U.S. FOOD & DRUG ADMINISTRATION

Biosimilar User Fee Act (BsUFA II) Reauthorization Public Meeting

October 20, 2016

Agenda

I. **Opening Remarks**
II. **FDA Presentations:**
   a. Background: Past is Prologue--BsUFA I
   b. BsUFA II Proposed Enhancements
   c. Fee Structure & Financial Issues

Break (10:30 – 10:45am)

III. **Panel 1 – Patient and Public Health Advocate Perspectives**
IV. **Panel 2 – Health Care Professionals Perspectives**

Lunch (11:30 – 12:30pm)

V. **Panel 3 – Regulated Industry Perspectives**
VI. **Open Public Comment**
VII. **Closing Remarks**

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Biosimilar User Fee Act (BsUFA II) Reauthorization Public Meeting

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Past is Prologue: BsUFA I

BACKGROUND

BsUFA Reauthorization Requirements

BsUFA REAUTHORIZATION and REPORTING REQUIREMENTS

(e) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a) and plans for meeting the goals, for the process for the review of biosimilar biological product application for the first 5 fiscal year after fiscal year 2017, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with, (A) the **Committee** on Energy and Commerce of the House of Representatives; (B) the **Committee** on Health, Education, Labor, and Pensions of the Senate; (C) **scientific and academic experts**; (D) **health care professionals**; (E) **representatives of patient and consumer advocacy groups**; and (F) the **regulated industry**.

(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall— (A) **present the recommendations** developed under paragraph (1) **to the Congressional committees** specified in such paragraph; (B) publish such recommendations in the Federal Register; (C) **provide for a period of 30 days for the public to provide written comments** on such recommendations; (D) **hold a meeting at which the public may present its views** on such recommendations; and (E) after consideration of such public views and comments, **revise such recommendations as necessary.**

(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

BPCI Directed FDA to Develop Recommendations for New User Fee Program for 351(k) Applications

- BPCI Act amended FD&C Act to create an abbreviated approval pathway in section 351(k) of the PHS Act for biological products, in addition to the existing pathway for original biological products under section 351(a)
- The BPCI Act directed FDA to develop recommendations for a user fee program for 351(k) applications for FYs 2013 through 2017.
- FDA was required to send recommendations to Congress by January 15, 2012

Unlike previous medical product user fee programs, the U.S. 351(k) biosimilars industry was just forming

PDUFA Program Characteristics at Initial Enactment	Biosimilar Program Characteristics 2011-12
~120 new drug marketing applications annually	**No marketing applications**
~200 establishments	**No establishments**
~2,000 drug and biological products	**No products**
Established process and history of drug development	**No established process or history of drug development**

Early non-user fee support for 351(k) review

- In FY2011, FDA received $1.8M under “Advancing Regulatory Science”

By 2011, FDA had received requests for 351(k) Pre-IND advice, but had not received 351(k) applications

Volume of future fee-paying applications was uncertain

Information available for user fee negotiations in 2011:

- Projections for the number of 351(k) applications that varied widely
- HHS 351(k) application estimates ranged from zero to seven per year
- Varying application estimates arose because of different assumptions, such as:
  - Number and timing of 351(k) applications FDA would receive for biosimilars marketed in EU
  - Number and timing of new 351(k) development programs in US based on economic competition and reference product expiration

BsUFA I: Industry stakeholders agreed to this FDA-proposed fee structure

Phase	Fee Category	Fee Administration	Fee Rate Explanation
Pre-Market Phase	Biosimilar Product Development (BPD)	Annual for each 351(k) IND, for duration of biosimilar product development phase[1]	10% of NDA/BLA application fee
	Reactivation Fee	Once upon reactivation	Twice the BPD fee for that fiscal year
	Application	For each 351(k) marketing application at time of application submission	Set equal to PDUFA original NDA/BLA fee, less sum of payments of Biosimilar Product Development (BPD) fees
	Supplement	For each supplement requiring clinical data	Set equal to half the 351(k) application fee requiring clinical data
Marketed 351(k) Products	Establishments	Annual per establishment	Set equal to PDUFA establishment fee[2]
	Products	Annual per product	Set equal to PDUFA product fee[3]

1. FY2011 NDA/BLA with Clinical Data Application Fee ~ $1,542,000
2. FY2011 PDUFA Establishment Fee ~ $ 497,200
3. FY2011 PDUFA Product Fee ~ $86,520

Review goals assumed additional staffing funded by $20 M in non-user fee spending to meet statutory spending trigger in addition to user fees. These goals were a more aggressive ramp-up than PDUFA I

SUBMISSION COHORT	PERFORMANCE GOAL				
	2013	2014	2015	2016	2017
Original Biosimilar Biological Product Application Submissions	70% in 10 months of the receipt date	70% in 10 months of the receipt date	80% in 10 months of the receipt date	85% in 10 months of the receipt date	90% in 10 months of the receipt date
Resubmitted Original Biosimilar Biological Product Applications	70% in 6 months of the receipt date	70% in 6 months of the receipt date	80% in 6 months of the receipt date	85% in 6 months of the receipt date	90% in 6 months of the receipt date

