FDA Hiring and Retention Interim Assessment
Public Meeting – July 30, 2020
Transcript

Ema Kamara:
Okay we are at 9:00. So, let's get started. Good morning and thank you for joining us today for public meeting on the FDA Interim Hiring and Retention Assessment. My name is Ema Kamara. I'm the acting director for the Office of Planning and Evaluation, under which this Interim Assessment contract was managed. I will be moderating the session today. We appreciate your patience and flexibility in joining us virtually as we all are trying to navigate such new formats for these public meetings.

Today we will hear from Andy Kish, the Director of CDER's Office of Program and Strategic Analysis. He will provide a brief summary of the PDUFA and BsUFA hiring and retention commitments as it pertains to this assessment. Then Dr. Elaine Brenner and Kristen Stanton from Booz Allen will provide an overview of their Interim Assessment findings and recommendations. Melanie Keller, FDA Director of the Office of Talent Solutions, will then present the FDA's response to the Interim Assessment; after which, we will open the floor for public comments.

Given our new virtual format, we ask that you submit your questions using the participant chat feature that will be available at the bottom of your screen, at the end of the presentation. Any questions and comments will be recorded as part of the meeting transcript for public record. As time allows, questions will be addressed by our presenters at the end of the presentation. There is also a public docket on regulation.gov that's open until September 30th where you may submit any additional comments or questions that you may have.

I will now turn it over to Andy Kish from CDER, to discuss the background of PDUFA and BsUFA hiring and retention commitments.

Andrew Kish:
Thank you Ema. I will get my video working. All right good morning everyone. I hope you have your coffee. Thank you for joining us for today's meeting and I am going to very briefly touch on the origin of this evaluation and why it's being presented today. And then, I will turn it over the bulk of the meeting to the presentation on the content of the report, and FDA's response. So, for those of you that might have joined for the PDUFA kickoff meeting last week, we talked about for the first time in PDUFA history, that we included something around hiring and finance. So the background of this evaluation is that during negotiations last time for PDUFA VI and BsUFA II, it became very clear of the critical nature of the FDA hiring function working well, and to maintain that scientific talent and to implement all these commitments, that we agreed to do as part of the PDUFA VI commitments. And make sure we have the right expertise to review the increasing volume of submissions and complex submissions. So, as many of you know, FDA has authorized to collect user fees for prescription drugs and biosimilars, as some of those authorizations that we have to do negotiations every five years to come up with what we would change, author, or maintain as part of a reauthorization package and a five-year cycle. So, as I mentioned, in the last cycle, it was clear that we wanted to include something around the hiring and retention as it is critically important to these programs. There are numerous commitments in this phase, and I encourage folks to take a look at to check out the PDUFA VI and BsUFA II commitment letters, which can be found on FDA's website, if you want to go through all the commitments. I believe the presenters after me are also going to dive into these commitments. The big takeaway is that FDA and industry agreed that it makes sense to have a series of three assessments of the hiring function, the processes, and how well it's working in terms of bringing staff on, having the capacity and capabilities to achieve the successes that we

want in the program, and to identify any potential problems, or delays in hiring human drugs and biologics review staff, and then to outline potential options that the FDA can adopt. So where are we right now, we are at the Interim Assessment, this is what this report is about today. The Initial Assessment was conducted that back in 2017. That report can be found on the FDA's website also. There is also a Final Assessment which will be in December 2021, which will be released at that point, and that will complete the PDUFA VI and BsUFA II evaluation assessment of the hiring commitments. So, I hope you can stick around for the duration of the meeting, and hear from Booz Allen, who conducted this assessment, and hear from our FDA colleagues who will be presenting responses to the assessment and plans to continue to move our hiring function forward. So, I will stop there and turn it over to Booz Allen, Elaine and Kristen.

Elaine Brenner:
Thank you, Andy. Good morning everyone. My name is Elaine Brenner and I'm joined today by my colleague Kristen Stanton. I will be providing some background on the Interim Assessment as well as reviewing progress since the Initial Assessment. Kristen Stanton will then go over the results of our Interim Assessment and the recommendations for FDA's path forward. FDA continues to face some of the ongoing hiring challenges identified in the 2017 and 2018: a "war for talent" with the private sector and academia; and a long history of internal HR complexities. In addition, an OPM audit in 2018 identified significant issues with FDA delegating examining activities. And lastly, the agency is facing a succession planning challenge with almost half of its senior leaders eligible for retirement this fiscal year.

The purpose of this Interim Assessment is to assess FDA's ability to recruit, hire and retain human drug and biologics review program staff, which refers to all staff within the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The purpose was to also provide information based on identified gaps or areas for improvement. Booz Allen worked with FDA to define a three-year timeframe in which to access data for the Interim Assessment. This timeframe was defined as the start of the fiscal year 2017 – which directly followed the end of the Initial Assessment's data timeframe – through the end in fiscal year 2019.

