# Prescription Drug User Fee Act and Biosimilar User Fee Amendments Hiring and Retention Assessment Public Meeting

September 24, 2025 - 9:00 a.m. EDT

***Meeting Transcript***

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# Welcome and Introduction

***Thamar Bailey:***

Good morning. Hi, everyone. It is 9:00 AM, so we're going to go ahead and get started.

But not without a technical difficulty.

Give me one moment.

All right. Good morning and thank you all for joining us today for a public meeting on the Prescription Drug User Fee Act, or PDUFA, and Biosimilar User Fee Amendments, or BsUFA, Hiring and Retention Assessment.

My name is Thamar Bailey, and I'm a social scientist within the Center for Drug Evaluation and Research's Office of Programs and Strategic Analysis. And today I'll be serving as your meeting moderator.

As a quick overview of why we are all here today, this public meeting is being held to meet performance commitments included in BsUFA, excuse me, PDUFA VII and BsUFA III commitment letters. The letters state that the FDA will utilize a qualified, independent contractor to conduct an assessment of its hiring and retention of staff for the human drug review and biosimilar biological product review programs.

For context, this assessment builds upon the findings from three previous assessments conducted by independent contractors under previous PDUFA and BsUFA reauthorizations. Following the completion of the assessment, the FDA agreed to hold a public meeting for the independent contractors to share their findings and recommendations. Today's meeting will ensure the completion of this commitment.

In terms of today's agenda, we have two formal presentations prepared for you. The first is from Valerie Overton, vice president at Eastern Research Group, or ERG. Valerie will provide an overview of ERG's assessment results and recommendations. We will then have a fifteen-minute break before Melanie Keller, FDA's Deputy Chief

Operating Officer, and Chantal Dawson, FDA's Acting Chief Talent Officer, present FDA's response to the assessment.

Following the FDA's response, we will have the prearranged list of public commenters to provide their comments.

While the public comment list is finalized, please keep in mind that you can submit comments to the public docket until October 24th. You can find the public docket on the FDA's public meeting web page, or directly through the Federal Register. We'll post a link to the public meeting, or the public docket in the Q&A for this meeting.

A few housekeeping items before we begin.

We have many people participating virtually today. Or at least registrants. If your audio or visual connection diminishes at any point during today's meeting, we recommend trying to reconnect to the system. If you experience other technical issues during the webcast, please type your issue into the Q&A online or e-mail CDERProgramEvaluation@fda.hhs.gov.

If schedule modifications are needed, we will communicate those verbally and post them to the Q&A. For those of you attending the meeting in person, restroom facilities are located down the hall to the right of the conference room. A video recording and transcription of today's meeting, as well as the slides presented, will be published on the FDA website after this meeting.

Now I'll turn it over to Valerie Overton who will present the assessment findings and recommendations.

Thank you.

## Presentation of the Assessment

***Valerie Overton:***

Thank you, Thamar.

So, as Thamar said, I'm Valerie Overton with Eastern Research Group, or ERG, and I'm here to present our third-party independent evaluation of FDA's hiring and

retention program for the human drug review and biologic/biosimilars staff in support of PDUFA and BsUFA.

In this presentation this morning, I'm going to first give an introduction to the evaluation itself in terms of what the key objectives of the evaluation were and what questions we attempted to answer in order to address those key objectives. And then I'll talk about the methods we used to conduct the evaluation. And then I'll present a summary of our results in the form of integrated, synthesized answers to the assessment questions, and our conclusions in the form of findings and recommendations.

So, with that, I'll give a quick introduction to the assessment. Sorry, the clicker is being a little sticky. So, there were three key objectives for this evaluation. As Thamar indicated, this evaluation is to fulfill an FDA commitment for PDUFA VII and BsUFA III. And the key objectives for the evaluation came from a combination of the objectives that are stated in FDA's commitment letter for PDUFA VII and BsUFA III, and also from FDA leadership who were interested in additional topics beyond those specified in the commitment letter.

So, the first of the three key objectives is to document and analyze enhancements made to FDA's human drug review program in hiring and retention since the final PDUFA VI assessment. And just to be clear, the enhancement areas that we will talk about this morning are ones that began before that final PDUFA VI assessment and have continued on since then, and so our task was to evaluate the progress made between the time of the final PDUFA VI assessment and the period of our evaluation, and the impacts of that progress.

The second key objective was to build on previous assessments to capture the current status of FDA's recruitment, hiring, pre-employment onboarding, and retention of new hires, and the effectiveness of current practices. The third key objective was to assess the transparency in the hiring process from the perspective of various interested parties. And so those parties include the agency-level HR staff in the Office of Talent Solutions and the Office of Human Capital Management; the center-level HR and HC staff and each center's Office of Management; and staff at the level of hiring managers; and also from the perspective of new hires – that is,

staff who've been at FDA for a year or less who were able to reflect on their experience as candidates through the recruitment and hiring process.

So, in order to address these key objectives, ERG created a set of three to five questions for us to answer for each objective. For key objective one, which was the evaluation of the progress on the enhancement areas to the HR/HC program, the assessment questions are: What is the status of the planned enhancements? What, if anything, caused any delays in implementation? To what extent were enhancements implemented with fidelity? And by that, we mean, to what extent was FDA's implementation of the enhancement areas consistent with the stated goals of those enhancements? And then, what is the impact of the progress made on those enhancement areas on hiring and retention outcomes?

The second key objective was the status of FDA's recruiting, hiring, pre-employment onboarding, and retention of staff for the human drug review program and biologic/biosimilar staff. And so, the assessment questions for that key objective are just that: What is the current status of FDA recruiting, hiring, pre-employment onboarding, and the retention of new hires? We also asked about how these outcomes compare to those of similar agencies – by which we mean agencies that are also have a science-based mission and of similar size and structure – and how do they compare with outcomes that we see in industry?

