions)
E&C Chair		
HELP Chair		
E&C RM		
HELP RM		
Total	**$650**	**$100**

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Funding the FDA: General Information

Background

Every five years, Congress must pass legislation allowing the Food and Drug Administration (FDA) to collect user fees from industry. The User Fee Act (UFA), as this legislation is called, allows the FDA to collect these fees to better facilitate review of applications for FDA approval of new drugs, generics, devices, and other medical products. In the United States, these products require FDA approval before they can go to market. The fees fund the staff and other resources needed to review these products. User fees currently constitute about 70% of the FDA's total budget.

The FDA and industry began working on the current User Fee Act two years ago, following normal protocol for UFA reauthorization. They sketched out broad parameters for the legislation, including changes to user fee amounts, jurisdiction of the FDA, and some additional policy changes to FDA programs. This framework was sent to Congress eight months ago for legislators and staff to make changes before a vote on the bill.

During these eight months, Congressional leadership has been negotiating the details of reauthorization. Congress usually passes UFA legislation in July, leaving at least two months of buffer time before the fiscal year and current five-year-cycle for user fees ends. However, there has been more controversy than usual this round.

After weeks of public criticism from patient safety groups, the pharmaceutical industry, and medical researchers, Congress finally agreed to the policies in this user fee reauthorization on September 25, five days before the deadline. If the user fees are not reauthorized before September 30, then the FDA will be forced to furlough workers who are paid through user fee funding. This would lead to several negative consequences: application delays, administrative backlog, drugs not being approved, products not going to market. There could even be potential ripple effects in other parts of the agency. With critical dollars being re-assigned, functions like food imports inspection could also be reduced.

This simulation was written by Brian Mandell, Mohamed Kamal Senior Lecturer in Negotiation and Public Policy, Monica Giannone, Program Director of the Harvard Kennedy School Negotiation Project, Elizabeth Patton, and Emily Schlichting at the John F. Kennedy School of Government, Harvard University (HKS) as part of the Harvard Kennedy School's "Teaching Legislative Negotiation Project." Funding for this simulation was provided by The William and Flora Hewlett Foundation. HKS simulations are developed solely as the basis for class discussion. They are not intended to serve as endorsements, sources of primary data, or illustrations of effective or ineffective management.

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The last remaining piece of the UFA legislation that Congress needs to agree on is how to pay for the additional policy changes in the bill that are not funded by user fees. **If Congress does not find the necessary funding to pass this legislation and meet separate demands set by the President, the FDA will be forced to begin furloughing workers on October 1.**

The Current Situation

With the fiscal year deadline only five days away, leadership of the House Energy and Commerce (E&C) Committee and Senate Health, Education, Labor, and Pensions (HELP) Committee have gathered to discuss how to pay for the additional policies laid out in the legislation. The participants are the Chairwoman of E&C, Ranking Member of E&C, Chairwoman of HELP, and Ranking Member of HELP.

A recent report from the Office of the Assistant Secretary for Financial Resources at the Department of Health and Human Services, which oversees the FDA, suggests that the agency has some reserve user fees left from the previous cycle, which Congress authorized the agency to carry over until they are fully expended. This will allow the FDA to furlough reviewers in waves rather than all at once. Once the FDA begins furloughing workers, it has enough reserve funds to furlough only 800 staffers per day for five days, beginning with generic drugs and medical devices. After that, the agency will have to accelerate the pace as carry over funds run out, furloughing staff in all centers at a rate of 1600 per day for an additional five days. Therefore, the FDA has enough funding to pace furloughs for ten days. At its end, if a shutdown continues, experts believe that the FDA workforce will be reduced by 80%.

Passing this legislation requires $650 million in offsets for additional FDA-related policies. These are essential to obtaining votes for passage and must be paid for. E&C and HELP, as committees with jurisdiction over UFA and the FDA, must find enough offsets to cover the additional policies. **Additionally, the President has made clear that he will only sign the UFA bill if it also cuts FDA appropriations by $100 million, as he believes the increased user fees should cover more of the agency's operating budget.**

The White House identified the following programs for reducing spending in appropriations, stating that industry should foot more of the bill themselves:

- Food safety
- New medical data enterprise
- Generic drug development
- FDA Innovation Account

Given the tight deadline for funding the FDA, each Congressperson or Senator in this negotiation has had a conversation with leadership of their chamber and party regarding offsets.

Therefore, each Member at the table has been deputized to make these decisions for the caucus to expediate the process and, hopefully, prevent any furloughs.

Passing legislation that meets these criteria ($650 million in offsets and $100 million of additional appropriations cut) will stop furloughs immediately and bring everyone back to work.

The Parties

E&C Chairwoman (Republican) is "the" Washington power player. She is also Chairwoman of the House Agricultural Appropriations subcommittee and has the ability to approve sufficient offsets and appropriations options to fully fund the FDA and meet the President's demands. She is sending her FDA staffer to these negotiations, who is broadly experienced on Capitol Hill. Within the House, the E&C Chairwoman has a strong relationship with the Speaker, who is working on a major energy bill for next year. Political experts believe that the Speaker currently has 90% support for the energy bill within her caucus.

