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U.S. FOOD & DRUG ADMINISTRATION  
Assessment of FDA Hiring and Retention

Thursday, November 30, 2017  
9:00 a.m.

U.S. Food & Drug Administration  
White Oak Campus, Bldg. 31, Great Room A  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
301-796-0674

Reported by: Irene Gray



<p style="text-align: right;">Page 6</p> <p>1 terms of the pace of hiring despite CRs, despite                  2 freezes and pending freezes. But it is not enough. We                  3 want to do more. We want to do better. We don't just                  4 want to hire by brut force. We want a modern system                  5 that will meet our needs not only now but into the                  6 future.</p> <p>7 And the final piece we will be discussing is                  8 the hiring pilot that we will be very shortly                  9 launching. And that is where we are testing our new                  10 processes and methods and where we will refine them so                  11 that they can serve the larger Agency.</p> <p>12 We also hope to get broad comment. And again                  13 in the scientific realm we often learn a lot from                  14 dockets. There are people out there who know more than                  15 we do about hiring amazingly. And so we would really                  16 appreciate any comments or thoughts that you have. We                  17 take these very seriously, we read them, study them. So                  18 please take advantage of this.</p> <p>19 And again our goal is to continue to have a                  20 world class workforce but make sure that we can keep up                  21 with the needs. This is a great place to work.                  22 Everyone is touched by hiring and retention. We either</p>	<p style="text-align: right;">Page 8</p> <p>1 from Health and Human Services, the department which                  2 FDA is a part of. Since then FDA has struggled                  3 implementing successful hiring program. The office of                  4 Human Resources is not alone in its struggle. The                  5 entire hiring system from hiring managers in the                  6 medical product centers to the Office of Human                  7 Resources to the Offices of Management have been a part                  8 of the struggle.</p> <p>9 As Dr. Sherman mentioned the Agency has a long                  10 history of successful implementation of substantial                  11 improvements associated with user fee commitments. To                  12 date most of those improvements have been focused on                  13 technical regulatory activities. During this latest                  14 round of user fee negotiations special attention was                  15 paid to other aspects of the functioning of the Food                  16 and Drug Administration that could use improvements.                  17 One that was singled out was the hiring process.</p> <p>18 So as part of the latest FDA Reauthorization                  19 Act, FDARA, passed recently in 2017 the Agency                  20 committed to taking a hard look at improving its hiring                  21 process so that the staff capacity can improve and so                  22 that we can meet the technical regulatory goals of the</p>
<p style="text-align: right;">Page 7</p> <p>1 get hired or hiring or we work with someone who was                  2 hired. And we want to be able to meet those needs.</p> <p>3 So I'd like to introduce our speaker. Our                  4 first speaker for today is Steve Berman. Steve is an                  5 Operations Research Analyst which means he studies and                  6 understands how systems and businesses work. He joined                  7 the FDA about four years ago, first in CDER and now in                  8 the Office of the Commissioner. And he is going to                  9 present the results of our report.</p> <p>10 FDA HIRING ASSESSMENT: Findings and Recommendations.</p> <p>11 MR. BERMAN: Thank you and good morning.                  12 I'm here as Dr. Sherman mentioned to present                  13 an overview of the diagnostic report that was published                  14 to the Web about two weeks ago. I'm going to speak                  15 briefly about some context behind the report and then                  16 go into some detail on an overview of the findings and                  17 the implication of those findings for hiring at the                  18 FDA.</p> <p>19 So before we delve into an overview of the                  20 report itself it might be useful to review some context                  21 to explain the impetus behind the report. Roughly five                  22 years ago the FDA regained Human Resources authority</p>	<p style="text-align: right;">Page 9</p> <p>1 Agency.</p> <p>2 One commitment specified in the PDUFA VI and                  3 BsUFA II commitment letters was to engage a third-party                  4 contractor to conduct a baseline assessment of the                  5 hiring system at FDA. I'm here to present their                  6 findings to you today.</p> <p>7 This assessment was focused on hiring with                  8 some attention paid to retention as well but I'm going                  9 to focus mostly on the hiring aspects of the report at                  10 this time. We did not examine things that were outside                  11 of the control of FDA; like Health and Human Services                  12 or Office of Personnel Management Policies.</p> <p>13 At a high level the issues seen in the hiring                  14 process are relatively well known. There are issues                  15 with timeliness, accuracy, employee satisfaction,                  16 quality, and customer service. The amount of time that                  17 it takes to hire for our mission critical occupations                  18 is long. Candidates have been frustrated with the high                  19 number of errors and the length of the process as well                  20 as the lack of communication throughout the hiring                  21 process itself.</p> <p>22 Hiring managers, those who are looking to fill</p>