Goal type	Performance goal timeframe	Performance goal target				
		2013	2014	2015	2016	2017
BPD meeting type 1	30 calendar days	70%	70%	80%	85%	90%
BPD meeting type 2	75 calendar days	70%	70%	80%	85%	90%
BPD meeting type 3	120 calendar days	70%	70%	80%	85%	90%
BPD meeting type 4	60 calendar days	70%	70%	80%	85%	90%

* BPD Meetings: Biosimilars Product Development meetings during the pre-market phase

Fast Forward to 2016
Challenges of Addressing Biosimilar Complexity

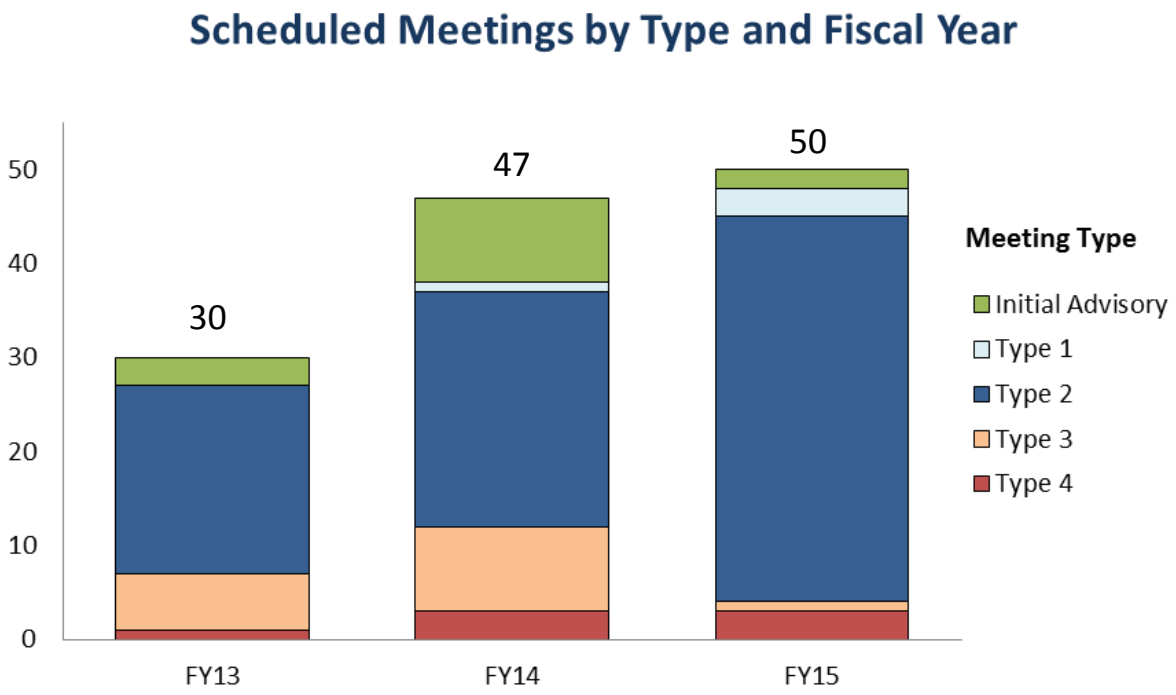
- Observations 3 years into BsUFA I operations:
  - Emergence and interaction of novel legal and novel scientific issues as sponsors develop these products newly authorized in BPCIA of 2010
    - Issues are actively surfacing in BPD meetings; require real-time deliberation by multidisciplinary team of FDA subject matter experts and is too early to provide useful, general guidance on many issues
  - Issues are novel and complex from every technical perspective. Examples:
    - Statistical issues are novel (e.g., analytic similarity not the same as clinical similarity) and often differ from the traditional statistical approaches for new or generic drugs
    - Quality/CMC packages are often much more extensive (more work to review) than for new biologics
    - RPMs stressed by the difficulties of scheduling extensive internal team meetings in addition to the external sponsor-requested meetings
  - Need rapid process for resolution of science and policy issues; however… Range, complexity and novelty of issues make “rapid process” nearly impossible at this time

Challenges of novelty/complexity compounded by greater than expected workload -- driven by sponsor requests

- As of October 5, 2016, 66 programs were enrolled in the Biosimilar Product Development (BPD) Program. CDER has received meeting requests to discuss the development of biosimilars for 20 different reference products.
- In addition, sponsors of some proposed biosimilar products have had a Biosimilar Initial Advisory meeting with FDA, but have not joined the BPD program to pursue the development of these products

- CDER holds development-phase meetings and provides written advice for ongoing development programs
  - Meeting requests increased 81% from 32 in FY 2013 to 58 in FY 2015.
  - Scheduled meetings also increased 67% from 30 in FY2013 to 50 in FY2015
  - Additionally, FDA provided written advice to sponsors for 16 out of 22 meeting requests that were denied or cancelled due to incomplete or premature requests (FY 2013-15)