The scope of the Interim Assessment includes reporting on progress since the Initial Assessment, assessing the current state, and providing recommendations for improvement. To note, while the Initial Assessment focused only on the hiring function, the interim scope was expanded to include recruiting and retention functions as well. FDA also identified four discrete but interconnected focus areas that looked at people and the processes – the capacity and capability of HR staff, and the effectiveness and efficiency of HR processes.

The recruiting, hiring, and retention of human drug and biologics review program staff impacts a large number of interconnected FDA stakeholders who were fundamental to this assessment. I'd like to take a moment and start by describing the various consortia of HR staff, for which this report, refers to any staff performing HR work. HR staff are aligned to the agency's HR organization (which is now the Office of Talent Solutions [OTS] and the Office of Human Capital Management [OHCM]). There are also staff performing HR functions who are aligned within each Centers' Office of Management (OM) as well as the Centers' program offices. Additional FDA stakeholders embedded in and impacted by the HR processes and activities include the program staff in CDER and CBER, hiring managers, managers of HR staff, HR senior leadership, and FDA and Center/Office leadership.

Booz Allen developed and applied a four-step methodology to guide the Interim Assessment, which you can see here: planning the assessment, capturing data, analyzing data, and then synthesizing results. Our data collection followed a multi-method approach which enabled the team to gather quantitative and qualitative data via objective and subjective methods. This included surveys of the Center and HR workforces, leadership interviews, focus groups, review of data files, and review of

organizational documents. Through analysis of the data, the assessment team generated integrated findings, synthesized relevant themes and complementary information to draw inferences across related findings, and then encapsulated these points into conclusions. Finally, based on a critical review of these conclusions, the team developed actionable recommendations to address the gaps identified in the assessment and to provide a path forward for FDA.

As expected with any organizational research, we encountered some limitations that can impact the results. These limitations were mainly related to the availability and the reliability of data, but also included potential for inherent bias in perceptual data, and different interpretations of key terms by study participants. We took these limitations into account when analyzing and interpreting the results.

I will now provide a summary of FDA progress since Initial Assessment.

For some context, the Initial Assessment identified three key recommendations that were focused primarily on the hiring process and led to directly FDA implementing the Scientific Talent Recruiting Staff (STRS) hiring pilot. In addition to the hiring pilot, FDA implemented four other improvement activities. A key component in this Interim Assessment, included looking at the progress against all five of those improvement activities. To do so, our team developed a simple maturity model, illustrated by the test here on the left. The three levels of implementation – foundational, integrated, and optimized, were defined by criteria that look at the degree of implementation, stakeholder awareness, impact, adoption and measurable transformation.

The five identified improvement activities were, as mentioned, the STRS hiring pilot, the OHR reorganization, use of the 21st Century Cures Act, the new scientific staff team, and the expansion of direct hiring authority. We found that all five improvement activities fell in the integrated level of progress, given the partial implementation, basic awareness by CDER and CBER, and the incremental impacts to HR functions. To reach the optimized level of progress, the activities will need to be fully implemented, widely embraced, and measurably transform HR functions at FDA. Since most of these activities were started and ramped up following Initial Assessment just two and half years ago, it's not surprising that they are still in the integrated stage of implementation. This in itself should not be interpreted to mean that the activities are not effective, as it takes times for newly implemented programs to show measurable results and transformational impact. However, our assessment of each activity – presented on the pages to follow – does identify some opportunities for midcourse corrections to enhance or accelerate their effectiveness.

The STRS hiring pilot began in July 2018 and followed a phased implementation approach to select offices in CBER and CDER. There were four goals: (1) setting the new FDA practices, (2) reducing the average time to hire, (3) building cohesive collaborative relationships, and (4) rapidly rolling out and scaling up new tools and approaches across the agency. Based on our assessment the hiring pilot has demonstrated some improvements to hiring. This includes: a reduction in time to hire through a streamlined process and the use of shared certificates; implementation of the applicants workflow tracking through the launch of the ATLAS system; and the introduction of a new Talent Strategy Officer role for increased communication with hiring managers. However, because of data limitations, it's not yet possible to determine if these improvements are repeatable for groups outside of the pilot. So going forward, greater data curation and data management – tied to outcome and success measures – can help improve data integrity and provide reliable information needed to make decisions for the pilot. The need exists to expand system integration, which could be accomplished in part with a full implementation of ATLAS, such as integration with USAStaffing and eClass. It would also be helpful to house and share pilot documentation and communication products through a centralized knowledge management repository, which can help drive greater transparency and consistency among pilot participants and HR staff.