The third key objective was about transparency, and so the assessment questions for that key objective: Are Hiring processes clear to FDA's HR/HC staff? How transparent is hiring to other FDA staff, in particular, hiring managers? And how transparent is hiring to new staff? Again, those reflecting on their experience as candidates during the recruitment and hiring process.

So, in order to conduct this assessment, we first created an evaluation design. We established the assessment questions, and we established sets of metrics that we would need to develop in order to have the data to answer those questions. We then created a set of data collection protocols and instruments that we used to collect those data. We then entered our data collection phase, in which we conducted surveys, interviews, and focus groups with the various categories of staff that I mentioned before – in terms of agency-level HR/HC staff; center-level HR/HC staff;

CDER and CBER staff in general; and including new hires – those who have been at FDA for a year or less and could reflect on their experience in the recruitment and hiring phases.

We also obtained data from FDA's internal data systems on HR so that we could evaluate the processes, the timeliness, the outcomes of those hiring, retention, and hiring processes. And we obtained publicly available data so that we could do some comparisons of hiring and retention outcomes between FDA and other similar agencies and industry.

So, to be fully transparent, I want to acknowledge that the results that I'm presenting here this morning pertain to the period of time of our data collection period, and that was from October 2023 to January 2025. We do not have data for the period after January 2025 and cannot characterize the state of hiring and retention at FDA after January 2025. So, throughout the presentation this morning, when I refer to the current status of FDA recruiting, hiring, pre-employment onboarding, and retention, I'm referring to this period of October 2023 to January 2025.

After collecting all of these data, we then conducted quantitative and qualitative analyses in order to interpret the results and develop our conclusions in the form of integrated, synthesized answers to the assessment questions, and a set of findings and recommendations.

And so, now I'll talk about our results, as I said, in the form of answers to the assessment questions. And I'll do that by key objective and by assessment question.

So, I mentioned earlier that the first key objective was to examine progress made and the impacts of that progress on HR/HC program enhancements since the time from the final PDUFA VI assessment through the data collection period that I mentioned. We looked at three enhancement areas. The first area was enhancements to FDA's HR data systems, and those include ATLAS, the Applicant Tracking Lifecycle Analysis Solution, which tracks agency-wide Office of Talent Solutions hiring processes; and AOIS, the Administrative Operations Information System, which is a CDER-specific HR data system that tracks and handles CDER-specific HR activities for human drug review staff; and PathHR, which is a CBER-

specific data system that tracks and handles CBER-specific HR activities for human drug review staff. So that was the first enhancement area that we looked at.

The second enhancement area was the integrated HR/HC service delivery model. This model seeks to integrate HR processes across the full HR workforce to streamline and enhance workforce planning, recruitment, development, and retention efforts across the agency.

The third enhancement area that we looked at was leadership succession planning. This planning seeks to manage and mitigate the potential impacts of attrition among senior FDA leaders.

So, again, we looked at these three enhancement areas for the period that I mentioned – October 2023 to January 2025.

So, I'll talk about each of those enhancement areas separately – the first is the HR data systems. What we found overall is that FDA's HR data system enhancements have modernized and streamlined HR processes, thereby improving efficiency and transparency. I mentioned we had a set of assessment questions for each enhancement area – the first one being, what is the status of the implementation? And what we found is that FDA has implemented all of the enhancements that were planned from the time of the last PDUFA VI final evaluation through our data collection period, and that FDA continues to refine the systems based on user feedback, which is best practice. We found that there were no significant delays, and that FDA implemented most enhancements on schedule.

We also found that there's a high degree of fidelity – that is, FDA's implementation of the enhancements to the HR data systems aligned closely with the stated goals for those enhancements, and that the impacts were positive. The enhancements to the HR data systems successfully automated and streamlined previously manual processes. They provide real-time data for status checking and decision-making. We found a decrease in the average time to complete the portion of the hiring process – the steps of the hiring process that are tracked in ATLAS for employees who support PDUFA and BsUFA. We also found that some users would like more integrations and broader access – and this is a typical finding. When we find that an agency has been successful in enhancing their data systems, people tend to want more. People

identify more areas of further enhancement, and so this finding that some users would like more integrations and broader access is consistent with a positive finding of successful implementation of the planned enhancements. And in fact, I know that FDA is planning, as I said, to continue to refine the data systems.

The second enhancement area is the integrated service delivery model. Overall, we found that FDA's HR/HC integrated service delivery model fosters a more unified, collaborative approach with improved skill-building and data. Again, with this enhancement area, we found that FDA completed all of the planned initiatives and action items on schedule – that they are fully implemented or are on track if the planning for those elements of the model are still ongoing in terms of the planned timeline. So, there are no significant delays.

We did find that FDA encountered some challenges along the way and was successfully able to mitigate those challenges in order to continue to make progress. We also found that FDA's implementation of the service delivery model enhancement aligned with the stated goals, and that the impacts have been positive. We found that people have reported improved training, development, and engagement; improved collaboration, although again, this is an area where further improvement continues to be desired – we'll talk about that a little bit more later; we found improved data analytics and integration to support decision-making; and expanded use of Title 21 to increase hiring flexibility and competitiveness. So, FDA has a variety of hiring pathways. I'm not going to describe them all because there are many, but Title 21 is one of those pathways that has been brought into greater use in order to expand flexibility.

The third enhancement area is leadership succession planning. And overall, again, for the period of the data collection that I referred to – October 2023 to January 2025 – we found that FDA's leadership succession planning initiatives have helped identify risks and strengthen the agency's leadership pipeline. All planned initiatives and action items are complete or on track, with no significant delays. We did find that some center-level planning was challenged by unexpected vacancies and resource limitations, but the centers have worked diligently to continue to make progress, and that the implementation aligns with the stated goals for the leadership succession planning initiatives.