Growth in FDA Development-Phase Workload for Biosimilars



The types of scheduled meetings shift with each fiscal year, with BPD Type 1 and Type 2 meetings becoming a larger portion of scheduled meetings in FY'15

Growth in Meeting Requests Shows Meetings Are Valuable for Sponsors, But Limits of Current Program Capacity Were Also Evident

- BsUFA Meeting Performance for FY2015 reflects real difficulties of conducting the "real time" analysis of such novel and complex issues by short-staffed FDA offices:
  - Able to schedule only 50% of Initial Advisory meetings within the 90 day meeting goal
  - Able to schedule only 67% of Type 1 meetings within 30 day meeting goal
  - Able to schedule only 49% of Type 2 *(most commonly requested)* meetings (n=41) within 75 day meeting goal
  - Not able to schedule any of Type 4 meetings within 60 day meeting goal
- Despite this BsUFA I performance challenge, Industry indicated that in BsUFA II they would like to see more meetings and faster turnaround of Agency advice

BsUFA I Accomplishments and Successes to Date

- FDA approved the first biosimilar in the US on March 6, 2015, Zarxio (filgrastim-sndz), a biosimilar to Neupogen
- FDA approved an additional 3 biosimilars
  1. Inflectra (infliximab-dyyb), a biosimilar to Remicade
  2. Erelzi (etanercept-szzs), a biosimilar to Enbrel
  3. Amjevita (adalimumab-atto), a biosimilar to Humira
- FDA has issued four final and five draft guidances since enactment of the BPCI Act

BsUFA II PROPOSED ENHANCEMENTS

Highlights of BsUFA II Proposed Enhancements

- Establish application review model similar to “the Program” under PDUFA for NME NDAs and original BLAs
- FDA may extend goal date if facilities are not adequately identified in an Original Application or Supplement
- Change goal date for Prior Approval Manufacturing Supplements
- Update for Special Protocol Assessments
- Enhance management of meetings for biosimilar development
- Development of new Guidance in specified areas
- Enhance review staff capacity

"The Program" Review Model

- Establish an application review model for original 351(k) BLAs similar to "the Program" under PDUFA for NME NDAs and original BLAs to promote the efficiency and effectiveness of the first cycle review process and minimize the number of review cycles necessary for approval.
- The parameters of the Program will include the following: 1) Pre-submission meeting 2) Original application submission 3) Day 74 Letter 4) Review performance goals (10 month user fee clock starts at 60-day filing date) 5) Mid-Cycle Communication 6) Late-Cycle and Advisory Committee Meetings 7) Inspections and 8) Assessment of the Program.
- The principles regarding review activities will be consistent with 21st Century Review for the Program under PDUFA.
- The additional 2-month review clock time is intended to provide FDA more time to complete additional late cycle activities added as part of the new review process (e.g., late-cycle meeting) and address other late cycle review work (e.g., application deficiencies, Advisory Committee advice, inspectional issues) to improve the efficiency of the first review cycle.

Review Goal Extension: Inspection of Facilities Not Adequately Identified in an Original Application or Supplement

- All original applications and supplements will be expected to include a comprehensive and readily located list of all manufacturing facilities included or referenced in the application or supplement. This list provides FDA with information needed to schedule inspections of manufacturing facilities that may be necessary before approval of the original application or supplement.

- If, during FDA's review of an original application or supplement, the Agency identifies a manufacturing facility that was not included in the comprehensive and readily located list, the goal date may be extended.
  - If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in an original application or supplement with clinical data, the goal date may be extended by three months.
  - If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in a manufacturing supplement, the goal date may be extended by two months.

Special Protocol Assessment and Agreement

The language in the goals letter is revised to include PK and PD similarity studies:

> Protocols that qualify for this program include any necessary clinical study or studies to prove biosimilarity and/or interchangeability (e.g., **protocols for pharmacokinetics and pharmacodynamics studies**, protocols for comparative clinical studies that will form the primary basis for demonstrating that there are no clinically meaningful differences between the proposed biosimilar biological product and the reference product, and protocols for clinical studies intended to support a demonstration of interchangeability). For such protocols to qualify for this comprehensive protocol assessment, the sponsor must have had a BPD Type 2 or 3 Meeting with the review division so that the division is aware of the developmental context in which the protocol is being reviewed and the questions being answered.

Addition of a Written Response Meeting Format for BIA and BPD Type 2 Meetings

- For Biosimilar Initial Advisory and BPD Type 2 meetings, the sponsor may request a written response to questions rather than a face-to-face meeting, videoconference or teleconference.

- FDA will review the request and make a determination whether a written response is appropriate or whether a face-to-face meeting, videoconference, or teleconference is necessary.

- If a written response is deemed appropriate, FDA will notify the requester of the date it intends to send the response. This date will be consistent with the timeframes specified for the specific meeting type.

