Public Meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments

Public Meeting
June 7, 2019
9:00 – 11:30 AM
<table>
<thead>
<tr>
<th>Topic</th>
<th>Presenter</th>
<th>Time</th>
</tr>
</thead>
</table>
| Welcome and Introduction                                             | **Patrizia Cavazzoni, M.D.**  
Deputy Director for Operations  
Office of the Center Director | 9:05 – 9:10 AM |
| General Overview of 5-Year Financial Plans                           | **David Miller**  
Director, Division of User Fees  
Office of Finance, Budget and Acquisitions | 9:10 – 9:40 AM |
| Resource Capacity Planning (RCP) and Modernized Time Reporting (MTR) Implementation Progress | **Andrew Kish**  
Director  
Office of Program and Strategic Analysis | 9:40 – 10:20 AM |
|                                                                       | **Josh Barton**  
Director, Resource Capacity Planning Team  
Office of Program and Strategic Analysis |               |
| Break                                                                |                                                                                             | 10:20 – 10:30 AM |
| Financial Management Evaluation for Human Drug User Fees              | **Jim Taylor**  
Grant Thornton, LLP | 10:30 – 10:50 AM |
| FDA Response to Financial Management Evaluation                       | **Jay Tyler**  
Chief Financial Officer  
Office of Finance, Budget and Acquisitions | 10:50 – 11:10 AM |
| Open Public Comment                                                  |                                                                                             | 11:10 – 11:30 AM |
9:05 – 9:10 AM

WELCOME AND INTRODUCTION

Patrizia Cavazzoni, M.D.
Deputy Director for Operations
Office of the Center Director | CDER
9:10 – 9:40 AM

GENERAL OVERVIEW OF 5-YEAR FINANCIAL PLANS

David Miller
Director, Division of User Fees
Office of Finance, Budget and Acquisitions
Overview of the PDUFA Financial Plan

Prescription drug program target revenue for FY 2018 through FY 2022

<table>
<thead>
<tr>
<th>Target Revenue</th>
<th>FY 2018</th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
<th>FY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statutory Base</td>
<td>$878,590,000</td>
<td>$935,903,507</td>
<td>$1,001,480,000</td>
<td>$1,050,763,000</td>
<td>$1,092,005,000</td>
</tr>
<tr>
<td>Inflation Adjustment</td>
<td>$14,820,056</td>
<td>$16,572,979</td>
<td>$23,999,467</td>
<td>$27,060,562</td>
<td>$28,122,678</td>
</tr>
<tr>
<td>Capacity Planning Adjustment</td>
<td>$22,415,658</td>
<td>$27,685,634</td>
<td>$8,329,713</td>
<td>$8,754,891</td>
<td>$9,098,517</td>
</tr>
<tr>
<td>Additional Dollar Amounts</td>
<td>$20,077,793</td>
<td>$21,317,472</td>
<td>$16,953,329</td>
<td>$5,426,896</td>
<td>$2,769,609</td>
</tr>
<tr>
<td>Operating Reserve Adjustment</td>
<td>($33,287,582)</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Additional Direct Costs Adjust.</td>
<td>$8,730,000</td>
<td>$8,842,303</td>
<td>$9,022,587</td>
<td>$9,213,173</td>
<td>$9,406,204</td>
</tr>
<tr>
<td><strong>Target Revenue Total</strong></td>
<td><strong>$911,346,000</strong></td>
<td><strong>$1,010,322,000</strong></td>
<td><strong>$1,059,786,000</strong></td>
<td><strong>$1,101,218,000</strong></td>
<td><strong>$1,141,402,000</strong></td>
</tr>
</tbody>
</table>

*Target revenue rounded to the nearest thousand dollars

- Base amount is set in statute
- The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation.
- The capacity planning adjustment is intended to adjust the PDUFA target revenue for changes in the workload, or capacity needs of the program. The method will be established through a process outlined in statute.
- The additional dollar amounts are enhancement funds, negotiated with Industry, that are added to the base each fiscal year.
- The operating reserve adjustment was established in statute to provide a mechanism to support the management of a reasonable amount of fee funds carried over from year to year. FDA has committed to keeping the carryover balance below 14 weeks of operating.
- The additional direct costs adjustment were directly negotiated with Industry and is added as a one time amount through statute yearly.
### Overview of the PDUFA Financial Plan

**Budgetary Resources**

<table>
<thead>
<tr>
<th></th>
<th>FY 2018</th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
<th>FY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Revenue</td>
<td>$911,346,000</td>
<td>$911,346,000</td>
<td>$1,010,322,000</td>
<td>$1,059,786,000</td>
<td>$1,101,218,000</td>
</tr>
<tr>
<td>Cash Collections</td>
<td>$911,346,000</td>
<td>$908,077,723</td>
<td>$1,010,322,000</td>
<td>$1,059,786,000</td>
<td>$1,101,218,000</td>
</tr>
<tr>
<td>Recoveries</td>
<td>$0</td>
<td>$13,149,599</td>
<td>$10,000,000</td>
<td>$10,000,000</td>
<td>$10,000,000</td>
</tr>
<tr>
<td>Carryover Available</td>
<td>$232,969,623</td>
<td>$232,969,623</td>
<td>$125,372,944</td>
<td>$102,422,710</td>
<td>$103,888,514</td>
</tr>
</tbody>
</table>