Page 10	<p>1 vacancies, have been dissatisfied with the amount of</p> <p>2 transparency in the process and the quality of the</p> <p>3 candidates who make it through. Incremental</p> <p>4 improvements to the hiring system have been tried</p> <p>5 before.</p> <p>6       What I'm here to discuss today is something</p> <p>7 new. We're approaching the entire hiring system</p> <p>8 systematically. The contractor was engaged to conduct</p> <p>9 a baseline assessment to assist us with</p> <p>10 transformational change and modernization.</p> <p>11       This external contractor conducted extensive</p> <p>12 data collection over a period of one year starting in</p> <p>13 the summer of 2016. Following data collection was the</p> <p>14 analysis. All of this work was to inform a future</p> <p>15 state that is highly responsive to the needs of the</p> <p>16 Agency is informed by data and by best practices.</p> <p>17       Let's begin by talking about some of the data</p> <p>18 collected and then we'll talk about the implications of</p> <p>19 these data.</p> <p>20       Here are some basic high-level facts and</p> <p>21 figures about the current state. There is a lengthy</p> <p>22 time to hire. It can take up to 550 days to hire for</p>	Page 12	<p>1 Agency-wide with regard to the hiring process itself.</p> <p>2 Hiring managers need better support.</p> <p>3       Once all of the data was collected by the</p> <p>4 contractor in support of the commitment a root cause</p> <p>5 framework was used to map that data into a larger</p> <p>6 context. We are going to review these findings in some</p> <p>7 details now.</p> <p>8       Here are the main findings at a high level.</p> <p>9 The report online has significantly more detail about</p> <p>10 these.</p> <p>11       First, it was determined that the process</p> <p>12 documentation is incomplete which led to substantial</p> <p>13 variation in the execution of the process.</p> <p>14       Secondly, the process suffers from substantial</p> <p>15 complexity leading to poor timeliness and poor customer</p> <p>16 satisfaction.</p> <p>17       Third, there are unclear roles and</p> <p>18 responsibilities in the process leading to confusion</p> <p>19 and poor accountability.</p> <p>20       Fourth, the IT systems are not user friendly</p> <p>21 and are not integrated leading to low efficiency and</p> <p>22 poor transparency.</p>
Page 11	<p>1 some mission critical occupations. There is a high</p> <p>2 vacancy rate as well. Some of the medical product</p> <p>3 centers are seeing vacancy rates around 15% which when</p> <p>4 compared with benchmarks at other agencies is</p> <p>5 significantly higher. Finally there is low</p> <p>6 satisfaction with the quality of the outcomes with only</p> <p>7 12% of hiring managers reporting being satisfied or</p> <p>8 very satisfied with the hires.</p> <p>9       On top of the quantitative and semi</p> <p>10 quantitative data that the contractor collected they</p> <p>11 also spent a lot of time listening to what people were</p> <p>12 saying. There were numerous pain points identified</p> <p>13 from various stakeholders.</p> <p>14       Candidates were frustrated by the lack of</p> <p>15 timeliness and transparency in the hiring process.</p> <p>16 Hiring managers were not satisfied with both their</p> <p>17 experience with the process and the outcomes of the</p> <p>18 process. The Human Resources specialists who actually</p> <p>19 conduct most of the hiring process itself were</p> <p>20 frustrated by the lack of recognition and reward and by</p> <p>21 lack of training. Training was noted to be lacking</p> <p>22 both within the Office of Human Resources and also</p>	Page 13	<p>1       And finally, there is a finding of a lack of</p> <p>2 collaborative and open dialogue leading to poor</p> <p>3 communication.</p> <p>4       Let's explore each of these in a little bit of</p> <p>5 detail over the next few slides.</p> <p>6       Results of a deep dive diagnosis showed that</p> <p>7 the hiring process itself is neither well designed nor</p> <p>8 even fully defined. In sum it is not simple, not</p> <p>9 standardized, and not efficient in its current state.</p> <p>10 The process is complicated. There are many steps</p> <p>11 within each sub-process. There are many people</p> <p>12 involved in each step. There are many handoffs between</p> <p>13 steps causing delays and confusion. There are numerous</p> <p>14 approvals throughout the process which create</p> <p>15 bottlenecks but don't necessarily insure quality.</p> <p>16       It was determined that there is significant</p> <p>17 confusion among hiring manager regarding the degree to</p> <p>18 which they themselves are responsible for preparing a</p> <p>19 package and getting a candidate through the hiring</p> <p>20 process. In a survey of approximately 140 hiring</p> <p>21 managers in the Center for Drugs a significant majority</p> <p>22 reported that the levels of engagement deviated from</p>