In July 2018, the Office of Human Resources (OHR) was reorganized into two separate offices with the intent of improving expertise in core HR areas and providing dedicated leadership focus. Policy, sourcing, recruiting, and hiring functions were organized under the new Office of Talent Solutions (OTS). Aspects of the employee experience – such as onboarding, developing, and supporting staff, and work-life retention programs – were organized under the Office of Human Capital Management (OHCM). The reorganization established internal governance and operations and set a foundation for more strategic, systematic approach to recruiting, hiring, and retention activities. However, our findings indicated that the Centers are still unclear about the reorganization's purpose and intended benefits and have not yet observed meaningful improvements. Our recommendations to help address these gaps center on enhancing organizational strategy, communication with stakeholders, and workload management.

For some context regarding 21st Century Cures Act, Cures was enacted in December 2016 and its hiring authority allows FDA to offer more competitive salaries to enable the Agency to better contend with the private sector and academia as well as strengthen retention of existing staff. The Act currently focuses on appointments of outstanding candidates in positions related to medical products. HHS is updating regulations of the Act to also include biomedical product assessment experts in the near future. With regards to progress against this improvement activity, FDA established internal governance bodies, developed policies and procedures, and delivered a mandated workforce planning report to Congress in May 2018. Feedback from this assessment indicated that there remains confusion within the Centers regarding the application of the Act and that there's a high demand for these policies and procedures, as well as a need for training. FDA has indicated plans to deploy documentation and communications and Cures-eligible Centers this year. To make their deployment successful, creating a strong stakeholder engagement strategy, a detailed communication plan, tactical communication products will be paramount to addressing such concerns from the Centers. In addition, defining outcome measures that are tied to specific Center goals and hiring targets will help determine the effectiveness of Cures hiring. In FY19 only 9% of all CDER hires and 2% of all CBER hires were Cures appointments. Whether or not these numbers reflect success cannot be determined until such outcome measures and targets are established.

In November 2018, a new Scientific Staffing Team, SST, was established with the goal of cultivating a sustainable talent pipeline through external strategic partnerships and a more unified online presence. The SST has made great strides in those goals and recorded an increase of online traffic as you can see on the screen. However, based on interviews and focus groups, Center staff expressed limited awareness of SST's scope and impact as well as concerns of limited coordination with the Centers. Recommended next steps include shifting to a more collaborative customer-centric culture and developing a strategic stakeholder engagement strategy and tactical communications. In addition, outcome measures that are tied to defined Center goals, and specific hiring targets can help show measurable impact and progress by this newly formed team.

Direct Hire Authority, or DHA, is a long-established hiring flexibility, under Title 5, intended to address critical hiring needs. The authority permits the appointment of individuals without regard to competitive rating, ranking, or Veterans' Preference for certain mission critical positions. In October 2018, OPM authorized a government-wide DHA expansion that included STEM and cybersecurity positions in certain occupational series. This assessment focused on the effectiveness of that expansion under DHA. Our assessment found that both CDER and CBER prioritized and leveraged the DHA expansion to hire STEM and Cybersecurity staff in FY19. About 30% of CDER's Direct Hires were associated with the authority's expanded positions. And CBER showed a dramatic increase in use of DHA in FY19, with 100% of their DHA falling within the expanded positions. That said, similar to the Cures appointments, DHA hires remain a small fraction of total hires: only about 12% for CDER and CBER in FY19. Defining outcome/success measures that are tied to specific hiring goals and hiring targets can help track the effectiveness of different DHA positions over time. Finally, interviews and focus group feedback recognized DHA as helpful in hiring

qualified people. A greater emphasis on communications and tactical guidance regarding OPM DHA requirements can help address concerns from hiring managers around perceived inefficiencies in the DHA hiring process.

At a high level, FDA has made incremental progress on the key findings from the Initial Assessment, which only focus on the hiring process. To note, many of them involve, complex situations with challenging root causes that do not necessarily have a quick fix. Our upcoming slides will highlight Interim Assessment factors, beyond those selected here in the initial findings.

I will now turn it over to my colleague, Kristen Stanton, who will review those broader assessment results and recommendations.

Kristen Stanton:
Great, thank you Elaine. Good morning everyone. In continuing on regarding the assessment results and recommendations, this slide presents an overview of the five key challenge areas that were identified during the Interim Assessment. They are strategy, data management and systems, HR staff capability and capacity, culture collaboration and communication, and recruiting and hiring processes. It then shares on the right-hand side, a high-level summary of our recommendations for addressing each of them. The upcoming slides provide more information about each of the challenge areas and specific recommendations in some instances by taking on new initiatives and others by building on the work already in progress. Next slide.

With regards to strategy, our assessment concluded, in general, that CDER and CBER do successfully hire employees, experience below average turnover, and put forth some noteworthy strategic efforts. That said, FDA lacks an enterprise-wide approach to integrate its recruiting, hiring, and retention function. That lack of integration across the HR functions makes it difficult to maintain consistency in the CDER and CBER workforce and, to quickly recover when specialized talent is lost. Our three recommendations with regards to strategy focus on (1) assessing the dynamic nature of the interconnection of recruiting, hiring, and retention, (2) Developing an enterprise-wide human capital strategic plan that addresses the linkages of those three HR functions, and (3) integrating the Center hiring targets into a unified strategic hiring plan that will allow for data-driven business decisions, around the prioritization of FDA recruiting efforts. Next slide.