HELP Chairwoman (Republican) has a long-time affiliation with the health industry and specifically the FDA, as she served as the CEO for a major pharmaceutical company before starting her career in public office. As such, her lead FDA staffer is one of the most expert on the Hill, having worked at the agency for nearly two decades before moving onto HELP. While the HELP committee does not have the capacity to contribute much towards offsets, the Chairwoman is the second-highest ranking Republican on the Senate Agricultural Appropriations subcommittee. The Chairwoman has a 53% approval rating in her home state.

E&C Ranking Member (Democrat) is a long-time Congressional leader on health policy issues. For these negotiations, the Ranking Member is sending an FDA staffer who has worked with him for nearly a decade. The Ranking Member and his staffer will seek to protect Medicare/Medicaid offsets, although it isn't yet clear if it is for the programs themselves or to use these offsets for something else in the future. The Ranking Member has been an advocate for an upcoming community health centers bill, which currently has 95% support within his caucus.

HELP Ranking Member (Democrat) is very interested in a fast resolution to this funding situation. With the FDA headquarters located in his home state, the Senator feels strongly that a catastrophe can be avoided if only the most influential powers will agree to cooperate. The Senator and his staffer leading this negotiation do not have the resources needed for resolution. The HELP Ranking Member would rather see HELP resources invested in other ways, such as funding the newly created regulatory and enforcement authority for the FDA to thoroughly review cosmetics. The Ranking Member is expected to introduce legislation establishing and funding cosmetics review enforcement, which currently has 70% support, after UFA is passed.

Conduct of the Negotiation

All parties should discuss solutions to the situation with the FDA. There is not a "right" or "wrong" outcome to this negotiation. Parties should be creative and explore different options before choosing solutions that will conform to their priorities. You can choose to negotiate multilaterally or bilaterally, as long as you keep to the time constraint.

Mechanics

Timing: This exercise is divided into three rounds of 30 minutes each. The HELP Ranking Member is the timekeeper and must record in what minute a deal was reached.

- ROUND 1: All four parties meet before the end of the fiscal year.
    - *First 10 minutes:* Parties may choose to issue a press release on whether each member will contribute to funding the FDA.
    - *Next 20 minutes:* Parties will negotiate how to fund the FDA.
    - A deal signed during Round 1 will fund the FDA before the end of the current fiscal year, which prevents furloughs.
- ROUND 2: Days 1-5 of the FDA shutdown.
    - Six minutes represent one day.
    - 800 FDA employees are furloughed each day
    - Note: furloughs begin immediately in Round 2 – at the start of Round 2, 800 workers are furloughed, at minute 6, another 800 workers are furloughed
- ROUND 3: Days 6-10 of the FDA shutdown.
    - Six minutes represent one day.
    - 1,600 FDA employees are furloughed each day.
    - At the end of Round 3, 80% of FDA employees are furloughed and the exercise concludes.

Funding constraints: A successful deal must include $650 million in offsets and $100 million cut in additional appropriations.

- Offsets refer to government money that is currently allocated to be spent in a specific way. Using offsets to fund the FDA will redirect money from one program to the FDA.
- Appropriations refer to new government spending that must be authorized by Congress. The President insists that Congress cut $100 million from additional appropriations requests related to FDA programs.
- Money cannot be moved between offsets and appropriations.
- A deal that violates the constraints or is submitted late will be considered a no deal.

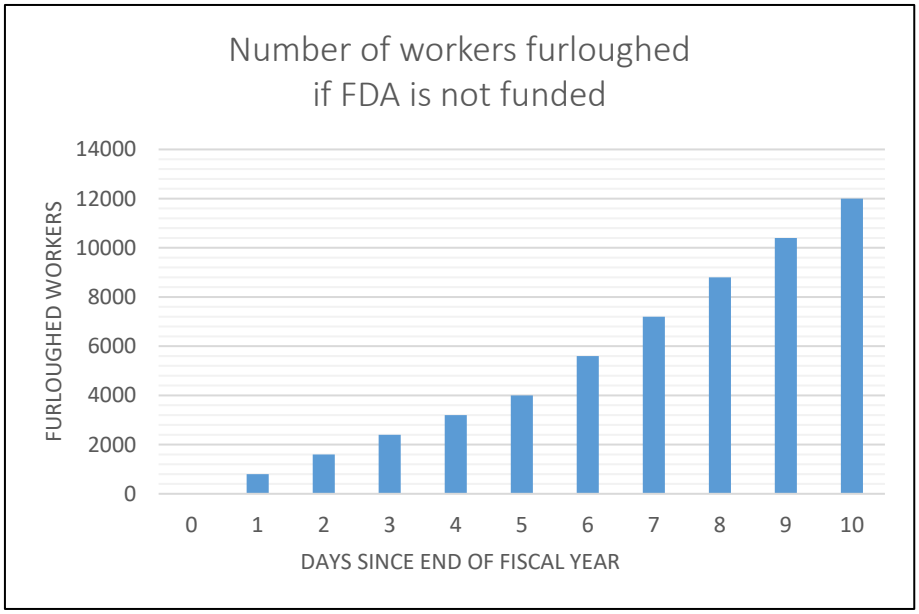
Sidebars: Parties are allowed to meet in smaller groups (sidebars) during the course of this negotiation.

Resources:

	Offsets ($, millions)	Additional Appropriations ($, millions)	Support (%)
E&C Chair			90% support for energy bill
HELP Chair			53% approval rating
E&C Ranking Member			95% support for community health centers bill
HELP Ranking Member			70% support for cosmetics regulation enforcement bill
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