<p style="text-align: right;">Page 14</p> <p>1 what was appropriate or expected. There is low                  2 accountability and low clarity in the process.                  3 In additions to findings regarding process and                  4 people there are also significant issues with the                  5 current IT systems that support the hiring process.                  6 There are more than six IT systems used that are not                  7 integrated, not automated and not user-friendly. This                  8 has resulted in poor utilization rates of the systems.                  9 And the proliferation of home grown center-based                  10 solutions.                  11 The lack of good data about the hiring process                  12 has additional downstream effects. One major                  13 consequence of the state of the IT system is that there                  14 is poor tracking of core metrics about how hiring                  15 functions at the FDA. There are a few metrics collected                  16 that measure process timeliness. But these data have                  17 questionable accuracy due to the manual nature of many                  18 of the IT systems.                  19 There were no metrics identified to assess                  20 process accuracy, outcome quality, customer                  21 satisfaction, and employee satisfaction. Without these                  22 core metrics accountability to the process is difficult</p>	<p style="text-align: right;">Page 16</p> <p>1 critical occupations. Candidates are frustrated by the                  2 process. Hiring managers are frustrated by the                  3 process. There are issues with accuracy, things from                  4 spelling of people's names to the content of the                  5 packages themselves. And customer service and employee                  6 satisfaction were also noted as needing improvement.                  7 Following these root cause outcomes the                  8 contractor suggested that without a fundamental                  9 redesign of the process, one that addresses the system,                  10 the people, the process, and the culture FDA's ability                  11 to hire the right people at the right time in the right                  12 way will continue to be impaired.                  13 To recap. Fulfilling a PDUFA VI and BsUFA II                  14 commitment a contractor was engaged to assess the                  15 hiring process at FDA. Over 600 new hires were                  16 surveyed. Nearly 200 hiring managers were surveyed.                  17 There were significant findings regarding process,                  18 people, and systems.                  19 The contractor recommended following a review                  20 of the data and the analysis to design and launch a                  21 controlled pilot one which has a clean sheet design,                  22 reconfigured stakeholder roles, one that explores new</p>
<p style="text-align: right;">Page 15</p> <p>1 to achieve. Further without these core metrics                  2 performance improvement efforts are rendered                  3 extraordinarily difficult.                  4 Finally the diagnostic also showed that the                  5 mindsets and behaviors observed at the Agency do not                  6 support an effective and efficient hiring process. It                  7 was observed that the climate lacks trust, operational                  8 discipline, and creativity. Motivation of those                  9 executing the hiring process is poor without focused                  10 leadership, personal ownership, and significant rewards                  11 and recognition. External customer orientation is weak                  12 towards hiring managers and towards candidates. And                  13 there is unclear direction due to insufficient shared                  14 vision, accountability, and employee involvement.                  15 It is important to note that these cultural                  16 findings are not limited to the Office of Human                  17 Resources but were observed throughout the Agency as                  18 regards to the hiring process.                  19 Together all of these root causes drive poor                  20 outcomes on timeliness, on accuracy, on employee                  21 satisfaction, on quality and on customer service. It                  22 can take six months or more to hire for mission</p>	<p style="text-align: right;">Page 17</p> <p>1 sources of talent, and one that leverages technologies                  2 that support meaningful workflow tracking. It was                  3 recommended that we evaluate the pilot performance with                  4 rigorous metrics and data collection to refine the                  5 design and to role out improvements FDA-wide.                  6 It was recommended that the pilot be designed                  7 with an eye toward future expansion. We will discuss                  8 the details of FDA's decision to implement these                  9 recommendations and to conduct such a pilot shortly.                  10 Thank you.                  11 MS. SHERMAN: Thank you, Steve.                  12 Our next two speakers will discuss both the                  13 recent accomplishments with their hiring and provide                  14 some more detail about the pilot.                  15 First Tania Tse is FDA's Director of OHR,                  16 Office of Human Resources. And as Steve pointed out                  17 several times hiring does not exist alone in the silo                  18 in OHR but OHR is the place where we've started. And                  19 we would not be making the progress that we are making                  20 without the full commitment and tireless efforts of                  21 Tania and her staff.                  22 Tania has been with FDA for over ten years;</p>