And again, positive impacts. We found that trainings and programs are available to develop needed skills; agency-level planning provides guidance for center-level activities; and reports and analytics to identify succession planning challenges are in place.

So, that was the key objective one – the enhancement areas. Now I'm going to talk about key objective two, which is the current state of FDA recruiting, hiring, pre-employment onboarding, and retention. And so, I'll talk about those topics one by one. Again, this is for the period of October 2023 to January 2025.

So, overall, for FDA's recruiting, we found that FDA's current practices yield a sufficient talent pool to produce skilled, qualified hires that meet CDER and CBER staffing needs.

So, I'm going to talk about successes and also some remaining challenges. One success that I've mentioned already is the expanded use of Title 21 to make FDA more competitive to applicants. We found that outreach at conferences and hiring events, use of social media, and strategic partnerships were all successes in contributing to FDA's ability to develop a talent pool sufficient to meet its needs. We also found solid satisfaction among HR/HC staff with the recruitment processes that they control, and importantly, we found satisfaction among new hires with the recruitment process and with their decision to work at FDA.

So, in terms of remaining challenges, one challenge is something that was identified in the previous PDUFA VI evaluation and continues to some extent during this period of evaluation for PDUFA VII and BsUFA III. And this is not a pervasive issue – it doesn't happen all of the time – but we did still hear that occasionally there are disagreements between the agency-level Office of Talent Solutions and center-level staff about whether candidates are qualified for a position. And when those instances do happen, that leads to inefficiencies and then needing to navigate those disagreements and determine what candidates can be pursued. We also found that there were limited mechanisms for potential applicants to learn about Title 21 – at the time, primarily through word of mouth and LinkedIn – although FDA has been piloting an expanded announcement process, and so that may have changed.

So, the next topic is hiring, and for that, we found that FDA's current practices appropriately evaluate candidates and identify future employees to support FDA's public health mission.

Again, I'll talk about successes and then remaining challenges. And again, so, the expanded use of Title 21 was found to be a success both for recruitment and also for hiring – in terms of streamlining hiring. Of the hiring process steps that are tracked in ATLAS, which is that agency-level data HR data system, we found that there was a reduced time to complete those steps, and so that reflects a speedier, more efficient process. Again, we found a solid level of satisfaction among new hires with the hiring process, and we also found that hiring managers were satisfied with the processes under their control, and that the Office of Talent Solutions – OTS – staff were satisfied with the overall hiring process. We also heard from folks in some of the center offices that they were using standardized interviewing and screening processes and found those to be effective in the hiring process, and so that we found at the office level not necessarily agency-wide.

So, in terms of remaining challenges, one is the length of the process overall, and this is largely outside of FDA's control – in that, with any federal agency, there is a lengthier process typically than you would find in the private sector, and that the length of the process sometimes leads candidates to seek jobs elsewhere. And in the case of the new hires who we surveyed and interviewed and focus-grouped – they, of course, did wind up at FDA; they were new hires – and some of them did say that because of the length, they had decided to kind of pursue other opportunities, but then they were able to persist and did go on to join FDA. We also heard from some of the HR/HC staff that they occasionally do lose candidates because of the length of the process. We did hear from some center HR/HC staff express concerns about the time that it takes to generate certificates of qualification for candidates and to generate tentative job offers. We also heard from some staff about workflow gaps in the HR data systems. So, I mentioned that there's ATLAS – the agency-wide data system – and center-specific systems. And so, in some cases, we heard about some gaps – for example, a lack of a tracking mechanism for hiring packages between the center and the center Office of Management and the agency-wide Office of Talent Solutions. So, for Title 21, the process is a little bit – the hiring process is a little bit

different than for some of the other hiring pathways. For Title 21, the Office of Talent Solutions qualifies candidates after the center has selected a candidate, and in a few cases, that led to inefficiencies if the Office of Talent Solutions – OTS – did not deem that candidate to be qualified for the position.

So, talked about recruitment and hiring; now I'm going to talk about pre-employment onboarding. So, what we found here is that FDA's current practices lead to successful completion of security checks and ethics pre-clearances within the expected timelines.

So, in terms of successes, we found standardized, clear processes for its staff responsible for those security checks and ethics pre-clearances. We found that the processes that are within staff control were occurring in a timely manner. Again, we found a good level of satisfaction among new hires with the pre-employment onboarding processes, and that includes the new employee orientation, which is cited as a positive.

In terms of remaining challenges, we did find, in some instances, that there was some confusion about who is responsible for initiating security and ethics clearances, and that, in some cases, we found that there were delays outside of FDA's control. So, for example, if a candidate did not submit their paperwork in a timely manner, that then led to some delays in either security or ethics pre-clearances.

In terms of retention, through FY 2024, which is the last fiscal year for which we had complete data, we found that FDA's retention practices have contributed to high retention rates and, conversely, low attrition rates.

In terms of successes, we found a high degree of satisfaction among new hires with their decision to work in their current position and in their center. We also found that a strong retention factor was staff's appreciation of FDA's science based public health mission. We also found agency-level HR/HC staff satisfaction with work-life balance and programs as a retention factor, and Office of Talent Solutions and Office of Human Capital Management staff satisfaction with HR/HC culture. We also found that one of the strongest retention factors that we found in surveys was telework and

work schedule flexibility. Again, that's for the period of October 2023 to January 2025.

So, remaining challenges, we did hear from some staff that there was a desire for more growth opportunities, and we did hear from some HR/HC staff and hiring managers about the difficulty of competing with industry salaries. Again, that is mostly outside of FDA's control.

As I mentioned, we looked at HR/HC outcomes for other similar agencies and industry, and overall, what we found is that FDA performs comparably across most outcomes and has better retention rates.