**Total Budgetary Resources**

|                      | $1,144,315,623 | $1,154,196,945 | $1,145,694,944 | $1,172,208,710 | $1,215,106,514 | $1,254,842,188 |

*Numbers rounded to nearest whole dollar

**User Fee Obligations**

<table>
<thead>
<tr>
<th></th>
<th>FY 2018</th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
<th>FY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payroll &amp; Operating</td>
<td>$134,345,871</td>
<td>$129,543,398</td>
<td>$133,147,243</td>
<td>$136,234,641</td>
<td>$141,237,332</td>
</tr>
<tr>
<td>CBER</td>
<td>$655,258,274</td>
<td>$688,935,477</td>
<td>$641,479,230</td>
<td>$670,583,126</td>
<td>$702,933,383</td>
</tr>
<tr>
<td>CDER</td>
<td>$1,292,304</td>
<td>$786,091</td>
<td>$2,630,174</td>
<td>$3,990,769</td>
<td>$4,125,016</td>
</tr>
<tr>
<td>CDRH</td>
<td>$8,307,191</td>
<td>$7,733,467</td>
<td>$8,498,654</td>
<td>$8,630,125</td>
<td>$8,895,537</td>
</tr>
<tr>
<td>HQ</td>
<td>$60,309,328</td>
<td>$54,211,488</td>
<td>$58,348,569</td>
<td>$47,861,070</td>
<td>$51,444,387</td>
</tr>
<tr>
<td>Total Rent</td>
<td>$64,632,000</td>
<td>$49,964,883</td>
<td>$65,278,320</td>
<td>$65,931,103</td>
<td>$66,590,414</td>
</tr>
<tr>
<td>Total Shared Services</td>
<td>$126,189,050</td>
<td>$130,936,781</td>
<td>$133,751,844</td>
<td>$135,089,362</td>
<td>$136,440,256</td>
</tr>
</tbody>
</table>

**Total Obligations**

|                      | $1,050,334,019 | $1,062,111,583 | $1,043,133,935 | $1,068,320,196 | $1,111,666,325 | $1,150,190,996 |

**Carryover**

<table>
<thead>
<tr>
<th></th>
<th>FY 2018</th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
<th>FY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Carryover, End of Year</td>
<td>$211,120,182</td>
<td>$209,223,939</td>
<td>$186,273,705</td>
<td>$187,739,509</td>
<td>$187,291,183</td>
</tr>
<tr>
<td>Carryover Unavailable for Use, End of Year</td>
<td>($83,850,995)</td>
<td>($83,850,995)</td>
<td>($83,850,995)</td>
<td>($83,850,995)</td>
<td>($83,850,995)</td>
</tr>
<tr>
<td>Carryover Available for Use, End of Year</td>
<td>$127,269,187</td>
<td>$125,372,944</td>
<td>$102,422,710</td>
<td>$103,888,514</td>
<td>$103,440,188</td>
</tr>
</tbody>
</table>

**Impact of fee change structure**

- Increase in efficiency and stability
- Elimination of burdensome fees and additional billing
- In FY18 FDA collected 99% of the planned target revenue

*Numbers rounded to nearest whole dollar

---

**Carryover Balance**

- Decreased from beginning of FY18 to end of FY19 (est.) by $46.7M
- Projected to stabilize from FY19 through FY22
- Ending balance in FY22 accounts for roughly 8.5 weeks of operating reserves

---

www.fda.gov
Overview of the BsUFA Financial Plan

Biosimilar program target revenue for FY2018 through FY2022

<table>
<thead>
<tr>
<th>Target Revenue</th>
<th>FY 2018</th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
<th>FY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actual</td>
<td>Actual</td>
<td>Estimate</td>
<td>Estimate</td>
<td>Estimate</td>
</tr>
<tr>
<td>Base Amount</td>
<td>$45,000,000</td>
<td>$40,214,000</td>
<td>$40,947,000</td>
<td>$41,922,000</td>
<td>$42,997,000</td>
</tr>
<tr>
<td>Inflation Adjustment</td>
<td>$ -</td>
<td>$733,463</td>
<td>$975,398</td>
<td>$1,075,132</td>
<td>$1,102,701</td>
</tr>
<tr>
<td>Capacity Planning Adjustment</td>
<td>N/A</td>
<td>N/A</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>Operating Reserve Adjustment</td>
<td>N/A</td>
<td>($2,100,000)</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>FY 2018 Adjustment</td>
<td>($4,786,000)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Target Revenue Total</td>
<td>$40,214,000</td>
<td>$38,847,000</td>
<td>$41,922,000</td>
<td>$42,997,000</td>
<td>$44,100,000</td>
</tr>
</tbody>
</table>

*Target revenue rounded to the nearest thousand dollars

• Base amount is set in statute
• The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation.
• The capacity planning adjustment is intended to adjust the BsUFA target revenue for changes in the workload, or capacity needs of the program. The method will be established through a process outlined in statute. This will include a third-party assessment of methodological options to be published for public comment.
• The operating reserve adjustment was established in statute to provide a mechanism to support the management of a reasonable amount of fee funds carried over from year to year. FDA has committed to keeping the carryover balance below 21 weeks of operating by FY22.
## Overview of the BsUFA Financial Plan