<p style="text-align: right;">Page 18</p> <p>1 first with CDER and then she joined OHR in 2012 as                  2 Deputy Director and she has been a Director since 2015.                  3 And she is joined by Melanie Keller who we                  4 recruited over the summer into the new position of                  5 Acting Associate Commissioner for Scientific and                  6 Clinical Recruitment. And falling under her umbrella                  7 is the pilot scientific recruiting team that FDARA                  8 hiring authorities which are a crucial tool for us and                  9 basically innovation and she has assembled what she                  10 refers to as hashtag team hiring which seems to be one                  11 of our most cheerful groups.                  12 So they will now join us.                  13 Thank you.                  14 FDA PDUFA VI and BsUFA II HIRING AND RETENTION PROGRESS                  15 MS. TSE: Good morning. Thank you, Dr.                  16 Sherman for that kind introduction. I am pleased to be                  17 here today to share initiatives underway within the                  18 Office of Human Resources to better support the hiring                  19 process and meet the commitments that FDA made to our                  20 industry partners during the recent PDUFA VI and BsUFA                  21 II negotiations.                  22 While it has been mentioned that hiring is at</p>	<p style="text-align: right;">Page 20</p> <p>1 intended to support improved hiring including the first                  2 six that I will talk a little bit about today. The                  3 ones highlighted in blue are the specific PDUFA VI and                  4 BsUFA II commitments that we've made.                  5 So first we'll talk about position based                  6 management. That was a PDUFA VI and BsUFA II                  7 commitment. That effort grew out of a need to track                  8 filled positions and funded vacancies across our Agency                  9 to support planning at the center and office levels,                  10 facilitate consistent information sharing with                  11 stakeholders including Congress, our regulated                  12 industries, the trade press, and the public. And                  13 improve our ability to strategically plan for hiring.                  14 The initiative began in 2015 as we worked with our                  15 summer partners to manually, I can't tell you how                  16 painful that was, gather and track data on filled and                  17 vacant positions to establish a baseline.                  18 The project has since evolved to an FDA                  19 position tracking system that we developed in house                  20 that leverages existing HR databases and financial                  21 systems. This new tool is currently being piloted by                  22 one of our smaller centers and is available for other</p>
<p style="text-align: right;">Page 19</p> <p>1 unprecedented levels for our Agency all of us recognize                  2 it is not enough. Not enough to close the hiring gaps                  3 that have existed at our Agency for years. And not                  4 enough to keep pace with FDA's growth over the last few                  5 years, a trend we expect to continue.                  6 In spite of our hiring challenges I do want to                  7 acknowledge FDA hiring managers, human capital teams                  8 and HR staff who've worked together to hire more than                  9 5400 people since Fiscal Year 2014 including 1100 last                  10 year alone when the hiring freeze and other limitations                  11 were in place for most of that year.                  12 And while FDA's attrition rate is low for an                  13 organization of our size averaging about five to six                  14 percent annually the loss we experience of skilled                  15 scientists, medical staff and other regulatory                  16 professionals is felt across our programs.                  17 So let me see if I can figure -- there we go.                  18 I forgot to get the tutorial. So what is OHR doing to                  19 help in partnership with many folks across FDA? In                  20 addition to participating in this assessment hoping for                  21 improvements and supporting the hiring pilot that                  22 you'll hear more about today we are engaged in project</p>	<p style="text-align: right;">Page 21</p> <p>1 centers to pilot as well.                  2 The next phase of our effort for position                  3 based management will be to leverage a new position                  4 management module that will be integrated into our                  5 expected new core HR system EHCM that we expect to                  6 launch later this year.                  7 EHCM, I'll share a little bit of information                  8 about that. While not a specific PDUFA of BsUFA                  9 commitment this project will modernize our core HR                  10 system and will include new tools and functionality                  11 like the position management module that I mentioned                  12 and also offer data analytics to support human capital                  13 decision making. And you heard data quality and                  14 security, something we can all agree is critical in our                  15 current environment.                  16 Position classification this is another one of                  17 our PDUFA commitments was to establish an online                  18 classification tool as well as a PD library. It                  19 continues to be an area where we have significant                  20 opportunities to improve. Rather than establishing a                  21 new position description for each time a position needs                  22 to be filled, we are focused on leveraging already</p>