So, for successes, we found that FDA's HR/HC structure and practices are comparable to those of similar agencies, that FDA's outcomes are comparable to similar agencies and industry in terms of length of service and accession rates, and that FDA – and in particular CDER and CBER, is/are the centers that we looked at; we did not look at other centers – retention rates are somewhat higher than similar agencies and substantially higher than in industry.

In terms of remaining challenges, we found that, despite the improved time to hire and salary flexibility – with Title 21 in particular – industry can still hire more quickly and at higher salaries. Again, that is something that's largely outside of FDA's control.

So, the third key objective that I mentioned was transparency of hiring to various groups within FDA, and I'm going to start with HR/HC staff. So, here, what we found is that roles, processes, communication, and collaboration are clear within an organizational unit, but sometimes less clear across organizational units.

In terms of successes, again, we found the clarity of roles and the availability of resources within an organizational unit, with the use of the enhanced HR data systems and improved ability to track status and to have ownership over hiring actions, which also included increased transparency for staff on those topics. We also heard about regular meetings about shared processes that were very useful and definitely cited as a positive.

In terms of remaining challenges, we did hear from some staff about insufficient or untimely communication about policy and process changes, and some lack of clarity about cross-office points of contact, communication, and collaboration, and again, some gaps in HR data system workflows, integration, and access.

So, I'm also going to talk about the transparency to other FDA staff, focusing primarily on hiring managers. What we found here is that hiring managers understand their roles and appreciate status tracking with data systems, but could benefit from improved communication. So, the successes here are largely the same as what I described for the HR/HC staff at the agency-level. Again, the clarity of roles, availability of resources, status tracking, and action ownership – regular meetings about shared processes.

Some of the remaining challenges are also similar in terms of some staff mentioning insufficient or untimely communication about policy and process changes, some lack of clarity about cross-office points of contact, communication, collaboration.
And for hiring managers in particular, we heard some express concerns about HR system data accuracy, access, and timing in the hiring process, and that really has to do with those workflow gaps – like, if there are gaps in workflows across systems, then the data that the hiring managers see might not be fully up to date.

So, in terms of new staff – again, these-we defined new staff as employees who've been at FDA for a year or less, who are able to reflect on their experience as candidates during the recruitment and hiring process, and pre-employment process. So, what we found here is that, while progress has been made, CDER and CBER new hires still have mixed experiences with hiring process transparency.

So, in terms of successes, again, there's been some progress on hiring process transparency. Remaining challenges is that in some cases, we heard from new hires that during the recruitment and hiring process, they sometimes were not receiving updates on their status or the timeline of the hiring process with sufficient frequency to feel confident that they understood where they were, and that led, in some cases, to candidates pursuing other job opportunities. We also heard, in some cases, that while they were applicants, they received contradictory information or multiple requests for information from different HR staff, which, in some cases, caused some

confusion – again, not a pervasive problem, but something that did occur from time to time. We also heard from new hires that they held a perception that their salary would be higher if they were hired into a different office within the same center, or within a different center.

So, with all of those results in mind, we developed a set of findings and recommendations, and I'm going to describe those findings and recommendations by category – in terms of overall findings and recommendations, and then by specific topic.

So, for HR/HC overall, what we found is that FDA's HR program has improved – FDA attracts and retains qualified staff – so, no action needed in this case. Due to its flexibilities, Title 21 – the Title 21 hiring authority – is attractive to both candidates and FDA's staff, so, no action needed here. As I mentioned before, we also found that communication-coordination across offices and centers continues to be a pain point.

So, here, what we recommend is that FDA clarify roles and touchpoints for processes that require cross-unit collaboration or coordination; consistently communicate and document policy and process changes directly to affected staff, and not necessarily through the trickle-down approach; and have changes take effect at predictable points, such as the start of a new pay period; and explore further HR data system integrations and various types of access, which I know is already on FDA's radar, and there's been some discussion and planning for that, even during our assessment period. So, that is really a recommendation to continue that effort.

In terms of the enhancement areas, FDA has successfully implemented each enhancement area with minimal to no delays and in alignment with the stated goals. So, our recommendation here is really to continue on – for the HR data systems, continue to implement updates and address missing or unintegrated workflows, including processes that span offices and centers, and expand access for more staff in more roles where feasible. And again, I know that this has already been part of the discussion and planning.

In terms of HR practices for specific topic areas, we found that FDA's recruitment and outreach strategies are effective in making opportunities visible to prospective

applicants, so, no action needed here. We found that FDA's hiring process is effective – good practices promote fair, consistent treatment of candidates. Staff sometimes experience challenges with which candidates are deemed qualified on certificates and confusion about who is responsible for initiating security and ethics preclearance processes. So, here, one recommendation is to expand the standardized screening and interview practices that I mentioned that some offices have already instituted within the centers. So, to be clear, this is based on office-level experience – we don't have data on this at the agency-wide level – to address qualifications procedures, to ensure hiring managers and Office of Talent Solutions HR specialists share common understanding about which candidates can be considered qualified, and to clarify roles and responsibilities for security and ethics pre-clearance initiation across all involved parties.

Another finding is that, due to the length of the hiring process and less than optimal frequency of touchpoints or communication, FDA sometimes loses qualified candidates. And so, here, the recommendation is to add touch points with candidates to communicate the status of their status within the hiring process and the timeline of the hiring process more frequently, and to express appreciation for their patience with that timeline.

Another finding is that agency- and center-specific new employee orientations are effective in preparing staff to begin work at FDA. So, no action needed there. And again, it was striking that we found that most new hires are satisfied with the decision to work in their current position and center. So, no action needed there. And FDA's retention initiatives are largely effective, but some challenges exist. And here what we would say is that, to the extent possible – or when possible – continue or reestablish valued retention initiatives, create and publicize leadership development and promotion opportunities, and convert employees to Title 21. So that is certainly like a "when possible" and "where feasible" recommendation.