### Budgetary Resources

<table>
<thead>
<tr>
<th></th>
<th>FY 2018</th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
<th>FY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target Revenue</strong></td>
<td><strong>Estimate</strong></td>
<td><strong>Actual</strong></td>
<td><strong>Estimate</strong></td>
<td><strong>Estimate</strong></td>
<td><strong>Estimate</strong></td>
</tr>
<tr>
<td></td>
<td>$40,214,000</td>
<td>$40,214,000</td>
<td>$38,847,000</td>
<td>$41,922,000</td>
<td>$42,997,000</td>
</tr>
<tr>
<td><strong>Cash Collections</strong></td>
<td>$40,214,000</td>
<td>$29,238,601</td>
<td>$38,847,000</td>
<td>$41,922,000</td>
<td>$42,997,000</td>
</tr>
<tr>
<td><strong>Recoveries</strong></td>
<td>$0</td>
<td>$1,074,997</td>
<td>$500,000</td>
<td>$500,000</td>
<td>$500,000</td>
</tr>
<tr>
<td><strong>Carryover Available for Use, Beginning of Year</strong></td>
<td>$48,223,308</td>
<td>$48,223,308</td>
<td>$38,257,343</td>
<td>$32,886,857</td>
<td>$27,739,865</td>
</tr>
<tr>
<td><strong>Total Budgetary Resources</strong></td>
<td><strong>Estimate</strong></td>
<td><strong>Actual</strong></td>
<td><strong>Estimate</strong></td>
<td><strong>Estimate</strong></td>
<td><strong>Estimate</strong></td>
</tr>
<tr>
<td></td>
<td>$88,437,308</td>
<td>$78,536,907</td>
<td>$77,604,343</td>
<td>$75,308,857</td>
<td>$71,236,865</td>
</tr>
</tbody>
</table>

### User Fee Obligations

<table>
<thead>
<tr>
<th></th>
<th>FY 2018</th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
<th>FY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Payroll &amp; Operating</strong></td>
<td>$208,018</td>
<td>$0</td>
<td>$460,297</td>
<td>$724,717</td>
<td>$743,303</td>
</tr>
<tr>
<td><strong>CBER</strong></td>
<td>$31,055,273</td>
<td>$31,113,433</td>
<td>$34,137,860</td>
<td>$37,269,255</td>
<td>$39,225,370</td>
</tr>
<tr>
<td><strong>CDER</strong></td>
<td>$1,382,041</td>
<td>$1,128,256</td>
<td>$1,407,248</td>
<td>$1,440,770</td>
<td>$1,477,720</td>
</tr>
<tr>
<td><strong>ORA</strong></td>
<td>$2,544,981</td>
<td>$2,293,521</td>
<td>$1,785,744</td>
<td>$1,138,350</td>
<td>$1,228,037</td>
</tr>
<tr>
<td><strong>Total Rent</strong></td>
<td>$1,505,875</td>
<td>$1,104,785</td>
<td>$1,520,934</td>
<td>$1,536,143</td>
<td>$1,551,504</td>
</tr>
<tr>
<td><strong>Total Shared Services</strong></td>
<td>$4,639,568</td>
<td>$5,405,403</td>
<td>$5,459,457</td>
<td>$5,514,052</td>
<td>$5,569,192</td>
</tr>
<tr>
<td><strong>Total Obligations</strong></td>
<td>$40,465,297</td>
<td>$40,279,564</td>
<td>$44,717,486</td>
<td>$47,568,992</td>
<td>$48,739,986</td>
</tr>
</tbody>
</table>

### Carryover

<table>
<thead>
<tr>
<th></th>
<th>FY 2018</th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
<th>FY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Carryover, End of Year</strong></td>
<td>$48,472,011</td>
<td>$38,757,343</td>
<td>$33,386,857</td>
<td>$28,239,865</td>
<td>$22,996,879</td>
</tr>
<tr>
<td><strong>Carryover Unavailable for Use, End of Year</strong></td>
<td>($500,000)</td>
<td>($500,000)</td>
<td>($500,000)</td>
<td>($500,000)</td>
<td>($500,000)</td>
</tr>
<tr>
<td><strong>Carryover Available for Use, End of Year</strong></td>
<td>$47,972,011</td>
<td>$38,257,343</td>
<td>$32,886,857</td>
<td>$27,739,865</td>
<td>$22,496,879</td>
</tr>
</tbody>
</table>

### Collection Shortfall

- Collections were short of our revenue target in FY18 by $11M
  - Fee paying applications were 56% lower than anticipated

### Carryover Balance

- Estimated to decrease each year until the end of the cycle
- FDA anticipates maintaining a balance close to 21 weeks by the end of FY22
  - The volatility of the program requires the need to maintain a higher balance than other programs