<p style="text-align: right;">Page 22</p> <p>1 classified PDs that can either be used as is or                  2 slightly modified to meet the needs of a hiring office.                  3 Over the last two years we worked with a                  4 contractor to organize more than 21,000 hard copy                  5 position descriptions into a useable SharePoint PD                  6 library which now includes 9,000 -- only 9,842 position                  7 descriptions but are searchable, established in a                  8 various variety of different occupations at multiple                  9 grade levels and varying career ladders that are                  10 available for use across the organization.                  11 The next phase to further improve                  12 classification we've spent the last year developing                  13 FDA's own eClass system, an online position                  14 classification tool to further automate the process.                  15 The new tool is currently being launched Agency-wide.                  16 This October we began introducing eClass                  17 center by center offering training on the new tool                  18 including a step-by-step eClass process and supporting                  19 resource materials available to users. This system is                  20 currently in use by a number of our center partners and                  21 is rolling out to additional organizations through the                  22 rest of this year as you see here.</p>	<p style="text-align: right;">Page 24</p> <p>1 biologists and microbiologists positions using the                  2 corporate approach in the Spring of 2018.                  3 While not a PDUFA commitment our most                  4 successful effort to date has been the launch of our                  5 Title-38 support team. That team supports the hiring                  6 of both medical officers and dentists across our                  7 organization. The Title-38 team manages a ten-business                  8 day process from the receipt of a completed package                  9 from hiring program to the issuance of a tentative job                  10 offer to a selected physician. This new process has                  11 reduced hiring times by 80% for these occupations. And                  12 to date we've hired 117 new physicians using the                  13 streamline process. In addition our Title-38 team                  14 supports the important work of FDA's physician                  15 compensation and credentialing board who works to                  16 assure appropriateness and equity in pay across our                  17 Agency.                  18 The final PDUFA commitment that I will talk                  19 about today is awarding a contract and we have actually                  20 completed this effort. On a regular basis FDA has                  21 special hiring initiatives either in support of new or                  22 expanding user fee programs or other special</p>
<p style="text-align: right;">Page 23</p> <p>1 Corporate recruitment, another one of our                  2 commitments made to our industry partners, that effort                  3 was designed to announce commonly filled mission                  4 critical positions at the FDA level on a recurring                  5 basis to provide managers with access to hiring                  6 certificates on a predictable schedule. Key goals of                  7 our corporate recruitment strategy were to reduce time                  8 to hire and reduce the burden of having to initiate                  9 individual recruit actions each time a hiring need is                  10 identified.                  11 Since 2015 when we began this effort we've                  12 launched corporate recruitment strategies for five                  13 different occupations including math stats,                  14 statisticians, pharmacologists, toxicologists and                  15 chemists and have successfully used a process to fill a                  16 number of positions in often hard to fill professions                  17 as outlined here.                  18 We are currently working with our center                  19 partners on the next round of announcements for each of                  20 these five series and new hiring certificates will be                  21 available for each beginning in early 2018. We will                  22 also begin as noted here work to announce both</p>	<p style="text-align: right;">Page 25</p> <p>1 initiatives. And to ensure that we have ready quick                  2 access to needed surge capacity we worked to award a                  3 large scale multi-vendor, multi-year contract. That                  4 contract was awarded this summer which does provide us                  5 ready access to contractors with a wide range of HR                  6 skills.                  7 Before I close I do want to share a couple of                  8 other efforts that were not committed to as part of the                  9 PDUFA VI and BsUFA II negotiations but are key to                  10 support the efforts that we are working on to improve                  11 hiring here at FDA. Our FDA university has also worked                  12 to develop a portfolio of workforce planning                  13 capabilities available to our centers including                  14 providing annual center workplace profiles that will                  15 help support human capital decision making from a data                  16 driven place; launched an FDA succession plan focused                  17 on growing future Agency leaders; and we expanded exit                  18 survey capacity Agency-wide so that we can share with                  19 our hiring managers and programs the reasons why our                  20 staff are making decisions to leave FDA.                  21 So in closing I want to insure everyone whose                  22 joining us today of OHR's continued focus on improving</p>

