

2. FDA will convene a public meeting on or before the end of the 3rd quarter of each fiscal year to discuss the BsUFA 5-year financial plan and the Agency's progress in implementing resource capacity planning, including the continual improvement of the CPA and time reporting, and the integration of resource capacity planning in resource and operational decision-making processes.

#### C. MANAGEMENT OF CARRYOVER BALANCE

FDA is committed to reducing the carryover balance to no greater than 21 weeks of the target revenue by the end of FY 2025.

In the annual updates to the BsUFA five-year financial plan, FDA will provide updates on its progress towards implementing its plan to reduce the carryover balance as outlined in the FY 2022 BsUFA financial report and the five-year financial plan.

#### IV. IMPROVING FDA HIRING AND RETENTION OF REVIEW STAFF

Enhancements to the biosimilar biological product review program require that FDA hire and retain sufficient numbers and types of technical and scientific experts to efficiently conduct reviews of 351

(k) applications. During BsUFA III, the FDA will commit to do the following:

##### A. SET CLEAR GOALS FOR BIOSIMILAR BIOLOGICAL PRODUCT REVIEW PROGRAM HIRING

1. The BsUFA III agreement provides FDA additional user fee funding to hire additional staff for the biosimilar biological product review program in BsUFA III. FDA will set clear goals to hire the new staff outlined in Table 1.

TABLE 1

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
CDER .....	14	1	0	0	0

2. FDA will report on progress against the hiring goal for BsUFA III on a quarterly basis posting updates to the FDA BsUFA Performance webpage.

##### B. COMPREHENSIVE AND CONTINUOUS ASSESSMENT OF HIRING AND RETENTION

The Directors of CDER and CBER will utilize a qualified, independent contractor with expertise in assessing HR operations to conduct a targeted assessment of the hiring and retention of staff for the biosimilar biological product review program. The BsUFA III assessment will be conducted under the same contract and by the same independent contractor that will conduct the assessment related to hiring and retention of staff for the human drug review program in PDUFA VII. The contractor will assess the factors that contribute to HR successes and challenges, including factors outside of FDA's control. The assessment will build upon the findings of previous evaluations conducted under BsUFA II and PDUFA VI with a focus on the changes and adjustments that have improved FDA's hiring and retention outcomes and which challenges remain. In addition to evaluating the outcomes of various hiring changes, the assessment will include metrics related to recruiting and retention in the biosimilar biological product review program, including, but not limited to, specific targeted scientific disciplines, attrition, and utilization of pay authorities. The report will include the contractor's findings and recommendations on further enhancements to hiring and retention of staff for the biosimilar biological product review program, if warranted.

The assessment will be published on FDA's website on or before June 30th, 2025 for public comment. FDA will also hold a public

meeting on or before September 30th, 2025 to discuss the report, its findings, and the Agency's specific plans to address the report recommendations.

#### V. INFORMATION TECHNOLOGY GOALS

Under BsUFA III, FDA will:

##### A. DEVELOP DATA AND TECHNOLOGY MODERNIZATION STRATEGY

FDA will progress a Data and Technology Modernization Strategy ("Strategy") that provides FDA's strategic direction for current and future state data-driven regulatory initiatives.

1. No later than Q4 FY 2023, FDA will establish a Data and Technology Modernization Strategy that reflects the vision in FDA's Technology and Data Modernization Action Plans, including:

a. outlining key areas of focus and approach including leveraging cloud technologies to support Applicant-FDA regulatory interaction;

b. articulating enterprise-wide approaches for both technology and data governance; and

c. aligning strategic initiatives in support of BsUFA review goals, drawing a line of sight between initiatives and the enterprise strategy (i.e. the agency-wide strategy also supporting components outside BsUFA).

2. The Strategy will be shared and annually updated to reflect progress and any needed adjustments. Milestones and metrics for BsUFA initiatives will be included in the updates.

##### B. MONITOR AND MODERNIZE ELECTRONIC SUBMISSION GATEWAY (ESG)

FDA will continue to ensure the usability and improvement of the ESG.

1. Annually, FDA will provide on the ESG website historic and current metrics on ESG performance in relation to published targets, characterizations and volume of submissions, and standards adoption and conformance.

FDA will advance the ESG cloud-based modernization with an improved architecture that supports greatly expanding data submission bandwidth and storage, while continuing to ensure its stable operation.

2. Annually, FDA will provide on the ESG website historic and current metrics on ESG performance in relation to published targets, characterizations and volume of submissions, and standards adoption and conformance.

3. By the end of FY 2025, FDA will complete ESG transition to the cloud, including set-up and integration of an enterprise Identity and Access Management solution that will streamline applicant access to FDA resources.