### Impact of Spending Trigger

- **Spending Trigger Background**
  - FDA may not spend BsUFA fees in a fiscal year unless it allocates a minimum of $20,000,000 in appropriated funds (excluding user fees), multiplied by the adjustment factor applicable to that fiscal year, for the BsUFA program. The specified minimum level for FY18 is $21,711,380. The statute provides that this requirement is met if at least an amount that is 15% below the FY18 minimum level is spent.
  - In FY18, FDA allocated and obligated $22,324,558 in appropriated funds (excluding user fees) for the BsUFA program. Since this was more than the specified minimum amount in FY18, the second legal condition was satisfied
  - Volatile workload impacts our ability to spend fees
  - Results in conservative spending approach
  - In FY18, FDA cleared the spending trigger by just 3%, or $600K
  - This impact is limited by the 15% threshold granted by Statute
    - FDA cleared the 15% below threshold by 21%, or $3.9M
Overview of the GDUFA Financial Plan

Generic drug program target revenue for FY 2018 through FY 2022

<table>
<thead>
<tr>
<th>Target Revenue</th>
<th>FY 2018</th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
<th>FY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base Amount</td>
<td>$493,600,000</td>
<td>$493,600,000</td>
<td>$501,721,000</td>
<td>$513,223,000</td>
<td>$526,039,000</td>
</tr>
<tr>
<td>Inflation Adjustment</td>
<td>$0</td>
<td>$8,121,201</td>
<td>$11,501,954</td>
<td>$12,816,205</td>
<td>$13,136,246</td>
</tr>
<tr>
<td>Target Revenue Total</td>
<td>$493,600,000</td>
<td>$501,721,000</td>
<td>$513,223,000</td>
<td>$526,039,000</td>
<td>$539,175,000</td>
</tr>
</tbody>
</table>

*Target revenue rounded to the nearest thousand dollars

- Base amount is set in statute
- The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation.
# Overview of the GDUFA Financial Plan

## Budgetary Resources

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Revenue</td>
<td>$493,600,000</td>
<td>$493,600,000</td>
<td>$501,721,000</td>
<td>$513,223,000</td>
<td>$526,039,000</td>
<td>$539,175,000</td>
<td>$539,175,000</td>
<td>$539,175,000</td>
<td>$539,175,000</td>
<td>$539,175,000</td>
</tr>
<tr>
<td>Cash Collections</td>
<td>$493,600,000</td>
<td>$493,655,974</td>
<td>$501,721,000</td>
<td>$513,223,000</td>
<td>$526,039,000</td>
<td>$539,175,000</td>
<td>$539,175,000</td>
<td>$539,175,000</td>
<td>$539,175,000</td>
<td>$539,175,000</td>
</tr>
<tr>
<td>Recoveries</td>
<td>$0</td>
<td>$4,920,184</td>
<td>$4,000,000</td>
<td>$4,000,000</td>
<td>$4,000,000</td>
<td>$4,000,000</td>
<td>$4,000,000</td>
<td>$4,000,000</td>
<td>$4,000,000</td>
<td>$4,000,000</td>
</tr>
<tr>
<td>Carryover Available for Use, Beginning of Year</td>
<td>$137,412,048</td>
<td>$137,412,048</td>
<td>$158,715,667</td>
<td>$175,416,181</td>
<td>$160,160,337</td>
<td>$145,671,792</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Budgetary Resources</td>
<td>$631,012,048</td>
<td>$635,988,205</td>
<td>$664,436,667</td>
<td>$692,639,181</td>
<td>$690,199,337</td>
<td>$688,846,792</td>
<td>$688,846,792</td>
<td>$688,846,792</td>
<td>$688,846,792</td>
<td>$688,846,792</td>
</tr>
</tbody>
</table>

## User Fee Obligations

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Payroll &amp; Operating</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CBER</td>
<td>$966,443</td>
<td>$49,462</td>
<td>$982,344</td>
<td>$1,004,864</td>
<td>$1,029,957</td>
<td>$1,055,677</td>
<td>$1,055,677</td>
<td>$1,055,677</td>
<td>$1,055,677</td>
<td>$1,055,677</td>
</tr>
<tr>
<td>Total Rent</td>
<td>$25,539,705</td>
<td>$22,019,962</td>
<td>$25,795,102</td>
<td>$26,053,053</td>
<td>$26,313,583</td>
<td>$26,576,719</td>
<td>$26,576,719</td>
<td>$26,576,719</td>
<td>$26,576,719</td>
<td>$26,576,719</td>
</tr>
<tr>
<td>Total Shared Services</td>
<td>$45,508,063</td>
<td>$57,291,257</td>
<td>$54,723,889</td>
<td>$55,271,128</td>
<td>$55,823,839</td>
<td>$56,382,078</td>
<td>$56,382,078</td>
<td>$56,382,078</td>
<td>$56,382,078</td>
<td>$56,382,078</td>
</tr>
</tbody>
</table>

## Carryover

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Carryover Unavailable for Use, End of Year</td>
<td>($5,000,000)</td>
<td>($5,000,000)</td>
<td>($5,000,000)</td>
<td>($5,000,000)</td>
<td>($5,000,000)</td>
<td>($5,000,000)</td>
<td>($5,000,000)</td>
<td>($5,000,000)</td>
<td>($5,000,000)</td>
<td>($5,000,000)</td>
</tr>
</tbody>
</table>

*Numbers rounded to nearest whole dollar

## Carryover Balance

- Estimated to increase in FY19 due to hiring challenges
  - Expected to decrease significantly by the end of FY22
  - Additional spending not expected to impact program going into FY23
9:40 – 10:20 AM

RESOURCE CAPACITY PLANNING AND MODERNIZED TIME REPORTING IMPLEMENTATION PROGRESS

Andrew Kish  
Director  
Office of Program and Strategic Analysis | CDER

Josh Barton  
Director, Resource Capacity Planning Team  
Office of Program and Strategic Analysis | CDER
Commitments

Under PDUFA VI, BsUFA II, and GDUFA II, FDA committed to developing a resource capacity planning function and modernizing its time reporting approach.