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<p>1 the service we provide to our customers and our                  2 commitment to improving how we support the Agency's                  3 public health mission. We look forward to our                  4 continued partnerships with our FDA centers and offices                  5 and continued engagement with the Office of Medical                  6 Products and Tobacco as they work to design a modern                  7 hiring process for the FDA.</p> <p>8 It is now my pleasure to turn over the podium                  9 to my colleague, Melanie Keller, who is going to                  10 provide some additional information on other efforts                  11 under way.</p> <p>12 Thank you.</p> <p>13 MS. KELLER: Thank you, Tania. The next PDUFA                  14 VI and BsUFA II commitment that we'll discuss today is                  15 establishing a staff, we call it the scientific                  16 staffing team, that will conduct continuous recruiting                  17 and staffing and retention of scientific technical and                  18 professional staff.</p> <p>19 So in April we established the staff. We've                  20 recruited 50% of the staff and we plan to achieve 100%                  21 by March 2018. And right now we have a national search                  22 underway for the Associate Director for Scientific</p>	<p>1 We go to on-campus scientific recruiting                  2 events. And the other thing that we're working on is                  3 establishing strategic relationships with academic                  4 institutions and professional associations an ongoing                  5 manner so that when we are teeing up to recruit for the                  6 corporate recruitment like Tania was speaking about we                  7 can reach out and advertise our positions so that it                  8 coincides with when those vacancies are open.</p> <p>9 We also believe that targeting on STEM                  10 occupations earlier in individual's careers perhaps in                  11 their pharmacy program or different kinds of targeted                  12 outreach could also help folks realize FDA is where                  13 they want to work.</p> <p>14 The next commitment is hiring; hiring the                  15 PDUFA VI and BsUFA II hires. This shows our targeted                  16 hires for the five-year period of the agreements. To                  17 date and it is only November we've hired three in CDER,                  18 seven in CBER for PDUFA VI, and one for BsUFA. And we                  19 have a lot of recruitment activity underway.</p> <p>20 We are targeting in the pilot the PDUFA VI and                  21 BsUFA II hires. So those will be an area of focus and                  22 I'll share that shortly.</p>
Page 27	Page 29
<p>1 Staffing that will lead that team. The kinds of things                  2 that they are focusing on right now primarily                  3 developing an FDA recruitment brand; we don't really                  4 have one and using that to deploy through social media                  5 strategy that we are working on.</p> <p>6 I think that when our scientific staffers go                  7 to some of these conferences a lot of people come to                  8 the table and they are surprised. FDA is hiring? What                  9 do you do at FDA? And so we really need to get our                  10 message out that we are recruiting and we are an                  11 employer of choice.</p> <p>12 We have several targeted strategies for how we                  13 can outreach and really be more proactive about the way                  14 we are identifying staff for our critical positions.                  15 One strategy is to establish recruitment ambassadors                  16 throughout the Agency. We have a far reach into                  17 industry and academia and professional associations                  18 with our staff. So having when they go to these                  19 meetings you know donning them as recruitment                  20 ambassadors providing them training and having part of                  21 their time spent at these really important conference                  22 be to help identify and recruit and outreach about FDA.</p>	<p>1 The last commitment and why you are here was                  2 to conduct a comprehensive review of the hiring process                  3 and staffing capacity and capabilities that enable our                  4 successes at the Agency. And Steve provided and                  5 excellent overview of the initial baseline assessment.                  6 The report was published I think after today we can                  7 check this commitment, not quite as complete because                  8 the docket will remain open until January but we've                  9 really focused on this commitment because it really                  10 provides the baseline for our future.</p> <p>11 Below you see outlined future commitment dates                  12 for the subsequent continuous assessment and out-                  13 briefs.</p> <p>14 So that concludes the portion of the meeting                  15 where we update on the PDUFA VI and BsUFA II                  16 commitments in progress.</p> <p>17 REIMAGINE FDA HIRING PILOT</p> <p>18 MS. KELLER: And now I'd like to move into                  19 sharing about the FDA reimagined Hiring Pilot. I'll                  20 provide an overview of the pilot's scope and                  21 objectives, talk about our approach and then share the                  22 path forward for the design and implementation.</p>