We also - you may have noticed that at certain points in the presentation I mentioned the timeliness - the amount of time that it took for specific steps that are tracked in specific data systems in the recruitment and hiring process. So, we were able to analyze the time it took for specific steps. However, FDA data on time to hire overall exists in those disparate data systems, making it difficult to accurately calculate the

total time to hire. So, within specific elements of the hiring process, as I mentioned in the presentation earlier FDA generally meets its service level agreements or SLAs. It would be useful to be able to evaluate the overall time to hire and what each step in the process looks like in terms of the time that contributes to that overall process. So, our recommendations here are to investigate mechanisms to calculate total time to hire across the disparate systems and to identify data for individual process phases, and to analyze factors contributing to total time to hire beyond the current service level agreements for specific steps and identify opportunities to reduce overall hiring timelines.

In terms of transparency, we found that new hires are generally satisfied with the hiring process and their decision to join FDA but lack transparency about their status during that process and that sometimes causes them to seek employment elsewhere. So, as I mentioned earlier, our recommendation is to add touchpoints to communicate status and next steps. Staff involved in hiring generally understand their own roles and processes but do not consistently find roles and processes in other offices and centers to be transparent. So, as I mentioned earlier, the recommendation is to clarify cross-unit communication and coordination. FDA's data systems have greatly improved the transparency of hiring actions and statuses, and opportunities for improvement continue to exist. And so, as I mentioned earlier, the recommendation is to continue to add workflows and expand access to more staff, which again I know has been in discussion and planning.

So those were our results and findings and recommendations for this assessment of hiring and retention for human drug review staff and biosimilars review staff who support PDUFA VII and BsUFA III. For more information, you can see the report – our full report, which has more details – that's published on FDA's website, and as Thamar indicated earlier, FDA is accepting public comments through October 24th.

***Thamar Bailey:***

Thanks Valerie. All right it is break time. I will put the time on the slide here.
I'll also put it in the Q&A but we're going to take a pause for about 15 minutes. Thank you all.

*[15-minute break]*

All right we're going to get started in about a minute or so.

*[Break continues]*

I'll just give folks a couple more seconds to get settled.

All right.

## FDA Perspective

***Thamar Bailey:***

Hi, welcome back to our PDUFA/BsUFA hiring and retention assessment public meeting. I'm now going to turn it over to Melanie Keller, FDA's Deputy Chief Operating Officer, and Chantal Dawson, FDA's Acting Chief Talent Officer, to deliver FDA's response to the assessment.

***Melanie Keller:***

Thank you, Thamar.

Good morning and thank you all for being here and those of you online.

Together with Chantal Dawson, our Acting Chief Talent Officer, we will present the FDA's response to the assessment. I definitely want to thank our partners at the Eastern Research Group – Valerie, you and your team. There's been some excellent work on this assessment, and it's been a few years that this has been ongoing. And I definitely want to thank Thamar, Kim Taylor, the whole CDER team that worked together, and all the staff that at FDA that participated in the assessment. I think it truly took a village to get us here today, and I'm grateful for the findings and the recommendations, and as I tell my staff and my children, feedback is truly a gift. And so, we will be taking that all in.

As Valerie mentioned, it's important to note that the assessment was conducted over the years of 2023 to 2025, January, and the FDA has experienced significant changes in the past several months in 2025. And I also want to note that this is the fourth assessment of hiring and retention, and as I look back to 2017, boy, we've come a long way as an agency, and the and the staff that work on HR have just had tremendous successes and accomplishments. And I'm really appreciative of industry

because over these past many years they have said, “hiring at FDA is so important that we are going to ensure that we’re monitoring it and giving it the support that it needs to be successful.” So that tells us how important this work is.

As I look back at the assessment overall, I kind of consider it our report card, and I would – I would say I’m very proud of all the accomplishments, of all the successes, and the tons of improvement that the agency has seen. And if I were to take this report card home to my mom, she would say, “good on ya!” So, really happy about that.

We can go to the next slide. Okay, great.

So, on January 21st, the president issued a government-wide hiring freeze. And this is a typical practice that we see in changes of administrations. The freeze has been extended twice and is presently set to expire on October 15th. But despite the hiring freeze, Commissioner Marty Makary was able to obtain a large exemption from the Office of Personnel Management for the FDA so that we could continue the critical work of hiring and retaining our world-class workforce.

Also, this past spring, FDA experienced significant reductions due to the HHS reduction in force. These reductions were felt predominantly in our administrative and business operations areas. These areas were identified as having duplication and some inefficiencies. The HHS’s RIF eliminated the staff – largely staff within CDER and CBER offices of management that performed HR and human capital support to the Office of Talent Solutions – and they also provided direct support to CDER and CBER hiring managers. It’s important to note that these changes were not just made to CDER and CBER; they were made across the organization at large, and the HHS RIF created for us a reduction of approximately 30% in the Office of Talent Solutions and the Office of Human Capital Management at the FDA’s enterprise level. So, reductions were felt across.

So, these major reductions have required FDA to operate differently and create a centralized shared service model to ensure that CDER and CBER and the rest of the agency have the HR support that they need. These reductions were executed quickly by HHS, and our FDA leadership – Commissioner Makary; Chief of Staff, Mr. Jim Traficant; Chief Operating Officer, Dr. Barclay Butler; Chantal Dawson; and

myself – along with our incredible teams of dedicated staff, are doing everything we can to stabilize, repair, and grow. FDA also experienced additional workforce departures from programs like the deferred resignation program – you may have heard it referred to as DRP or “the fork.” We had voluntary early retirement offerings, voluntary separation incentives, and all of that was in addition to our regular retirements and separations that FDA sees.