4. Annually, FDA will share progress against the implementation project plan.

5. FDA will engage industry to provide feedback and/or participate in pilot testing in advance of implementing significant changes that impact industry's interaction with the enterprise-wide systems.

#### VI. DEFINITIONS AND EXPLANATION OF TERMS

A. The term "review and act on" means the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

B. A resubmitted original application is a complete response to an action letter addressing all identified deficiencies.

#### RECOGNIZING THE 38TH ANNIVERSARY OF ANTI-SIKH VIOLENCE IN INDIA

Mr. TOOMEY. Mr. President, as a proud member of the American Sikh

Caucus, I would like to join my Sikh friends in Pennsylvania's Sikh community and Sikhs around the world in recognizing the 38th anniversary of the November 1984 anti-Sikh violence in India.

For those of you who are not familiar, Sikhism traces its nearly 600-year history to the Punjab region of India. With nearly 30 million followers globally and 700,000 here in the U.S., Sikhism is one of the world's major religions.

Historically, Sikhs have showcased a commitment to serving individuals from all religious, cultural, and ethnic backgrounds—demonstrating their generosity and deep sense of community. During the COVID-19 pandemic, Sikh communities across Pennsylvania and the United States came together to deliver groceries, masks, and other supplies to tens of thousands of families in need no matter their race, gender, religion, or creed. In my many years serving the Commonwealth, I have personally witnessed the spirit of Sikhs and have come to better understand the Sikh tradition that is founded on equality, respect, and peace. It is clear that the presence and contributions of Sikh communities have thoroughly enriched their neighborhoods across the country.

1984 marks one of the darkest years in modern Indian history. The world watched as several violent incidents broke out among ethnic groups in India, with several notably targeting the Sikh community. Today we are here to remember the tragedy that commenced on November 1, 1984, following decades of ethnic tension between Sikhs in the Punjab province and the central Indian Government. As so often in such cases, the official estimates likely do not tell the whole story, but it is estimated that over 30,000 Sikh men, women, and children were deliberately targeted, raped, slaughtered, and displaced by mobs across India.

To prevent future human rights abuses, we must recognize their past forms. We must remember the atrocities committed against Sikhs so that those responsible may be held accountable and that this type of tragedy is not repeated against the Sikh community or other communities across the globe.

#### ADDITIONAL STATEMENTS

##### 100 YEARS OF THE LEBANON AMERICAN CLUB IN DANBURY, CONNECTICUT

● Mr. BLUMENTHAL. Mr. President, today I rise to recognize the Lebanon American Club of Danbury, CT, as they celebrate 100 years of devoted cultural engagement and civic service in their community.

The Lebanon American Club—or "the Club," as it is affectionately known as by its members—was founded in 1922 as

the Syrian American Club. In its early days, this organization assisted members in becoming American citizens, learning English, and served as a vital social support system for Lebanese and Syrian immigrants. After initially meeting at various locations across Danbury, the Club established a permanent home in "Little Lebanon" on New Street in Danbury in the 1930s, before moving to its current West Street location in 1993.

Highly active in the civic and cultural life of the Arabic speaking community in Danbury, the Lebanon American Club boasted many members who were major contributors to the economic, professional, and social fabric of the region. After the election of Chicory Buzaid as Danbury City Sheriff in 1937—the first Lebanese American elected to public office in the State of Connecticut—the Club's members became more politically active as well.

From the 1940s through the 1960s, the Club's activities expanded with regular dinners, scholarship programs for students, fundraisers to aid members in need, and an annual Labor Day weekend "Mahrajan" festival celebrating their Lebanese and Syrian heritage.

In the 1970s, a new wave of Lebanese immigrants sparked a revitalization of the Lebanon American Club and their activities expanded. New Club programs were established—and continue today—including a children's Christmas party and a scholarship award dinner which has grown tremendously over the years, providing tens of thousands of dollars in college scholarships to high school graduates. Additionally, the Lebanon American Club Ladies Auxiliary routinely holds dinners and wine tastings and is a significant contributor to the Club's overall activities.

In recent years, the Lebanon American Club has continued to expand and flourish. The Lebanon American Teacher Exchange program was established in 2002, and the annual Lebanon American Day flag raising ceremony was first held the next year in 2003. In 2009, the Club established a heritage monument committee to pay tribute to their immigrant ancestors, and the monument was unveiled at city hall during the 2010 Lebanon Day celebration. The Club has continued to thrive of late, including hosting regular blood drives throughout the COVID-19 pandemic to provide lifesaving aid to the community.