Reduce the Scheduling Timeframe for Biosimilar Initial Advisory meetings

- Biosimilar Initial Advisory meetings will occur within 75 calendar days, instead of 90 days, from receipt of the meeting request and meeting package.

- This type of meeting is limited to a general discussion on whether a proposed product could be developed as a biosimilar product and to provide high-level overarching advice on the expected content of the development program.

Increase the Scheduling Timeframe for BPD Type 2 Meetings with Phased-In Performance Goals.

- To provide necessary time for FDA discussions and to develop comprehensive responses, BPD Type 2 Meetings will occur within 90 calendar days, instead of 75 days, from receipt of the meeting request and meeting package with the following phased-in performance goals- 80% FY2018-2019, 90% FY 2020-2022.

- The Agency will send preliminary responses to the sponsor's questions contained in the background package no later than five calendar days before the face-to-face, videoconference or teleconference meeting date for BPD Type 2 and Type 3 meetings.

Prior Approval Manufacturing Supplements

- Prior approval manufacturing supplements will be reviewed in 4 months, instead of 6 months, with phased-in performance goals- 70% FY 2018, 75% FY 2019, 80% FY 2020, 85% FY 2021, 90% FY 2022.

- Review timeframe aligns with goal for same supplements under PDUFA

Development of New Guidance

- FDA will publish revised draft guidance on *Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants* no later than September 30, 2018 to reflect agreed upon changes to meetings and to provide clarity on key issues related to meetings.

- FDA will update draft guidance on *Best Practices for Communication Between IND Sponsors and FDA During Drug Development*, to apply to communications between IND sponsors and FDA during biosimilar biological product development. FDA will publish a revised draft or final guidance by December 31, 2018.

Development of New Guidance (Cont.)

- FDA will publish draft or final guidance describing the following:
  - Considerations for designating biosimilar biological products as interchangeable to a reference product (draft on or before Dec. 31, 2017 & revised or final guidance 24 months after close of public comment period)
  - Statistical considerations for analytic similarity for biosimilar biological products (draft on or before Dec. 31, 2017 & revised or final guidance 18 months after close of public comment period)
  - Processes and further considerations related to post-approval manufacturing changes for biosimilar biological products (draft on or before March 31, 2019 & revised or final guidance 18 months after the close of the public comment period)
  - *Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product* (*draft guidance published in May 2014*, revised or final guidance will be published on or before May 31, 2019)
  - *Nonproprietary Naming of Biological Products* (*draft guidance published in August 2015*, revised or final guidance will be published on or before May 31, 2019)
  - *Labeling for Biosimilar Biological Products* (*draft guidance published March 2016*, revised or final guidance will be published on or before May 31, 2019)

Enhancing Capacity for Biosimilar Guidance Development, Reviewer Training, and Timely Communication

- FDA will strengthen staff capacity to:
  - Develop new regulations and guidance to clarify scientific criteria for biosimilar development and approval
  - Develop or revise MAPPs and SOPPs, and review templates
  - Deliver timely information to the public to improve public understanding of biosimilarity and interchangeability
  - Deliver information concerning the date of first licensure and the reference product exclusivity expiry date, to be included in the Purple Book

Hiring Capacity Enhancements

- The ability to hire and retain qualified staff is critical to ensure the availability of new safe and effective drugs.

- FDA will:
  - Modernize the hiring system and infrastructure.
  - Augment human resources capacity through the use of dedicated expert contractors.
  - Establish a dedicated function for the recruitment and retention of scientific staffing.
  - Set clear goals for hiring.
  - Conduct a comprehensive and continuous assessment of hiring and retention practices.

Enhance Management of BsUFA Resources in BsUFA II

- Establish a capacity planning function utilizing modernized time reporting.

- Enhance financial transparency and efficiency:
  - 3rd party assessment to evaluate the financial administration of the BsUFA program to identify recommendations for improvement.
  - Publish a BsUFA 5-year financial plan in FY 2018 and publish updates to the 5-year plan each subsequent fiscal year.
  - Convene a public meeting each fiscal year starting in FY 2019 to discuss the BsUFA 5-year financial plan, and the Agency's progress in implementing modernized time reporting and the capacity planning function.

FEE STRUCTURE AND FINANCES

Changes to Fee Structure

FDA and industry agreed to the following goals for BsUFA II:

- Establish an independent, efficient user fee structure based on BsUFA program costs
- Enhance predictability of BsUFA funding levels and sponsor invoices
- Minimize inefficiency by simplifying the administration of the program
- Improve FDA's ability to manage program resources and engage in long-term planning

Proposed BsUFA II fee structure:

- Removal of the supplement fee and establishment fee
- Retain the initial, annual, and reactivation biosimilar biological product development (BPD) fees
- Modification of the product fee (now called the "BsUFA Program fee") with a new provision that sponsors shall not be assessed more than 5 BsUFA Program fees for a fiscal year per application
- Modification of the application fee to discontinue the reduction of the application fee by the cumulative amount of BPD fees paid for that product
- Modification of the statute so that sponsors are assessed the annual BsUFA program fee for a fiscal year for each product approved as of Oct. 1st of that fiscal year to minimize clean-up billing

Proposed modification to the budget authority spending trigger:

- Spending trigger requirements are considered to be met in any fiscal year if the costs funded by budget authority are not more than 15 percent below the inflation adjusted amount for that year (the spending trigger will remain $20M adjusted for inflation)

Target Revenue and Fee Restrictions

FY 18 total revenue amount and FY18 adjustment:

- Negotiators estimated that FDA needs ~$45M to cover program costs in FY18. FDA and industry agreed to establish fees to generate a total of $45M (~158 FTEs) in revenue for FY18.