In looking at specific findings, as mentioned, despite relatively low turnover, CDER and CBER net gains are limited and the Centers struggle to recover from losses of specialized talent because of a lack of an integrated strategy across HR functions. So as you can see, on the top left portion of the screen, the 5% and 6% attrition rates in CDER and CBER are not at all high when compared to the Federal Government as a whole. While pockets of higher attrition in a few CDER and CBER offices can still be considered problematic, very few of them exceed the federal government attrition rate of 16%. Like all organizations, FDA experiences an ongoing cycle of gains (including new hires and transfers into each Center) and losses (including employees leaving FDA and transfers out of each Center). You can see here that between FY17 and FY19, CDER and CBER averaged 566 hires per year, which covered their average annual losses of 377. What we are trying to note here is that only about one third or fewer of those hired contributed to new workforce growth, while the rest of the hiring actions contributed to filling the vacancies left by losses. Our assessment found that on average only about 20% of survey respondents agreed that HR processes actually meet the needs of the Agency. To be clear, existing FDA plans established strategic elements, but they did not necessarily address ways to fully integrate all three HR functions in a way that proactively manages risks and drive targeted workforce growth in priority areas. Next slide please.

Moving onto data management and systems. Our assessment concluded that a lack of consistency in what data elements to collect, and how and where these data are collected inhibits the FDA's ability to measure the performance and effectiveness of HR processes. We also found that the non-

integration of FDA's IT systems led to difficulties accessing complete, reliable data and compiling that data for comprehensive reporting. Recommendations for improvements in these areas include establishing uniform procedures and accountability for data collection, management, and reporting. It also includes compiling an inventory of the IT systems supporting the HR processes, and then employing additional technological solutions to enhance integration linkages and data across the systems. Next slide please.

Our Interim Assessment found that the same data management and system issues that were documented in the Initial Assessment continue to challenge the effectiveness of recruiting, hiring, and retention. Systems are not integrated, not automated, and not efficient. The Initial Assessment established that FDA used six or more IT systems for the hiring process each with limited integration and numerous pain points. Our Interim Assessment found that although FDA has made some changes in HRIT systems and pilot programs, there are still over six non-integrated systems used in the hiring progress. Now, once fully implemented, ATLAS may be able to address some of these data management's and integration challenges. The system was built to improve the hiring workflow through data tracking, which in turn improves transparency, accountability, and quality control. However, it's important to know the ATLAS only offers a partial solution because the system does not currently apply to major portions of the process, such as recruiting, classification, and position management. Next slide.

Our assessment concluded that although the OHR organization established some important building blocks, FDA lacks a comprehensive organizational infrastructure to enable consistent high-quality HR service delivery. That disconnected infrastructure then inhibits the ability to truly track HR workload and manage HR staff performance. To make progress in these areas, we recommend that the FDA enhance collaboration by reframing to the roles of OTS's HR staff as "HR Business Partners" to CDER and CBER. We recommend the FDA establish clear and standardized HR workload management processes. We recommend FDA hold managers of HR staff more accountable for actively managing their HR staff, based on consistent and standard performance goals. Next slide please.

With regards to HR staff capability, our assessment found that the lack of a consistent set of competency requirements to be a key inhibitor. Survey results from Managers of HR staff provided insight to proficiency, as noted on the left-hand side of the screen. Most reported that their staff meet or exceed proficiency requirement in identified core competencies. They did identify gaps in a few the technical competencies, with the largest gap being in classification. It is important to caveat that Core Competencies are required for all the HR staff whereas technical competencies, such as classification, are required only for subset of HR staff who use it in their work. If you look at the on the right-hand side, hiring managers rated their satisfaction with HR staff's abilities in several capability areas such as HR policies/procedures and taking initiative to solve problems. Results showed a consistent pattern of variation, not by the different abilities but rather interestingly, by where the HR staff are organizationally aligned. Across all capability areas CDER and CBER hiring managers were least satisfied of the abilities of OTS and OHCM, were more satisfied with their own Center's Office of Management HR staff and were by far, most satisfied within their own program offices – those who were organizationally closest to them. Next slide.