<p style="text-align: right;">Page 30</p> <p>1 This is an overview of how the hiring pilot                  2 will be run alongside the current state. Several                  3 positions will be entirely pulled out and dropped into                  4 the pilot and run through the new process from start to                  5 finish. We expect the pilot to launch in early 2018                  6 and will likely run through the year given the scope.                  7 Once the endpoints have been reached, scale up                  8 and implementation across a broader organization                  9 particularly focused in CDER and CBER will begin. And                  10 then eventually the future state will look like an                  11 entirely new engine running the reimagined process for                  12 all positions.                  13 The pilot includes a significant percent of                  14 vacancies for both CDER and CBER and within CDER we've                  15 been including a range of PDUFA IV commitments and                  16 mission critical occupations from select offices; the                  17 Office of Strategic Programs, the Office of New Drugs,                  18 and the Office of Surveillance and Epidemiology. From                  19 CBER we will be focusing primarily on the PDUFA VI                  20 commitments across all offices.                  21 The team's objectives are rooted in the                  22 objectives of testing hypothesis early and using the</p>	<p style="text-align: right;">Page 32</p> <p>1 and candidates. We conducted the policy assessment                  2 from OPM and we engaged an expert contractor to really                  3 do the complete policy review so we know what the                  4 boundaries are what we have to follow within regulation                  5 and then what our flexibilities are within the Agency.                  6 We've engaged a contractor to pressure test                  7 our design, conduct external benchmarks from peer                  8 agencies like the National Institutes of Health, the                  9 National Oceanic and Atmospheric Administration and                  10 also an extensive network of external experts in design                  11 thinking and process excellence.                  12 Very quickly to know we've been making a lot                  13 of progress in the pilot design. This is an overview                  14 of the journey that the team has been on in designing                  15 and developing the pilot. We kicked off early in                  16 September and expect to begin implementation planning                  17 starting in December which is Friday.                  18 So as you can see we are going to launch that                  19 pilot in early 2018 and then with the goal of meeting                  20 the PDUFA VI and BsUFA II commitment of implementing                  21 the findings from the initial report in December of                  22 2018.</p>
<p style="text-align: right;">Page 31</p> <p>1 pilot as a vehicle to make real progress and to act as                  2 a testing ground for a process which just doesn't work                  3 in a vacuum but can be scaled across the organization.                  4 The design challenges conventional wisdom and the team                  5 has been asking themselves why? So as we go through                  6 the process and we're designing it we really question                  7 that current state. Why do we do that? Well, why do                  8 we do that? And really getting to the deeper reasons                  9 to uncover if its really necessary or if it can be                  10 changed.                  11 One thing we also did is we did an inventory                  12 of policies, government policies, HHS policies, FDA and                  13 really were able to ask those deeper questions and                  14 investigate the assumptions of each step of the process                  15 that has been designed.                  16 Our approach to reimagine the future state                  17 incorporates multiple sources of insight. So we didn't                  18 just sit in a room. We included significant data                  19 collection which as you know has been ongoing since                  20 2016 and we leveraged all of that data that was                  21 discovered in the initial assessment. We gained                  22 customer perspectives. We talked to hiring managers</p>	<p style="text-align: right;">Page 33</p> <p>1 As I mentioned a minute ago the team routed                  2 our approach in insuring we create a process which adds                  3 value to customers and the customers in this instance                  4 are hiring managers and candidates. We come to the                  5 data that was collected as a part of the diagnostic                  6 which included over six qualitative and quantitative                  7 surveys and over 35 in depth one-on-one interviews with                  8 new hires and hiring managers to create a typical                  9 hiring manager and candidate persona.                  