For a century, the Lebanon American Club has provided cultural, civic, and social support to its members, the Lebanese community, and the Danbury community at large. I have attended many Club activities and greatly appreciate and admire their long-standing commitment to preserving and promoting their cultural heritage while selflessly serving their community through their many activities and programs. I hope my colleagues will join me in congratulating the Lebanon American Club of Danbury, CT, on this

momentous occasion of their 100th anniversary.●

#### TRIBUTE TO DR. JOAN PHILLIPS

Mr. MANCHIN. Mr. President, I rise today to honor the legacy of Dr. Joan Phillips for her many years of service dedicated to child well-being and to all people of West Virginia.

I have often said there is no greater accomplishment than to find yourself in a position to give back to the community you love. Dr. Phillips embodies giving, always willing to lend support and knowledge to those in need throughout her career.

Protecting and serving vulnerable people was her passion, one that motivated her throughout four decades of professional work. Dr. Phillips is viewed by her colleagues, and rightfully so, as an advocate for vulnerable children of West Virginia. Most recently serving as the co-medical director of Child Advocacy Center of Charleston Area Medical Center, her list of accomplishments is staggering, continuously pioneering child advocacy standards across the region.

As West Virginia's first ever board-certified child abuse pediatrician, Dr. Phillips has always been pivotal in ensuring that the children of our State receive the correct level of care. Over the course of her admirable career, Dr. Phillips has changed countless lives, both internally through the Child Advocacy Network and externally consulting through private practice. As a result of her efforts, she was in the first round of child abuse subspecialty recognized by the American Academy of Pediatrics.

Dr. Phillips always made time to consult on cases and never turned down the opportunity to assist regardless of location. Other physicians, law enforcement officers and child protective services workers regularly sought her expertise and advice.

Over the years, Dr. Phillips held many leadership roles, including president of the American Academy of Pediatrics, numerous boards of local and statewide organizations, community health agencies, family service agencies, as well as State and national committees related to issues regarding child well-being.

Not only did Dr. Phillips fiercely dedicate her time to advancing child healthcare, but she also found time to pass her knowledge along to others. She regularly presented at conferences, mentored other child abuse medical providers and taught within medical and residency programs at West Virginia University and Marshall University. I know she has inspired many young leaders throughout her illustrious career, and I am confident they will carry the torch to ensure a brighter tomorrow. Truly, her legacy of dedication to health and childcare services is one we should all instill in ourselves.

With an unrivaled, strong spirit of optimism and innovation, her commit-

ment to preventing and treating child abuse in our communities is something to admire. Her work has undoubtedly changed the quality of healthcare in the State of West Virginia. I will always be grateful to Dr. Phillips for her lifetime of influential work.

While she is retiring and everyone is sure to miss her strong leadership, Dr. Phillips' unwavering dedication will leave a lasting legacy on the countless lives she has touched. Again, I congratulate Dr. Phillips for her remarkable years of service and her outstanding dedication to improving our great Nation, and I am honored to wish good health and much happiness to her and her family in the days and years ahead.●

#### TRIBUTE TO KEVIN FERN

● 1Mr. MORAN. Mr. President, I rise today to pay tribute to a notable Kansan, Kevin Fern. Mr. Fern is currently executive director of Visit Shawnee, a division of the Shawnee Chamber of Commerce and the official Destination Marketing Organization for the city of Shawnee. He has served the city of Shawnee since 2008 and was also nominated by Governor Laura Kelly to the Kansas Council on Travel and Tourism.

Prior to his current position he spent a number of years in politics, working a variety of campaigns, including for Presidential candidate Dick Gephardt's campaign in 1988—always noting that he "wanted to be the guy behind the scenes, making everything happen." Following a number of years in campaign politics, Mr. Fern entered the hospitality industry, where he worked for more than 15 years in the hotel industry.

Mr. Fern is a long-time native of Shawnee, KS, and his passion for the city mixed with his ethos to "make our world just a little better" embodies the true Kansas spirit. I can confidently say Mr. Fern's impactful career has truly made the world and the city of Shawnee a better place.●

#### REMEMBERING P.J. O'ROURKE

● Mr. PORTMAN. Mr. President, I rise today in tribute to P.J. O'Rourke, one of America's greatest humorists. P.J. passed away after a brief illness earlier this year, leaving behind his beloved wife Tina and his three children, as well as countless readers who will miss the laughter and delight he brought them over a career that spanned nearly half a century.

P.J. was born 74 years ago in Toledo, OH. We are proud to call him an Ohio native. His father owned a car dealership; his mother was a homemaker. P.J. was the product of Toledo's public schools, then of Miami University in southwest Ohio. One of his English professors, spotting a unique talent, arranged a scholarship that allowed him to continue in school and get his degree in English, with honors.