With regards to HR capacity, while FDA's HR servicing ratio of 1:60 appears to fall within range as OPM and GSA benchmarks. It is difficult to determine with certainty if the ratio is effective due to high vacancies and the distribution of HR staff across FDA. Organizations may also choose a higher or lower ratio as part of a strategy of HR services provided. On the top right, an important data point to note here, is that numerous HR staff positions supporting the 1:60 ratio were vacant and having an understaffed HR function likely plays a large role in resource capacity challenges such as the ability of HR staff to get the work done. While OHCM is currently fully staffed to support the Centers, OTS, CBER Office of Management, and CDER Office of Management are operating with large HR

staff deficits of 21 percent, 27 percent, and 15 percent, respectively. Such large gaps in recruiting and hiring result in an increased workload on existing staff, often trailed by burnout and undesired attrition. It is also relevant to note that FDA's HR staff are decentralized. Depending on their organizational alignment and role, HR staff often perform different yet complementary work related to HR functions. However, the HR work performed by each of these professionals is often not tracked or documented in official data systems which makes it difficult to determine a complete and accurate count of the HR staff or to assess workload attribution. Next slide please.

Moving on to culture, collaboration, and communication – our report concluded that long-standing challenges in these areas continue to hinder the efficiency and effectiveness of FDA's recruiting, hiring, and retention. With the understanding that there is no quick fix to challenges involving engrained behavior, we recommend that FDA undertakes some foundational and tactical improvement efforts on several fronts, including; starting to take the difficult steps of shifting to a more collaborative customer-centric culture, strengthening productive engagement that focuses on shared HR goals, knowledge sharing, and collaborative messaging. Also establishing tactical reinforcements such as co-developed and integrated communications plans and co-led standing meetings to support collaboration. Next slide.

The Initial Assessment found the issues related to culture and mindsets with the FDA hiring process. During the Interim Assessment similarly, stakeholders cited collaboration and communication challenges as major ongoing hindrances to performing their HR roles in an effective and efficient manner. It is important to emphasize that the various HR stakeholder groups that provided input for this Interim Assessment are all responsible for the success of the recruiting, hiring, and retention of human drug and biologics review staff. However, our assessment indicated—and you can see on summary findings on the right side of the screen—that they do not have a shared perspective on the processes nor the value that each party brings to the table. Ultimately, these differences in perspective and mentality towards each other continue to impact how people work together and hinder the efficiency and effectiveness of HR activities at FDA.

Lastly, this assessment concluded that in general, FDA's recruiting and hiring processes do bring qualified employees into FDA. However, substantial data deficiencies and process delays hinder FDA being able to fully evaluate effectiveness. For the Interim Assessment, the only hiring data available were derived from the hiring pilot which represents only a small subset of all FDA hiring. Recommendations to improve include streamlining and documenting recruiting and hiring processes and consistently tracking outcome measures; resolving the classification backlog; and building an official, centralized repository of HR process guidance. One reminder at this point is that the retention strategies was a part of this Interim Assessment and is addressed in the earlier strategy portion of our presentation and of the report, as retention in and of itself is not a process.

Overall, the STRS hiring pilot data shows some hiring efficiencies and some progress with data tracking. For example, on this side the light blue chevrons represent the traditional Title 5 process as it was recorded during the Initial Assessment. This was a timeframe of 150-550 days with an additional 22-300 days up front if classification is required. These ranges were recorded from qualitative stakeholder interviews, whereas the hiring pilot data are now recorded within data systems. The shorter dark blue chevrons indicate the redesigned hiring pilot process, which as you can see, demonstrated time savings compared to the traditional Title 5 process. The time-to-hire ranges depended on the type of certificate – or list of eligible candidates – that was used. The use of shared certificates (in which one list of eligible candidates was used for multiple similar positions) allows the first three hiring pilot process stages to be skipped. This saved between 15 and 53 days in the process and improved the overall time to hire by 60%. Shared certificates are not a new concept or process invented by the hiring pilot however, it has begun tracking the data surrounding the time to hire which objectively shows that time savings can be achieved through their use. One final note on the slide is that classification remains a stage of the streamlined hiring process, if applicable.

However, it is excluded from the time-to-hire calculations because the hiring pilot was not designed to track the classification stage.

All right, so with regards to next steps, now that the Interim Assessment is complete, and the report is published, the public has through September 30th to provide comments. FDA will soon start the third round of these assessments, the Final Assessment which will be conducted by an objective third-party evaluator and is scheduled to be published in December 2021.

I will now turn it over, to Melanie Keller Director of the Office of Talent Solutions to deliver an update on FDA's response to this Interim Assessment, thank you.

Melanie Keller:
Good morning, I am Melanie Keller, the Director of the Office of Talent Solutions and I would also like to introduce my colleague, Tania Tse who is the Director of Office of Human Capital Management. I will be presenting management's response to the assessment and at the end Ms. Tse and I will both be available for any questions related to this portion. I also want to thank Booz Allen Hamilton for conducting the assessment and providing their findings and recommendations, the Agency is grateful for their feedback. In my presentation I will share what we have done since the end of the assessment which was last fall and also share future action plans that we are developing in response to the assessment. Next slide, please.