- FDA may adjust this amount to reflect updated workload and costs estimates for FY18 when we publish the FR notice establishing fees for FY18. The adjustment cannot increase the target revenue more than $9M (e.g., $54M maximum target revenue for FY18). FDA must describe the methodology used to calculate the FY18 adjustment in the FR.

Fee restrictions and target revenue allocation:

- To enhance predictability of sponsor invoices, fee amounts for each BsUFA fee type cannot increase more than 25% from the FY18 fee amounts until the capacity planning adjustment is available (FY2021). The fee restriction will be removed once capacity planning is available so not to arbitrarily constrain the results of the new methodology.

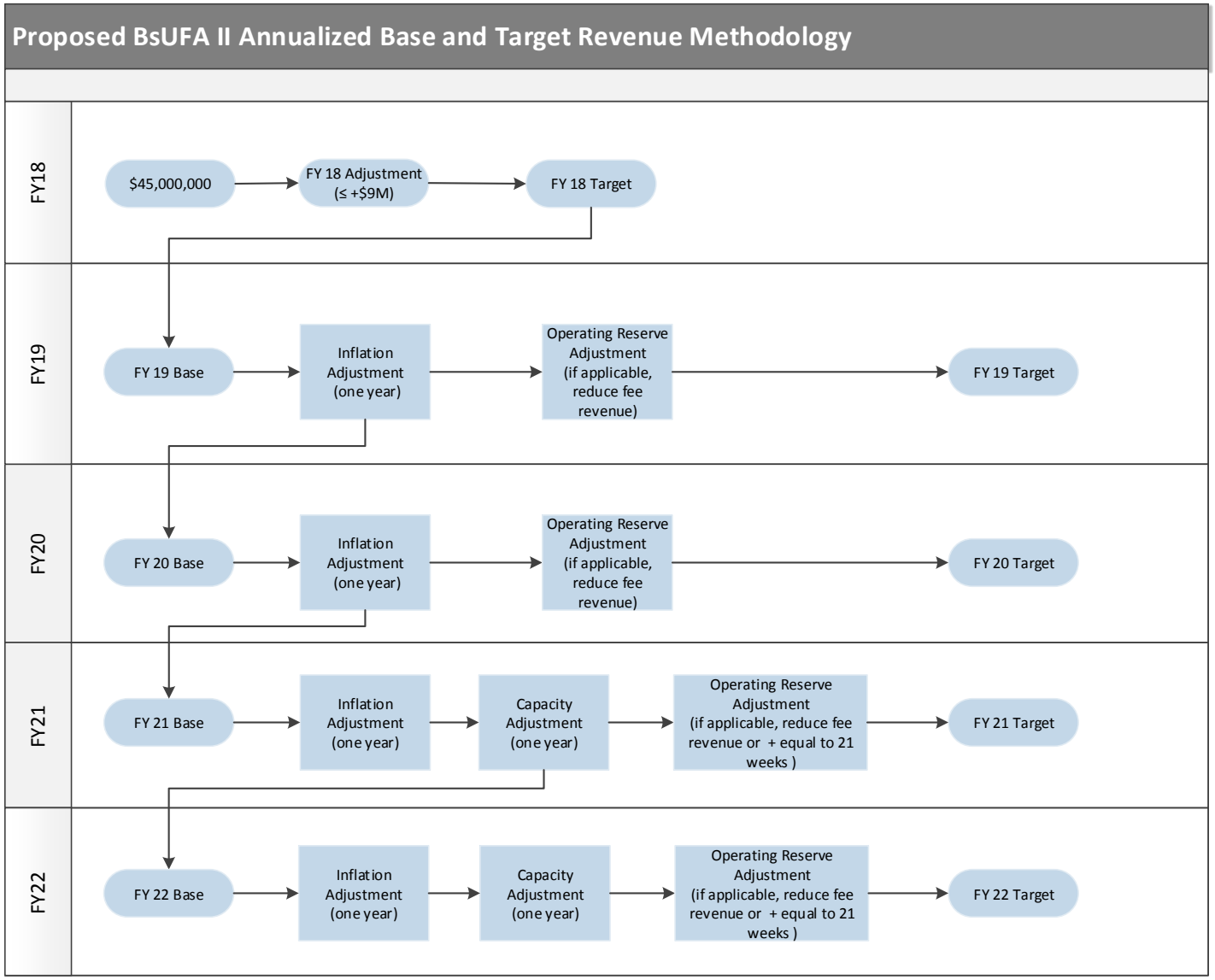
- To alleviate fluctuations in fee amounts and ensure FDA can comply with the fee restrictions, FDA can modify the amount of target revenue generated from each fee type each fiscal year. FDA will publish the rationale for the target revenue allocation in the FR notice establishing fees each fiscal year.