<table>
<thead>
<tr>
<th>Commitment</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publish an RCP/MTR implementation plan incorporating recommendations from a 3rd party by end of Q2 FY18</td>
<td>Complete: <a href="https://www.fda.gov/media/112562/download">https://www.fda.gov/media/112562/download</a></td>
</tr>
<tr>
<td>Staff an RCP team to implement and manage RCP system</td>
<td>Team established in CDER</td>
</tr>
<tr>
<td></td>
<td>HQ team established</td>
</tr>
<tr>
<td>Conduct 3rd party assessment to recommend new methodology to adjust fee revenue amounts based on capacity needs</td>
<td>Evaluation to be conducted in FY20</td>
</tr>
<tr>
<td></td>
<td>After public comment, FDA may adopt new revenue adjustment method for FY21</td>
</tr>
</tbody>
</table>
What is Resource Capacity Planning?

Long-term vision: **maximize operations to deliver on mission**

Develop a **unified and trusted resource management capability** to foster **innovation** and maximize our **operational performance**, facilitating a flow of products to patients **first in the world** in order to **protect and promote public health** and **meet our commitments** to the American public.
What is Resource Capacity Planning?

Identifying the resources you need before you need them

Industry Model:

New Project

- **Strategy / Priority Review**
  - Should we do it?

- **Capacity Review**
  - Are the roles and skills available to do the work?

  - If yes: Get it done!

  - If no:
    - Get more resources
    - Reprioritize work portfolio
    - Delay project initiation

FDA Model:

New Submission

- **Have Performance Goals?**

  - If yes: Get it done!

  - If no: As resources permit

FDA needs to understand its likely resource demands with enough lead time to adjust staff levels
What is Resource Capacity Planning?

Identifying the resources you need before you need them

**Capacity Balancing**
Identify ops to prioritize existing resources

**Revenue Adjustment**
PDUFA & BsUFA

**Hiring Plans**

**Financial Forecasting**
e.g. Improve ability to manage BA

**Insight**

**Time Reporting**
52-week time reporting to provide:
• Better measure of level of effort
• Better analysis of available productive hours

**Workload Forecasting**
Advanced analytics to forecast likely incoming work & productivity

**Operational Data**
HR Data (attrition, hiring times)
Financial Data

**Outputs**

**Projected Demand**
Available Staff by Role
Full maturation requires progressive capability development over many years.
Benefits at the completion of Phase 3:

- Ability to track actual effort versus forecasted effort and continually refine forecasts
- Systematic and consistent resource capacity analysis across the organization
- Resource forecasts integrated with financial planning processes
- Emerging pro-active ability to identify resource gaps and develop tactics to address gaps
- Emerging holistic and comprehensive view of resource needs

User Fee Program Cost Projections
Improving ability to project mid-term financial resource needs based on forecasting capability

Validating Resource Forecasting & Projecting 2-Year Staffing Requirements
Improving ability to identify mid-term staffing requirements and to develop appropriate strategies to address identified gaps

Operational Backbone
- HR Data
- Financial Data
- Project Management Data
- Harmonized MTR Data
- RCP Forecasting Capability

Capabilities

Support Infrastructure
Staffing, Governance, Business Processes integrated into Resource Management

www.fda.gov
How Are We Going to Get There?

Capabilities

- Review Process Optimization & Continuous Improvement
  Provides data/visibility into process/operations to systematically enhance ability to meet performance goals, while maintaining standards and minimizing strain on staff

- Business Intelligence & Reporting
  Provides real-time reporting and analysis to enable visibility into authoritative book of work, support prioritization decisions & identification of potential constraints impacting process operations and commitments

Operational Backbone

- Integrated Project Management Data
  Serves as the authoritative source of work activity data, providing the foundational infrastructure for an operations capability that integrates HR data, financial data, and resource forecasting/management capabilities while also streamlining the systems environment and data entry burdens on programs

- Real-Time Resource Forecasting & Staffing Requirements
  Enables pro-active ability to develop real-time data-driven resource forecasts by job role informing staffing plans

- Real-Time User Fee Program Cost Analysis
  Supports real-time analysis of program costs to improve trigger analysis and enhance confidence to utilize available fee resources to hire needed staff

- Resource Balancing
  Provides real-time transparency to shifting workload demands to enhance ability to align resources as appropriate

Support Infrastructure

- Staffing, Governance, Business Processes integrated into Resource Management

Benefits at the completion of Phase 5:

- Authoritative source of planning data to enable sharing of best practices across organizations
- Ability to provide key tactical resource capacity information to front-line management and to inform proactive user fee trigger analysis and the annual budget process
- Robust and flexible portfolio reporting capability based on one holistic book of work
- Improved tools to support operational strategies and prioritization of work
- Ability to deliver authoritative portfolio and resource capacity data as needed across all levels of the organization to support strategic and operational decision making

www.fda.gov
Status Update
Program Timeline

Planning

Pre-Planning
Planning Engagement (PwC)
Write Plan

Time Reporting

Acquisition Process
Technical Development
Technical Enhancements
TR Category Work
Production Pilot
Shutdown Delay
CDER Insight Implementation
ORA, HQ, CDRH Implementations

Implementation Planning
Acquisition Process
PwC Implementation Support and Advisory Services

RCP Capability

Change Management & Communications Workstream
Workload Forecasting Workstream
Resource Forecasting Workstream
Reporting & Tech Reqs
Adjustment Method Study

Org Development

Organizational Development incl. Recruiting, Hiring, Staffing

FDA Governance Established
Program Vision
Long-term Plan

FDA

PDUFA Reauthorized
Published

RCP Capability

PDUFA Reauthorized
Published

FDA

www.fda.gov
**Objective:** Predict regulatory submissions to inform likely sustained workload levels

**Timeframes for initial model development:**

- **Wave I – PDUFA/BsUFA**
  - Feb – July 2019
  - NDA/BLA Originals
  - NDA/BLA Resubmissions
  - INDs (New & Active)

- **Wave II – PDUFA/BsUFA**
  - June – Sept 2019
  - Efficacy Supplements
  - Manufacturing Supplements
  - Labeling Supplements
  - Formal Industry Meetings

- **Wave III – GDUFA**
  - FY 2020
  - ANDA Originals
  - ANDA Supplements

We are in essence working towards predicting activity for a large portion of the pharmaceutical industry.
PRELIMINARY ANALYSIS – For discussion purposes only

The Survival Random Forest output for individual INDs shows drastic differences in NDA/BLA submission rates for out-of-bag survival rates.

This is a promising result in being able to predict the timing of a marketing application submission.

Example: IND-phase activity can predict NDA/BLA submission

End of P2 Meeting: 3-4 years prior
Proprietary Name Doc: 6-12 months prior
Meeting Request Doc: 6-12 months prior

By the end of N2, there is a 60% chance this IND will be referenced by a Type 1 NDA/BLA

Out-of-bag predictions are calculated when an IND is selected in the validation set of an individual tree

End of P2 Meeting: None
Proprietary Name Doc: None
Meeting Request Doc: None

By the end of N2, there is a less than 1% chance this IND will be referenced by a Type 1 NDA/BLA
Adjustment Methodology

Statute outlines public process for implementing new fee adjustment mechanism

Sec 736(c)(2)(C):

CAPACITY PLANNING METHODOLOGY.—

(i) DEVELOPMENT; EVALUATION AND REPORT.—The Secretary shall obtain, through a contract with an independent accounting or consulting firm, a report evaluating options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the process for the review of human drug applications. The capacity planning methodological options and recommendations presented in such report shall utilize and be informed by personnel time reporting data as an input. The report shall be published for public comment no later than the end of fiscal year 2020.

(ii) ESTABLISHMENT AND IMPLEMENTATION.—After review of the report described in clause (i) and any public comments thereon, the Secretary shall establish a capacity planning methodology for purposes of this paragraph, which shall—

(I) replace the interim methodology under subparagraph (B);

(II) incorporate such approaches and attributes as the Secretary determines appropriate; and

(III) be effective beginning with the first fiscal year for which fees are set after such capacity planning methodology is established.

3rd party evaluation
(Nov’19 – Feb ‘20)

Published for public comment
(Mar ‘20)

New adjustment
Current state adjustment:

- Lagging indicator using 3-year averages
- Compensates for increases occurring in the past
- Based on submission counts
- Timing compounded by hiring timeframes

Once hired and trained, gap persists

Commercial INDs with Activity

FY18 fee adjustments based on this level
Adjustment Methodology

Opportunity to develop a **forward-looking** fee revenue setting methodology

**Future state adjustment:**
- Forward looking
- Compensates for likely sustained increases
- Translates submission activity to likely sustained resource demand
- Times resources to account for hiring and training timeframes

---

Example: 2 Year Resource Forecast

Sustained workload at this level, all other things being equal, translates to a need for additional resources to maintain performance:

**Forecast by Job Role**

- **RPM in Office A**

- **PharmTox in Office A**

**Forecast by Submission Category**

- **RPM Resource Forecast for NDA/BLA**

- **MO Resource Forecast for Meetings**

---

Commercial INDs with Activity
10:20 – 10:30 AM

BREAK
10:30 – 10:50 AM

FINANCIAL MANAGEMENT EVALUATION FOR HUMAN DRUG USER FEES

Jim Taylor
Grant Thornton, LLP – Health FFRDC
Fiscal Year 2018
Financial Management Evaluation for
Human Drug User Fees

Presented by:
The MITRE Corporation & Grant Thornton, LLP
June 7, 2019
The **CMS Alliance to Modernize Healthcare (The Health FFRDC)** is the first federally-funded research and development center (FFRDC) dedicated to protecting and promoting health and well-being.