As we look back from the original Initial Assessment of hiring and retention that was published in November 2017, this assessment and associated public meetings provided incredible feedback to the Agency on its hiring and retention programs. This report served as really a foundation for how to move the Agency forward with these programs. Between then and the Interim Assessments, that was just completed, we've accomplished quite a bit. You can see that timeline here. As Booz Allen mentioned in July of 2018, the reorganization of the Office of Human Resources occurred and similar timings we began phase 1 of the hiring pilot. And then in December, we developed an HR framework roadmap and also conducted a study to look at our capacity of HR resources that were dedicated to talent acquisition within the Agency. This study was conducted by McKinsey. Moving on to January 2019 we started to look at culture and communication and launched a program called "Office Operations Thrives", in April we began phase 2 of the hiring pilot, and then in May we received additional resources for the talent acquisition function to support hiring across the Agency. In September 2019, we launched new talent strategy planning sessions for both CDER and CBER management, and then in December new service level agreements for HR services, and then since October 2019, we actually pushed out 25 updated policies, procedures, and staff manual guides for staff which sort of brings us to the assessment findings up to today. A lot of work has happened from the Initial Assessment and Interim Assessment and we will walk through the more specifics.

Again, and in looking at the recommendations from Booz Allen, FDA does agree that we lack an enterprise-wide systems approach to integrate and optimize our HR functions. We look forward to further partnering with the Centers. So far, we have worked very closely with CBER and CDER to create something we call "talent strategy plans" and we are trying to shift the HR function to what I call the "order taker" (e.g., "I need two biologist, three chemists, and a consumer safety officer…") to more of a strategic partnership where we are looking and forecasting the hiring needs of each of the Centers and really trying to plan ahead, not only for the current vacancies that they have in the moment, but anticipated vacancies that will need to fill due to attrition. This is also what is incorporated here in the talent strategy planning session with each Center. We conducted those last year. That has actually yielded an allocation of resources for my staff and the Center staff so that we are all working together, aligned, and on the same page on those hiring needs. In addition, we definitely agree that the classification program at the Agency has been problematic and for some time. We've done a lot of internal shifting, created a centralized classification unit and saw new leadership. I am really proud to say that in the second quarter of FY20—and we achieved this for the

first time—we made our key performance indicator where 75% of classification actions were completed in less than 22 days. This is a major accomplishment since the Agency has experienced the backlog in the past. Also, with respect to the 21st Century Cures hiring authority, since this program was enacted in December—the authority was given to us in 2016—we have built and deployed a brand-new hiring and pay system and now we are in the implementation stage and I'm proud to say that both CDER and CBER have increased their hiring by 200% over the same time from FY19. And 50% of those represent external recruitment. This has increased in volume and enable the Agency to recruit and retain top talent, many of those new recruits are people that the Agency would not have been able to recruit absent of the Cures authority.

As we look to the future based on Booz Allen's recommendations, the Office of Talent Solutions will also expand its talent strategy session with both managements at CDER and CBER, what you will find is we are moving to a system where we will partner with the Centers and have them complete a talent strategy plan refresh each fiscal year. So, we get into the normal business of planning ahead and working together to really anticipate the needs of each of the Centers. Those will be represented in the FDA talent acquisition plan that we will do for the whole Agency incorporating each Centers' talent acquisition plan. We also happy to say that Office of Human Capital Management is renewing FDA's Succession Plan for 2021- 2023, we want to recruit the best and the brightest and we also want to retain them. OHCM and Enterprise Risk Management team are also conducting an FDA retention study to focus on retention—as the Agency may have not done in the past—and find methods we can use to enhance the program. OHCM is also developing a strategic human capital plan to better integrate the human capital function so we have a robust program there.

As we look at data management systems, this was definitely reflected in the Initial Assessment and we are not surprised to see it in the in that Interim Assessment as well. We agree that we struggle with data measurement and integration and we have developed an HRIT framework to address these challenges. If we look at what we have accomplished today, we have developed and implemented some tracking and analysis lifecycle solutions which we referred to as ATLAS. And OHCM did develop HR IT framework and roadmap and we have allocated funding to address necessary system improvements. Next slide.

As we look to the future, we agree a lot more work needs to be done in this area. While ATLAS was developed as part of the hiring pilot, we are planning to enhance it and develop it and have a wider acceptability for the ATLAS system. It is important to note that the hiring pilot, as Booz Allen mentioned, represents a very small portion of FDA's hiring. FDA has nine different hiring authorities, Title 5 which is our most used and popular one, that is where the hiring pilot tried and succeeded in reducing the time to hire. But nine different hiring authorities has a lot of complexity involved. And the ATLAS system will actually have each of those nine hiring authorities and will track the workflow for each of those within the Agency. Making things a lot more transparent and easier to track and also give us more data and having it in one single repository. To a large extent we will automate the hiring process, knowing that we have to work with six different systems we will be integrating some of them. It will be a much more seamless process for the hiring manager and the HR staff, and we will have data and metrics available that we just did not have available before. It will also provide I think what is real time integrated data, I think one of the biggest challenges we saw the initial report and in the interim report is the hiring manager doesn't know, "where's my action? What is the status?", In this new ATLAS tool that we are continuing to deploy will provide this real-time data and a hiring manager will be able to see anywhere in the hiring process where the action is, how long it has taken and whether it is meeting the KPI for that particular vacancy announcement. We will have rich data on that process, and it will be helpful for the hiring manager and HR staff. I am very excited about ATLAS. The Office of Human Capital Management will continue to focus on the framework and implement the roadmap looking across the enterprise and the HR needs. We will continue to allocate funding and make sure we have those resources for system improvements.