Next slide.

So, like any great change, FDA’s transformation shows that while the workforce reductions, the hiring freezes, and the restructuring create short-term declines, we are rapidly focused on executing our centralized shared service model, streamlining the HR processes that Valerie spoke about to enable a recovery and to drive long-term improvement over time.

So, as you look at this J-curve, after the reductions we experienced a decline in HR support – in a way, if we think about it, the hiring freeze kind of helped mitigate the impact of that because we weren’t used – we weren’t expected to rapidly hire as we normally are. So, our focus then was to stabilize, identify the resources that remained, centralize – because we could not operate the way we did before – and create efficiencies, and move forward.

So, as I look at the J-curve, I would say we’re in the upward slope of the recovery, but not quite back to the status quo. And our intention is to create more efficiencies to reach an even higher HR service delivery over time.

We have an incredible staff. They’re working hard every single day. They want to climb the curve, shorten the time, the duration, and the impact. And lastly, we are very grateful to Congress for giving us the Title 21 authority that Valerie mentioned a few times in her presentation. That Title 21 hiring and pay flexibility truly enables us to reduce that time to hire and to have the flexibility to attract and retain those experts. We’re also grateful to HHS and the White House for their continued support of the agency and that authority.

So now, we can go to the next slide – I will turn it over to Chantal Dawson who, by my book, is an impactful HR executive; she has deep experience, and she will lead us through this critical time. Chantal.

***Chantal Dawson:***

Good morning.

Thank you so much, Melanie, and thank you to Valerie and the ERG. I appreciate the walkthrough of the findings this morning and sharing such detailed information to give us insight into the assessment, the various pieces, and then as we talk about the path forward. So, I appreciate the opportunity. I consider it a privilege to be able to stand before you as the current human resource leader here at the Food and Drug Administration, being a part of the assessment, now seeing these findings, and looking forward to the solutions that we will incorporate from the findings to continue to push hiring forward for the Food and Drug Administration in a positive way.

FDA has transitioned to implement a centralized shared-service model, and this model distinctly streamlines services, eliminates redundancies, and delivers a more consistent, efficient, and responsive support to FDA centers, offices, and programs. When we think about this shared-service model and what's been implemented, it's across twenty different business lines – of course, one being human resources. And so, we're super excited to share that this shared-service model is producing many more efficiencies. For instance, it's allowing much more direct connection with hiring managers. It's increasing the level of collaboration. It is delivering a higher level of quality-of-service with the hiring managers – all to ensure that in hiring, we are reducing the time to hire, we are creating additional efficiencies, and delivering hiring selections and actions in a more timely and effective manner.

I also think about the CDER and CBER staff that existed or previously existed in the centers, as we've heard through the assessment. We're excited to also share that those staff that do remain have been realigned to the Office of Operations to help continue the HR efforts. And so, having those additional resources join addresses a lot of the findings, creates a lot better collaboration – more consistency in processes and procedures – and also helps to support the model that we've put in place.

We've also been able to look at the steps in the process—and we heard about that through the findings. And through creating the shared-service model, the collaboration and inclusion of the CDER and CBER staff that remain, and through the work that we're doing with managers, we've been able to eliminate 2 to 4 steps in the process, which will significantly impact the flow of the process, the efficiencies, the relationships, the timeliness to hire, and our ability to execute on HR actions. Additionally, we've been able to leverage, as you've heard about, different IT innovations and solutions to help drive those things forward. When we think about the gaps in the process that have been identified, these IT systems reduce workflow backlog; they create transparency into the system; they create much more transparency and clarity with the hiring manager regarding where we are in the process; and they give much more visibility to ensure that we are executing on hiring actions as quickly as possible, and that we are identifying the right steps in the process.

We can go to the next slide.

As we look forward, again, as Melanie shared, we are so appreciative of our commissioner and his support of hiring here at the agency and his understanding of the need for us to ensure that we have the right mission-critical support to execute the mission of the FDA. And so, our commissioner has specifically gone and received approval for us to hire over 1,050 staff to support the direct reviewer, inspector, and criminal investigator work here at the agency, which is the heartbeat of the agency.

Coupled with our shared service model, we are very confident that we will be able to quickly and efficiently execute on those hirings, and those hirings will significantly impact CDER and CBER.

For much of CDER and CBER, our commissioner's also been able to successfully secure for FDA approvals for hiring exceptions. As Melanie stated, earlier this year we've gone through a hiring freeze with two extensions. However, that has not slowed down the ability for us to meet our mission-critical responsibilities and hire the mission critical positions for the agency. And so, with the support of the commissioner, we've been able to partner with HHS and OPM to secure exceptions

and approvals to the hiring requests that specifically support CDER and CBER hiring activities and work – again, to be able to ensure that we are able to fill our mission-critical work and to make sure that we're able to execute on that. Our commissioner will continue to advocate for the agency to ensure that we're hiring a world-class workforce. And we are prepared to continue to support those efforts, to be able to drive hiring forward for the agency and to be able to implement a lot of the findings and things that we've heard today through the report.

We can go to the next slide.

I'm super committed as the current HR leader to ensure that we first of all acknowledge – I think – the accomplishments that we've seen through the various assessments that have been completed and to be able to learn and to yield – to review those recommendations and findings and look for opportunities to implement additional practices into our shared-service model to continue to drive efficiencies, to reduce redundancies and duplication, and to be able to drive forward the hiring of the agency.

So, I again appreciate this opportunity. Thank you to the ERG for the work that was done, and I look forward to how FDA continues to take hiring forward to support the efforts for the Center for Drugs and the Center for Biologics. Thank you.

## Public Comments

***Thamar Bailey:***

Thank you, Melanie, and thank you, Chantal, for delivering the FDA response.