The Health FFRDC is sponsored by the Centers for Medicare & Medicaid Services (CMS) and all divisions of the Department of Health and Human Services (HHS). MITRE, an objective not-for-profit organization, operates the Health FFRDC in partnership with CMS and all HHS agencies to implement innovative ideas to solve our nation’s toughest health problems.

The Health FFRDC is composed of an alliance of partners and members who are committed to providing conflict-free, objective expertise to HHS and its divisions.
Background & Purpose

- FDA collects over $1.4 billion in human drug user fees annually.
- New user fee programs, including Generic Drug User Fee Act (GDUFA) and Biosimilar User Fee Act (BsUFA), have increased financial management complexity.
- Reauthorization agreements for Prescription Drug User Fee Act (PDUFA), GDUFA and BsUFA included FDA commitments to engage an independent third party to conduct an evaluation of its financial management practices.

PURPOSE

- Develop a comprehensive evaluation focused on five specific areas of FDA’s financial management capability for PDUFA, BsUFA, and GDUFA programs during FY 2018.
- Provide recommendations based on best practices to help ensure that FDA’s user fee financial management capability is consistent with best practices in the federal government.
The Health FFRDC conducted an assessment that includes five focus areas (FA):

- **FA 1**: Resource Planning, Request and Allocation, and User Fee Administration
- **FA 2**: Administration of Fee Program Resources
- **FA 3**: Oversight and Governance
- **FA 4**: Technical Capabilities
- **FA 5**: User Fee Estimating Methodology
What did we find?

**FA 1: Resource Planning, Request and Allocation, and User Fee Administration**

Financial management practices fully comply with current financial management requirements.

**FA 2: Administration of Fee Program Resources**

FDA realized improvements in user fee administration: enterprise-level systems at the Agency-level support budget execution, billing and collections; provides robust reporting capabilities.

**FA 3: Oversight and Governance**

User fee governance structure is mature with some opportunities for improvement.

**FA 4: Technical Capabilities**

FDA is able to financially manage and administer human drug user fees.

**FA 5: User Fee Estimating Methodology**

In FY 2018, FDA was within 2% of target revenue across all human drug user fee programs, with some opportunities for improvement.
Conclusion

- FDA’s financial management maturity is appropriate for the governance, management, and oversight of its current human drug user fee programs.
- FDA is fully compliant with financial management requirements.
- FDA was within 2% of target revenue across all human drug user fee programs, with no over-collection of user fees.
- FDA is on a path to improve its policies, processes, and procedures – and its technology systems – to meet the increasing complexity within the human drug user fee programs.
Key Findings by Report Focus Area
Key Takeaways:
- FDA meets Agency-level user fee financial management requirements using HHS and FDA financial systems for routine tracking and reporting of user fee program funds.
- FDA is developing enhanced system capabilities (e.g., implementation of Full Time Reporting (FTR) for staff hours).
- The PDUFA, BsUFA, and GDUFA billing and collection functions and processes are well executed, and the process teams are continually exploring ways to innovate and automate processes.

Opportunities*
- FDA lacks a fully integrated User Fee Management policy and procedures framework resulting in localized processes; the resulting variation in practices leads to a lack of standardization.
- Centers and Offices rely on distributed tools and systems that require manual reconciliation and validation, which can lead to process inefficiency. (FDA plans to extend the central system to the Centers and Offices.)

*refer to Assessment report for full list of opportunities
FA 2: Administration of Fee Program Resources

FDA has realized improvements in user fee administration particularly at the Agency-level where enterprise-level systems support budget execution, billing and collections, and provide robust reporting capabilities.

Key Takeaways:

- Within the Centers, particularly CDER, management has encouraged process improvement and adoption of lean practices.
- Staffing changes over the last few years were deemed positive as new perspectives were introduced and levels more aligned with workload.

Opportunities:

- Further efficiency gains can be realized through center-level automation:
  - electronic billing for PDUFA and BsUFA, and
  - use of automated-workflow tools to streamline waiver and exemption processing.
- Efforts are already underway to leverage existing FDA customer service technologies to streamline customer service and request processing for PDUFA, GDUFA, and BsUFA.

*refer to Assessment report for full list of opportunities
**Key Takeaways:**

- The decision-making structure for user fees is understood and working efficiently, decision authority is respected, executive leadership is engaged, and oversight bodies are actively seeking improvement.
- FDA is continuously improving its decision-making process.
- The CDER Financial Council (CDER FC) in particular has led the way in better management of their user fee portfolio of investments, basing decisions on available evidence, and following up to see if established outcomes have been accomplished.

**Opportunities:**

- FDA would benefit from the creation of higher-level strategic objectives that cut across all user fee programs and describe the plans to achieve the negotiated, individual program performance commitments.

  Doing this would help user fee oversight bodies align their investments to projects that achieve optimal long-term outcomes and performance.

*refer to Assessment report for full list of opportunities*
Key Takeaways:

- 62% of employees are at or above their supervisors’ desired proficiency level in the financial management skills required to manage user fee resources.
- This assessment indicates FDA staff meet expectations for program knowledge and have the skills to meet legal and regulatory requirements.
- Financial management has been able to hire and retain staff with all but one of the desired technical competencies.

Opportunities:* 

- Based on supervisors’ desired proficiency, the FDA and financial management staff should:
  - Increase proficiency in decision support, problem solving and analytical skills.
  - Improve training in financial and related systems.
  - Enhance organizational structure knowledge.