This is a very important aspect of the recommendations to us, HR staff capability and capacity. We did separate the HR function into two different offices. I think that actually in and of itself created dedicated leadership and focus to make sure we have talent acquisition that has been such a critical function for the Agency, if we cannot recruit the best and brightest and keep them, the Agency's mission struggles. So, I think leadership made a very good decision providing dedicated leadership and Tania Tse and I work very collaboratively to ensure that the entire HR enterprise cycle meets the needs of the Agency. And really knowing that we take the information we have, and we will move it forward. We have done a lot on this front since the assessment was completed. We had an independent study completed by McKinsey in 2018 and it found that OTS did lack the necessary resources to perform its hiring work. So, with that information, FDA allocated an additional 53 FTEs to support hiring in FY20. Very exciting. We also recognize how critical it is to ensure our vacancies are filled. Within the office we had a hiring sprint—for the hiring office—and we are very focused on filling our vacancies and making sure we are recruiting competent staff that can fill the hiring service to the Centers. I also want to say that as we look at competencies, we also want to ensure that the staff that we do have are performing at the level they need to and have the trainings that they need. So sometimes we will have attrition, I think every office and company has attrition, and sometimes it is good and sometimes it is bad, but we are really focused on filling the vacancies that we had in the first place and the additional 53 that we have been granted and we've made exceptional progress in a short period of time to do that. We did provide dedicated resources to the CDER and CBER hiring pilot as we look to test new ways to streamline the process, the results have yielded impressive hires for both the CDER and CBER Centers. I think that the findings showed that there was a concern or a perception, depends on who you ask, that many of our HR managers believe that there staff have the competencies that were necessary and the hiring managers felt that they didn't, regardless, we've implemented a new entity called the Talent Academy and it has training requirements and we do have it as a performance metrics for our HR staff. One thing we've also done because HR is such a technical field and a compliance-based field, so there are basics that every HR-specialist needs to know. Even if an HR specialist within our office had taken the fundamental training we require them to take it again to make sure our staff has the same baseline of that technical training and additional course work has been added on top of that to ensure where focusing on what the staff needs. One thing we plan to focus on moving forward is IDPs or individual development plans as well. We also implemented a new service agreement for all of our HR services in partnership with the Centers to make sure our services are meeting the needs, that we are improving transparency on how we are meeting goals and not meeting goals, and ensuring accountability of our delivery of services. A lot of the attention has been focused on our capability and capacity so far at the end of the assessment period. Next slide, please.

What is next? We are definitely planning to continue to collaborate and enhance our quality, quantity, and transparency of our services with enterprise solutions that are reflected in our HRIT roadmap as long as we have those investments. We will also continue to implement the ATLAS system. The really great thing about the ATLAS system as it tracks the HR workload for our staff. So, it actually gives us new capability to manage the distribution of work, monitor productivity which is a very exciting tool that we just did not have before. We will be able to see which staff are producing more or less and we will be able to dig in and see what is going on here?, is there an issue?, do we need to reassign or shift work in a real-time manner?, if necessary. The system gives us alerts, you can see on the sample there is a red, yellow, green, for each hiring process, we will know if that particular part of the process is meeting its targeted KPI. When it turns yellow, that is an indicator to my manager that something is going on there that needs to be looked at so that we can take a look and resolve it proactively.

Culture, collaboration and communication is clearly an essential function for us to be able to focus on. We've done a lot so far. We definitely agree we need robust process documentation to help us guide our hiring process and I think something we continue to work on and will improve is our

communication of what is working well and leverage best practices across the Agency. Now that we are in our new structure—both of our offices—we communicate with hiring managers on a regular basis and also FDA leadership; we conduct regular meetings with Center staff to review HR activities, remove any barriers and make sure our staff are accountable. It looks different depending on the needs of the Center. We may have weekly meetings with a Center, we may have less frequent meetings depending on where we are at in the talent strategy and what the goals are; we are very flexible in meeting the needs. We have done a lot of policy work and to the extent that we have documented policies and procedures and we make that available to the Centers, the more information they have to strengthen the HR program across the board, we've done a lot of work there. We also know classification had been an issue and continues to be an important area for us to focus on, we awarded an interagency agreement with the Office of Personal Management to really improve and optimize this program. We are doing that in partnering with the Centers and identifying's practices to make it a very simple process. And Jim Sigg, the Chief Operating Officer also implemented a new culture and communications program which is called Office of Operations Thrive. The Office of Talent Solutions was the first office to go through this program and it has been a great foundational program to strengthen communication to look at culture and look at customer service; and really across the board, provide information and tools to our staff to improve our communications and strengthen our culture. We also provide training guidance to stakeholders that highlights our special placement program, this could be hiring people with disabilities or veterans, and those are really important tools for us to use. Next slide, please.