Our next session is dedicated to public comment. Before this meeting, FDA invited everyone who registered for this meeting by September 15th to indicate whether they would like to provide public comments at today's meeting. Today, two people will provide public comments on the perspectives of patients, consumers, healthcare professionals, scientific and academic experts, regulated industry, and others. Each speaker will have approximately 10 minutes or shorter to provide their comments. It's my responsibility to notify speakers when they have reached their time limit. I'll invite each participant to speak one at a time.

Our first speaker is Ms. Juliana Reed from the Biosimilars Forum. Juliana is joining us virtually. Juliana, you may unmute and begin when you're ready.

***Juliana Reed:***

Thank you very much and sorry I'm not there in person, but thank you for having this meeting and giving us an opportunity to comment on this very, very important subject.

So, I'm Julie Reed. I'm the executive director of the Biosimilars Forum. It's my honor to represent the US biosimilar industry here in the US and to be part of this meeting.

First thing, I want to thank all of you at the FDA. We know it's been a year of change, and you have – we want to share with you how grateful we are and how much we support what you do. It is so important for not just our industry, but for the patients we serve, that the FDA is able to continue what it does and have the resources it needs.

We're also appreciative, though, of the potential changes and improvements at the FDA to increase efficiencies and to decrease redundancies in regulations that slow review and approval of biosimilars in the US. We believe that the biosimilars program is an excellent example of an opportunity inside the agency to streamline the development of biosimilars and to decrease the cost and time of review of a biosimilar application, but also to use the right FDA resources at the right time and in the right place.

We're celebrating the 10th year this year of the first biosimilar approved in the US. The FDA has approved over 70 biosimilars in the last 15 years, and we also have 15 years of biosimilar development here, both on the FDA side but also industry, and with our Forum's member companies. Now is exactly the right time to take a look internally at the FDA with the support of industry to improve the way biosimilars are developed, but also reviewed and approved inside the agency. There are efficiencies that could occur and be implemented, again, that'll decrease cost and decrease time and allow industry to bring more biosimilars to the US.

This is extremely important. Right now, given the cost and time and the market barriers in the US, the biosimilars industry is facing what is called the "biosimilar

void." Over 80% of the brand or reference biologics that will have expiration of their patents in the next 10 years do not have a biosimilar in development. Again, that is due to the cost and length of time for biosimilar development under today's current regulations and review process, but also because of market barriers.

There is a potential, if we do not decrease this void and support the development of biosimilars in the US and decrease the market barriers, the US could lose – could stand losing over $180 billion in cost savings over the next 10 years. I don't believe the country, consumers, or patients and their families would like to lose an opportunity to have decreased costs of their biologic medicines through biosimilar competition or potentially decreased access because they can't afford these.

So again, as industry and the representative of the US biosimilars industry here in the US, we look forward to continuing this conversation, and we look forward to supporting and working with the FDA to improve the efficiencies, reduce the cost, and reduce the time, and put the right resources inside the agency to do the right things and improve biosimilar development, evaluation, and approvals. Thank you again for allowing me to speak on behalf of the biosimilars industry. And again, thank you all for what you do every day to support patients and their families here in the US – we appreciate all of you. Thanks.

***Janet Krommes:***

*[Inaudible]*…for having us here today. We share so many goals. We are the advocates for the FDA on the Hill. We are the educators to our fellow physicians as to the importance of the FDA, and the opportunity to be here today to talk to those people who are working so hard to ensure that the mission is achieved of safe and effective drugs is incredibly important to us. The final common pathway for every drug and every medical device is the exam room. And that's where a physician sits with a patient and has a discussion: "Will this work?" "Is it safe?" And that is our investment in being here today.

We are concerned that the reduction in force will create limitations for the FDA. We as physicians also have a mission that we need to uphold. Whether the constraints are significant, whether the resources are few, we still have to meet that mission. So, we understand the pressure that the FDA is under, and yet for both groups, we have

to work to achieve that breaking of the constraints and adequate resources to do the job. We know that there is a finiteness to time and energy, and that has to be recognized in what the FDA is granted the ability to do, whether that includes hiring or the backup, legislatively, from Congress.

According to a ProPublica analysis from August, the RIF resulted in a decrease of about 21% of staff of the FDA. That's obviously a rough estimate; we don't know exactly how many staff were let go, but most concerning were the number of scientists – estimated to be over 900 – as well as 500 regulators, investigators, and compliance officers. And it is our concern that this might impact on the mission of the FDA and might do so over a period of years. We reviewed the report on hiring and retentive practices, and it created – if this were the status quo – a sense of optimism. Much progress has been made; thought has been put into the processes to hire and retain people. But, necessarily, we are now in a state of total transition with many unknowns, and it is the unknown unknowns that worry us as physicians. How is this really going to happen? We know how difficult this task is.

In particular, we're worried about the ongoing pain points as noted in the July report resulting from inadequate communication and coordination across offices. And while consolidation into the operations office may solve some of that, I think one of the sticking points is determining whether candidates meet that very specialized technical need that the FDA has. And that's something that does involve participation of specialists across fields, and that still is going to be difficult to achieve from consolidation of human resource people.

We're also happy to see the improvement in retention, and we noted that – like we do much of our work – the majority of the candidates who are happy with their FDA positions said that they believed in the FDA mission. I mean, certainly there were some that were concerned about pay and the ability to advance, but it's that mission-belief motivation that has been so strong in the FDA. And we worry that the decrease in morale is going to affect that component of, "who do you retain?" You retain the people who are very altruistic. And we also worry about the lack of flexibility – attracting talent from across the country is difficult; bringing people to a finite-sized FDA is difficult. And we would appreciate increased flexibility so that those experts

could be brought to – their talents could be brought to the FDA. We'd rather have their talents at the FDA than their bodies at the FDA.