Annual Fee Adjustments

- Established process for setting the annual target revenue amount to provide for an annualized base
- Adapted the PDUFA inflation adjustment methodology to the annual base revenue for each fiscal year to ensure fee revenue and fee rates cover inflationary costs in the program
- Adopted a capacity planning adjustment that once effective will allow FDA to adjust fee revenue and fee rates to acquire resources to keep pace with increases in program workload/costs. The capacity planning methodology will be reviewed by an independent accounting/consulting firm and the firm's report will be published for public comment no later than the end of FY2020.
- Created an operating reserve adjustment to ensure the program can survive fluctuations in fee collections, avoid accruing unnecessarily high carryover balances, and to mitigate substantial increases in fee rates.
  - Until the capacity planning adjustment is effective, FDA can utilize an interim operating reserve adjustment that permits FDA to reduce the fee revenue and fees in any given fiscal year as determined appropriate for long-term financial planning purposes
  - Once capacity planning is effective, FDA may continue to reduce the fee revenue and fees and also increase the fee revenue and fees to not more than 21 weeks of operating reserves (~40% of the target revenue)

- Additional enhancement in commitment letter:
  - Reduce carryover balance to no greater than 21 weeks of the FY 2022 target revenue by the end of FY 2022. If FDA is unable to reduce the carryover balance during the final year, FDA will outline its plan to reduce the carryover balance in the FY 2022 financial report and update the BsUFA 5-year financial plan.

Proposed Target Revenue Methodology



BREAK

PANEL 1 – Patient and Public Health Advocate Perspectives

AARP Perspective on BSUFA Reauthorization

Leigh Purvis, Director, Health Services Research

AARP

Overview

- Why does this issue matter to AARP?
- Thoughts on BSUFA
- Outlook for the future

Growing importance of biologics

- Biologics represent a growing share of the drug development pipeline
- More than 50% of the US prescription drug spending is expected to be biologics by 2018
- Indications for existing biologics are expanding
    - Some have 10 to 15 indications with more in development

Treatment costs can be extraordinarily high

- Many new products are entering the market with extremely high prices
  - Annual costs can range from $25,000 to $400,000
- Patient population sizes are growing
  - PCSK9 inhibitors could potentially be used by for 10-15 million patients
    - Annual cost: ~$14,000 per year

Older adults are particularly vulnerable to biologics-related costs

- Older adults use more prescription drugs than any other segment of the population
    - 68% of Medicare beneficiaries are being treated for 2+ concurrent chronic illnesses
- Biologics are often used to treat conditions that are more commonly found in older adults (e.g., multiple sclerosis, cancer, rheumatoid arthritis)
- Older adults do not have the financial resources to absorb high prescription drug costs

Medicare and its beneficiaries are under increasing pressure

- Medicare Part B prescription drug spending doubled from $11 billion to $22 billion between 2007 and 2015
- In 2014, 9 of the top 10 drugs with the highest total Part B expenditures were biologics
- Part B beneficiaries are responsible for 20% of their prescription drug costs
    - Out-of-pocket costs for expensive Part B drugs can reach as much as $100,000

Medicare Part D costs are also growing

- Medicare Part D spending reached $85 billion in 2015
    - Share of spending attributable to biologics increased from 6% to 10% between 2009 and 2013
- Share of high-cost enrollees that filled at least one prescription for a biologic increased from 8% to 12% over the same time period
- Part D plans are increasingly using coinsurance
- Out-of-pocket spending is limited by catastrophic cap ($4,950 in 2017)
    - However, enrollees can face out-of-pocket costs that exceed $10,000/year

In other words: biosimilar competition can't come soon enough

- The costs associated with biologics are not sustainable for patients or payers
- Multiple biologics with sales in the billions will lose patent protection by 2020
- Spending on biologics is projected to grow by more than 10% annually until key biosimilars become available

Overview

- Why does this issue matter to AARP?
- Thoughts on BSUFA
- Outlook for the future

Overarching theme

- FDA should ensure that unnecessary barriers do not preclude the monetary savings that were intended by the creation of the biosimilar approval pathway

More specifically…

1. Ensure sufficient capacity to support biosimilar review to prevent unnecessary delays in the development and approval of biosimilars

2. Ensure that review/approval processes can evolve with analytics

   - Goal is to achieve approval process that resembles traditional generic approval process

   - Pathway will not be attractive unless it provides cost savings

3. Ensure that science overrules speculation when making regulatory decisions

   - No compelling evidence that unique INNs are needed

   - Build on FDA experience with manufacturing process changes

Overview

- Why does this issue matter to AARP?
- Thoughts on BSUFA
- Outlook for the future

What if the biosimilar market never develops?