There is a lot more to be done. We definitely got a lot of wins with the hiring pilot and reducing the time-to-hire and streamlining the process, and we plan to communicate what works well and we have begun to leverage those best practices in a fuller HR function for CDER and CBER. We will also develop a plan to remediate our classification issues and we will have a standardized operation plan by September 1, working with OPM. We have already employed a very robust internal communication campaign to orient CDER and CBER on our new Title 21 21st Century Cures effort, and we just met with the staff yesterday that are working on that. With very high positive response rates and the information is helping across the board to strengthen the 21st Century Cures hiring program, which is why you are seeing an increase in results in that area.

So, at the foundational level, the process of hiring is key. Making sure that we do have better documented processes, training on those, and strong communications is critical. We've completed two phases of the hiring pilot so far and that has resulted in an average reduction of 60% in time to hire, which is great. The talent strategy session, we have implemented those, and we are really working to maximize the appropriate use of the nine different hiring authorities. What I will share is FDA is shifting from a “how many vacancies do you have?” (which is a static number in time), to “what are the net gains or losses?”; moving to “what is your target net gain in CDER and CBER for the year?” and “what are the activities we need to achieve and exceed those?”. We have exceeded our hiring gains thus far for part of the Center and are on track to exceed them by the end of the fiscal year. The shift in strategy has positioned us to be able to achieve those net gains in a new way that we have not been able to in the past. Next slide, please.

And we will complete the phase 3 of the FDA hiring pilot, we also just implemented something new called HHS hire now. This is a system that the department has deployed and actually gives us access at FDA to any vacancy, and a list of candidates that have applied to any vacancy across the department so our hiring manager has access to a greater pool of candidates. Before, we would advertise and provide the list to the managers, but now they have a very neat system where they can look for candidates across the department. It is a very powerful tool and I think it will reduce the administrative burden of hiring if they can look at candidates that are already there. We will conduct refreshers by the end of September, creating a larger FDA talent strategy plan. We will continue the deployment of the ATLAS system—it will go out Agency-wide for all of the nine hiring authorities,

and we will analyze best practices and making sure the capabilities of the hiring pilot can be expanded Agency-wide because they were so impactful. Next slide, please.

That wraps it up for me and I will turn it over to Ema Kamara for the open public comment period.

Ema Kamara:
Thank you, Melanie. In accordance with the federal registry notice we are now entering the open comment portion of the meeting, where individuals have the opportunity to provide questions or comments to the FDA. Given this new virtual format, we ask that you submit your comments in the chat box in the bottom corner of the screen. As a reminder, all comments will be recorded for public record. At this time if you have any questions, we will take those in the chat box.

[Pause]
Again, this is an open time for questions, if you have a question you can put it in the participant chat box on the bottom right-hand corner of your screen.

[Silence]

I will leave this chat box open for another three minutes, so we will have five minutes total for any questions that come through and so that they can be answered.

We have one question, "Do these improvements carry over to CDRH?". I will turn it over to Tania, can you address that?

Melanie Keller:
Melanie is here, I can start to address it and Tania you are welcome to chime in. I can share that all of the improvements that we have made for CDER and CBER are carrying over to CDRH, with one small exception. The hiring pilot itself was dedicated to CDER and CBER, that was part of the user fee commitment and we will be taking all the best practices and deploying them across the Agency to include CDRH. Tania, do you have anything to add?

Tania Tse:
Good morning, no, Melanie I think you covered it. Absolutely all of our enterprise-wide efforts will apply to all of our Center and office partners across the Agency. We will be expanding any best practices for the benefit of all of our Centers.

Ema Karmara:
We have one more question, "will there be similar webcast on the MDUFA hiring commitments?"

Melanie Keller:
This is Melanie, this was a specific user fee commitment in the PDUFA and BsUFA commitment letter so that is why; and it was an initial, interim, and Final Assessment. So, I do not believe there is a MDUFA public meeting or report that is outlined in that commitment letter. So, there will not be a webcast for that.

Ema Karmara:
Thank you, Melanie. Now we will take any final questions in the participant chat.

[Pause]

No additional questions at this time. This concludes our meeting today. We want to thank all of the presenters and participants for joining us, as a reminder there is also public docket open on

www.regulations.gov until September 30th where you can submit any additional comments you may have. Thank you very much for joining us and enjoy the rest of your day.

[Event Concluded]