*refer to Assessment report for full list of opportunities
Key Takeaways:

- FDA drug user fee programs annually assess and collect user fees to meet revenue targets, as authorized by the United States Federal Food, Drug, and Cosmetic (FD&C) Act.
- The programs’ forecasting methodologies evolved over time to meet changing internal and external circumstances, including market dynamics, trends and fee structures.
- Despite these challenges, as well as those posed by unforeseen one-time policy changes, FDA was within 2% of target revenue across all user fee programs in Fiscal Year 2018 (FY 2018).

Opportunities:

- While the portfolio performed well in FY 2018 overall, the FDA could:
  - Improve the forecasting accuracy of individual fee units based on Federal best practices for predictive modeling.
  - Research alternate methodologies, quality data and policies with the help of stakeholders.
  - Apply methodological approaches that leverage industry inputs, external market data and subject matter expert opinion.

In FY 2018, FDA was within 2% of target revenue across all user fee programs.
This presentation was produced for the U. S. Government under Contract Number 75FCMC18D0047, and is subject to Federal Acquisition Regulation Clause 52.227-14, Rights in Data-General.

No other use other than that granted to the U. S. Government, or to those acting on behalf of the U. S. Government under that Clause is authorized without the express written permission of The MITRE Corporation.

For further information, please contact The MITRE Corporation, Contracts Management Office, 7515 Colshire Drive, McLean, VA 22102-7539, (703) 983-6000.
MITRE is a not-for-profit organization whose sole focus is to operate federally funded research and development centers, or FFRDCs. Independent and objective, we take on some of our nation's—and the world's—most critical challenges and provide innovative, practical solutions.

Learn and share more about MITRE, FFRDCs, and our unique value at [www.mitre.org](http://www.mitre.org)
10:50 – 11:10 AM

FDA RESPONSE TO FINANCIAL MANAGEMENT EVALUATION

Jay Tyler
Chief Financial Officer
Office of Finance, Budget and Acquisitions
Focus Area 1: Resource Planning, Request and Allocation, and User Fee Administration

Health FFRDC finds that an integrated user fee management policy and procedures framework will lead to process standardization and efficiency.

Finding:
Further improve the management of user fee funds with:
- a more uniform approach and consistent, automated toolsets used across the Agency, center and offices

FDA
Takes nuanced recommendations under consideration for this focus area and will consider their cost-benefit analysis

FDA's systems and tools are state of the art in the federal space and allow for micro level tracking, reporting, and analytics
Focus Area 2: Administration of Fee Program Resources

Health FFRDC finds that **cross-collaboration** and **communication** supports the objective of meeting customer and stakeholder needs.

**Finding:**

Centers and offices can better integrate with and utilize the Agency level systems and tools; clarify roles and responsibilities, and increase analytic support.

Broaden **training opportunities** on the use of the Agency level tools and systems and leverage newly reconstructed **User Fee Financial Management Committee (UFFMC)** and the **FDA Executive Committee** to facilitate clear direction on user fee policy, strategic direction and financial management.
Focus Area 3: Oversight and Governance

Health FFRDC finds that aligning investments to projects that achieve long term outcomes and performance requires strategic objectives that cut across all user fee programs.

Finding:

Creation of higher-level strategic objectives that link to program performance commitments would help user fee oversight bodies make evidence-based decisions and align investments to strategy.

User Fee Financial Management Committee

The newly restructured UFFMC will work to ensure strategic alignment of investment decisions and policy direction, with direct feedback from FDA’s Executive Committee.

FDA

Appreciates the need for return on investment (ROI) data to inform user fee investment decisions

Takes advice on the utility of ROI under advisement but have no plans to mandate that quantifiable ROI data inform all user fee investment decisions as it is recognized that ROI information is not readily quantifiable, and is more often qualitative in the federal government.
Health FFRDC finds that financial management and administration of human drug user fees requires knowledgeable and skilled staff that can meet the legal and regulatory requirements.

Finding:
Successfully hired and maintained financial management staff with all but one of the desired technical competencies.

- Invest in additional staff training within program centers to ensure that systems, tools, and processes are fully understood and leveraged.
- Seek additional opportunities for greater collaboration between the CFO’s team and the program centers.
- Develop more comprehensive policies, procedures, and automated shared data repositories, to increase integration and consistency.
Focus Area 5: User Fee Estimating Technology

Health FFRDC finds that predictive modeling requires an **ongoing multi-pronged approach** to achieve improvements in **forecasting accuracy** as well as estimating confidence.

**Finding:**

Broadening of the methodologies applied would improve fee forecasting accuracy, help balance FDA’s inherent strengths and weaknesses, as well as provide programs with a more comprehensive understanding of fee unit behavior.

Several fees associated with GDUFA and BsUFA are new, which can cause a higher deviation early in the programs and the relatively small size of the BsUFA program inherently contributes to forecasting uncertainty for that program.

**Advanced Predictive Analytics**

FDA is developing **advanced predictive analytics** to forecast regulatory submissions as part of its **Resource Capacity Planning initiative**. FDA expects this new capability will improve the number of fee-paying submissions.
11:10 – 11:30 AM

OPEN PUBLIC COMMENT