- The costs associated with biologics are not sustainable for patients or payers
- Many patients will be unable to afford biologics if competition does not provide some level of price relief
- Medical advances are meaningless if no one can afford to use them

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PANEL 1 – Patient and Public Health Advocate Perspectives

PANEL 2 – Health Care Professional Perspectives

BsUFA II

Angus B. Worthing MD
American College of Rheumatology

Outline

- Interchangeable designation
- Labeling
- Enhancing capacity

Interchangeable Designation

- Draft by 12/31/2017
- Self-administered biosimilars could be dispensed before then (e.g., adalimumab-atto, etanercept-szzs)
- Lower cost or higher margin could incentivize payers, pharmacy benefits managers, and pharmacies to switch stable patients from originator biologic to a non-interchangeable biosimilar, and back, and forth

Interchangeable Designation

- FDA options:
  - Issue guidelines for biosimilar substitution
    - FDA website
    - Electronic prescribing drop-down boxes
    - Purple book
  - Postmarketing program for AEs after substitution of non-interchangeable biosimilars

Biosimilar FDA Labels

- Include “Interchangeable” or state “Not interchangeable”
- Include Clinical data
  - On label
  - Via hyperlink
- Encourage discussion of clinical data

Enhancing FDA capacity

- Biosimilar program funding
  - BsUFA
  - $20M taken from other FDA programs
  - No Congressional appropriations
- ACR calls on Congress to increase FDA capacity to hire staff and issue rules, guidance

Summary

- Issue guidance on substitution to help pharmacists avoid inappropriate substitution
- Include biosimilar/interchangeable status and clinical data (or hyperlink) in labels
- ACR supports Congressional appropriations to enhance FDA capacity
- American College of Rheumatology supports safe and effective biosimilars to improve access to treatments

ASHP Views on BsUFA Reauthorization

Jillanne M. Schulte, JD
Director, Federal Regulatory Affairs
October 20, 2016

ashp™
pharmacists advancing healthcare

ASHP Policy: Approval of Biosimilar Medications

- To encourage the development of safe and effective biosimilar medications in order to make such medications more affordable and accessible; further,
- To encourage research on the safety, effectiveness, and interchangeability of biosimilar medications; further,
- To support legislation and regulation to allow Food and Drug Administration (FDA) approval of biosimilar medications; further,
- To support legislation and regulation to allow FDA approval of biosimilar medications that are also determined by the FDA to be interchangeable and therefore may be substituted for the reference product without the intervention of the prescriber; further,
- To oppose the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance; further,

ASHP Policy: Approval of Biosimilar Medications, cont.

- To oppose any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed; further,
- To require postmarketing surveillance for all biosimilar medications to ensure their continued safety, effectiveness, purity, quality, identity, and strength; further,
- To advocate for adequate reimbursement for biosimilar medications that are deemed interchangeable; further,
- To promote and develop ASHP-directed education of pharmacists about biosimilar medications and their appropriate use within hospitals and health systems; further,
- To advocate and encourage pharmacist evaluation and the application of the formulary system before biosimilar medications are used in hospitals and health systems.

ASHP Concerns

- Publication of Interchangeability Guidance
- Biologic Naming Conventions
- Postmarketing Surveillance of Biologic Products

FDA Biosimilar User Fee Act Public Meeting

Mary Jo Carden, RPh, JD
Vice President, Government & Pharmacy Affairs
Academy of Managed Care Pharmacy

October 20, 2016

AMCP Academy of Managed Care Pharmacy®

AMCP Academy of Managed Care Pharmacy®

- **Mission**
  - Empower its members to serve society by using sound medication management principles and strategies to ***improve heath care for all***
- **Vision Statement**
  - Managed care pharmacy ***improving health care for all***

Overview

- **Interchangeability guidance**
  - Release as early as possible to ensure certainty
  - AMCP's position
- **Final naming and labeling guidance**
  - Release final guidance as soon as possible
  - AMCP's comments
- **AMCP's biosimilar education initiatives**
  - Biosimilars Resource Center www.biosimilarsresourcecenter.org
- **FDA should encourage and provide guidance for active post-marketing surveillance**

Interchangeability Guidance

AMCP's Position

- Clarity needed to designate biosimilars as interchangeable with reference product
- First determine biosimilarity then interchangeability
- Pharmacist substitution should be permitted without additional steps, including prescriber notification and other recordkeeping
- No exclusivity

Naming and Labeling Guidance

AMCP's Comments

- **Naming**
  - AMCP concerned about confusion with use of random 4-letter suffix added to nonproprietary name
  - Suffix is unnecessary addition of new data
    - Use National Drug Codes on all claims
    - FDA should provide final guidance with information on impact of naming on stakeholders
- **Labeling**
  - Reconsider requirement for biosimilarity statement
  - Ensure that final guidance is consistent with naming and interchangeability

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Announcing a new biosimilars resource for health care providers. BRC is your source for educational programs, including accredited continuing education. Click "Stay Informed" to receive updates from this site and on biosimilars.