The PDUFA framework requires the FDA to review 90% of new drug applications within 10 months on a standard basis and 6 months with priority. That's a very fast timeline. I, as a rheumatologist, am even more concerned about the Biosimilar User Fee Amendments because those are much more complex drugs. They require much more interaction with senior FDA officials, and that requires expertise of a variety of types. And what we don't know is who's still here – who's missing. And we worry, in the medical community that those experts, that are truly going to assure that those drugs are safe and effective, may not be here.

So, we mourn the loss of expertise. We've all been through institutional mergers and realized that – you know – that disruption can result in increased number of fail points. And fail points are reached when – you know – it may be a small decrease in personnel. but it is the right person that's missing that can create that fail point, and we're very concerned about that possibility. We don't have a way of perfectly analyzing what's happening at the FDA, but we are concerned about the delays in meeting deadlines that have been published. So, we know there are about five drugs that we know of that have not met deadlines. And we're concerned about whether that represents transition and working things out, or is that the tip of the iceberg of problems that really requires up-staffing of the FDA? The administrative strain, I think, is something that cannot be ignored. Obviously, the expertise and depth of expertise at the FDA in the scientific fields is incredibly important, but that institutional knowledge – where people know how to talk to Congress; they know how to get things through the bureaucracy – is invaluable. I mean, I know, as a physician, you know, going down to the lowest levels, if that unit-clerk is not on my side, I'm not going to get anything done. And so, we appreciate how all the support staff really fill a vital role in the FDA and we're concerned about that.

There could be credibility risks. Do we believe that the FDA is achieving its goal of safe and effective drugs? Can we believe that plants are being inspected? Are the personnel going to be there as is documented or demanded in the PDUFA agreements? And we're also worried about the lack of keeping up with regulatory complexity, particularly with the biosimilars that require a regulatory framework that

is plastic, is ready to change, can spin on a dime, can incorporate innovative technology. And, without the people there who can do the draft guidances and then analyze the public comments, and then proceed with articulation of formal policy, we think that this market could be significantly affected, and time is of the essence here.

You know, we're seeing what's playing out with KEYTRUDA, the number one biologic in the world right now – beat out Humira – and they are formulation hopping. They're introducing a subcutaneous form. By the time a generic comes onboard, all physicians will have switched to the subcutaneous form, and that biosimilar is not going to have that market. So, time is incredibly important in treating our patients cost-effectively, with the best drugs.

The specific impact on PDUFA is a concern for us. Reuters has reported that many of the senior negotiators are gone, and that institutional memory could put the FDA at a disadvantage as it speaks to big pharma. They've been preparing for this. They can cherry-pick their teams, and we're concerned that that can impact on the ability of the FDA to assure that they are going to get what they need to do their job. So, increased transparency in this area is very important – that's where we as advocates – we're not funded by industry, whether it's big pharma or insurance, you know – we are speaking for our patients; we share that agenda. And so, we want to be helpful to the FDA in that regard.

We think the impact on public trust is – you know – it's intangible to some degree, but to keep doctors on the side of prescribing drugs and devices, and to keep patients comfortable with using those drugs and devices – I've had many a talk with patients on a new drug – I mean, I'm not the kind of person who will prescribe a drug the minute it's out of the gate; I generally like to wait and see what our collective experience is, if I haven't heard from the primary investigators and the word on the street – but once that perception starts to shift, people are going to self-retreat from the newest innovative technology that may save their lives, that may make that our healthcare costs improve. If the personnel are not there, it can diminish the ability of the FDA to respond to crises, and those staffing shortages could, in unpredictable ways, affect that response. And most of all, we're concerned about reduced transparency and communication. It takes a lot of people to communicate to the general public, including us as physicians, what's going on with the FDA – you know

– do they craft an approval that's going to the news outlets – which, of course, is the primary way that our patients are getting information. I mean, frankly, I get a lot of medical information from the New York Times too; it comes out before the medical journals – so that communication interface between the FDA and the general public is incredibly important, because that's going to be at the top of patients' minds.

So, our recommendations – we appreciate the work that Dr. Makary has done to restore the staffing to the extent that he's been able to. We have argued on the Hill for the importance of a fully staffed FDA, but we think that that battle should continue. We would like to see – not a leaner-leaner FDA – but an effective FDA. Much of the funding comes from pharma. The appropriations that Congress spends on the FDA, we feel, is well spent in terms of what it provides to the American public. And so, we would like to see restoration of all critical staff. We would like public reaffirmation of performance goals, and increased partnering with Congress. We're worried about the floors of funding – you know – so, working with congressional appropriations to make sure that the money is being spent so that we don't hit those triggers that are listed under PDUFA and the Biosimilars Use Fee Amendments, is incredibly important. What we don't want to see is a collapse. What we don't want to see is a retreat from spending because we know that the world is ever more complex – that our competitors – you know – may, in China, approve drugs more quickly, but it is not going to have the weight of the gold standard of safety and efficacy that the FDA has, and that we would like to see maintained.

So, again, I would thank all of you. I know how hard you are working, and how difficult it is when you're – this is essentially emergency-type work, and we are here with you and to work for you and advocate for you, and I greatly appreciate your kind attention and the time that you provided for us today. Thank you.

## Closing Remarks

***Thamar Bailey:***

Thank you, Janet. That concludes our public comment session, and today's public meeting on FDA's third-party hiring and retention assessment. Big thank-yous abound. Thank you, ERG, for all of the work that you did. Thank you for all of the support in CDER as we went through this, all of the support in HR/HC staff, thank

you to the public commenters, and thank you all for attending virtually and in person. Before we depart, I just want to remind you all that the public docket to provide written comments on today's meeting and assessment report, will be open to October 24th. With that we will close, thank you. I hope you enjoy the rest of your day.

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