NCPA NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

NASPA NATIONAL ALLIANCE OF STATE PHARMACY ASSOCIATIONS

HOPA Hematology/Oncology Pharmacy Association

ASCP American Society of CONSULTANT PHARMACISTS

American Association of Colleges of Pharmacy AACP

American Pharmacists Association APhA

WHAT ARE BIOSIMILARS?
Learn more.

LEGISLATIVE MAP
View legislation in your state.

AHIP America's Health Insurance Plans

NEWS AND PERSPECTIVES
FDA Approves Erelzi, First Biosimilar Etanercept

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AMCP Academy of Managed Care Pharmacy®

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@Biosimfacts

The twitter feed for the new Biosimilars Resource Center - your first stop for unbiased, up-to-date information and education on biosimilars.

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AMCP Academy of Managed Care Pharmacy®

BsUFA Reauthorization Public Meeting

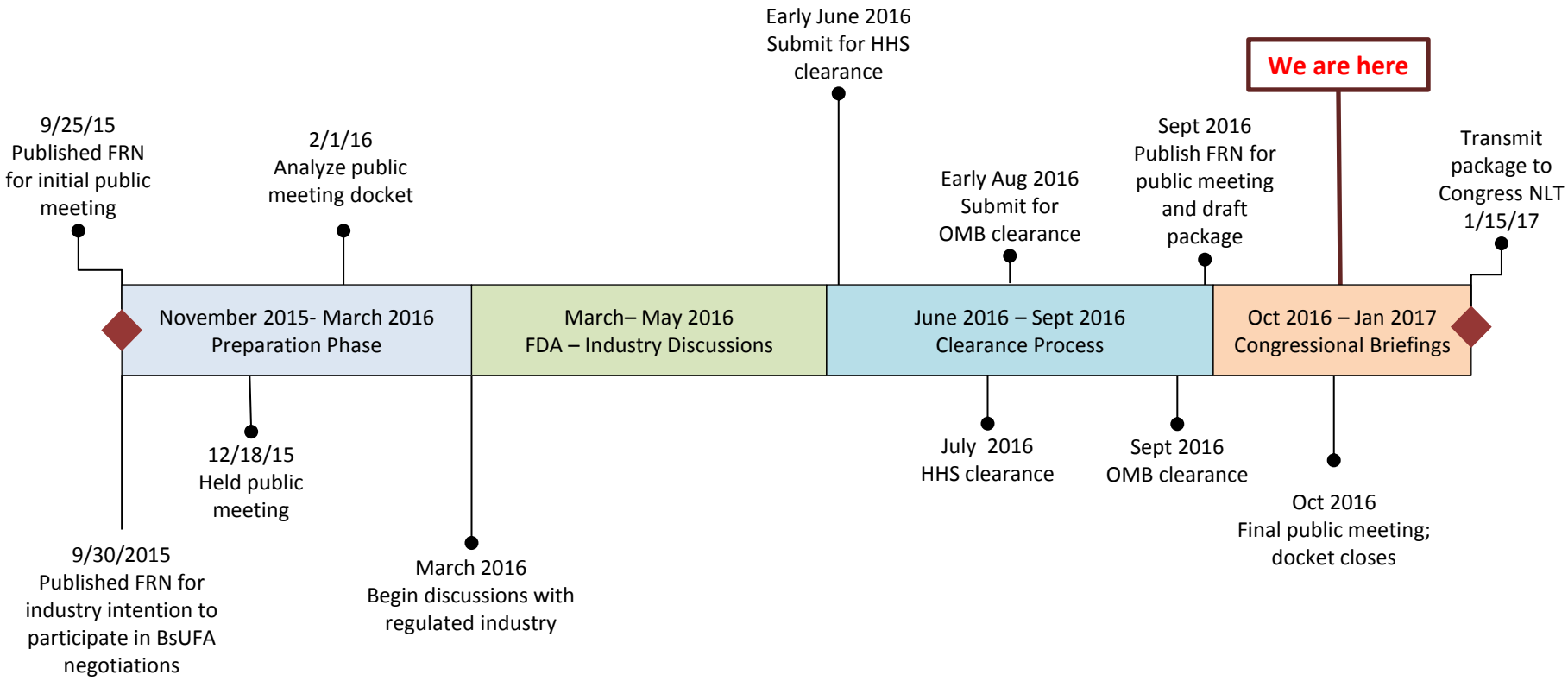
We will now break for lunch, the meeting will resume at 12:30pm

PANEL 3 – Regulated Industry Perspective

OPEN PUBLIC COMMENT

CLOSING REMARKS

BsUFA II Reauthorization Targeted Timeline



Next Steps

- Review and analyze public comments on proposed recommendations – deadline for public comments is October 28, 2016

- Transmit final proposed package to Congress

Thank you for coming!