10 So we're really taking a look at what the                  11 customer, the candidate and the hiring manager, needs,                  12 what motivates them, what success in the hiring process                  13 looks like. And we've designed the process around that                  14 and with that in mind. We looked at pain points and                  15 also points of delight with a goal of having many more                  16 points of delight.                  17 And also governance for implementing the                  18 recommendations from the assessment was also key. And                  19 so we have a pilot steering committee which is                  20 comprised of the CDER and CBER Center Director, the                  21 Chief Operating Officer, the Principal Deputy                  22 Commissioner, Dr. Sherman, and then myself. And then</p>

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<p>1 we have the hiring pilot build team. We have contract                  2 support. We have been collaborating very closely with                  3 Tania in the Office of Human Resources, DHHS Office of                  4 Human Resources. We have SharePoint team,                  5 communications team. We also found as I mentioned that                  6 the customer is at the center so we have a customer                  7 advisory board which is comprised of center executive                  8 officers. We've hired our first detailee to lead the                  9 pilot operations team, Chantal Dawson. CDER was kind                  10 enough to let her on loan. But we will be in December                  11 and January populating the pilot operations team                  12 further. And we've also met with various customer,                  13 we're calling them customer engagement focus groups,                  14 talking directly to hiring managers.                  15 So we have these ideas for the process and                  16 then we are sitting down with managers and testing it.                  17 Well what do you think of this? Would you like someone                  18 from HR to schedule interviews? You know how can we do                  19 to sort of take care of you in the hiring process to                  20 reduce the administrative burden.                  21 So there is a lot of governance for the pilot                  22 because it is so important and I'm pleased that we have</p>	<p>1 jobs effectively.                  2 Quality - one thing we heard from the report                  3 is that managers need better fitted candidates in the                  4 right roles at the right times. That is definitely a                  5 focus for us.                  6 Customer Service, it is not last, it is not                  7 least. It is most important actually. Hiring managers                  8 that have a designated single point of contact and who                  9 acts as the interface with the HR engine. And then we                  10 really are going to be collecting ongoing customer                  11 service feedback from hiring managers as well.                  12 A lot has been considered in how we are going                  13 to measure success of the pilot.                  14 This concludes the overview of the FDA                  15 reimagined pilot. I really thank you for your                  16 attention.                  17 We'll now move into a 15-minute break and then                  18 return at ten o'clock.                  19 DR. SHERMAN: Can I ask a quick question?                  20 MS. KELLER: Sure.                  21 DR. SHERMAN: How many people do we have                  22 registered to speak? Is there anyone who wants to</p>
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<p>1 such commitment from senior leadership at the Agency.                  2 So to have a successful pilot it is really                  3 important, I think Steve pointed out, that metrics                  4 really have been lacking and we really need to focus on                  5 those moving forward. And so we are looking at success                  6 metrics along five dimensions.                  7 So timeliness, can we do things in parallel.                  8 And are we really reducing time in the end-to-end                  9 hiring process, that is top of mind.                  10 Accuracy, so ongoing performance process                  11 management. And in the pilot we want to enable as I                  12 mentioned rapid real-time testing but then also a rapid                  13 issue escalation. So in the future we never want                  14 someone to feel that they have to go to the top of the                  15 Org Chart to resolve something because the process is                  16 being monitored so closely it never has to get to that                  17 point.                  18 Employee satisfaction is mentioned; many of                  19 the employees involved in the hiring process they need                  20 to feel rewarded and recognized. And we also need to                  21 make sure there is adequate training and they have                  22 documented standard operating procedures to do their</p>	<p>1 speak, who hasn't registered?                  2 Okay. In a quest for efficiency and we are                  3 very democratic, how many people would like to skip the                  4 break?                  5 Okay. Let's go to our speaker.                  6 MS. SHERMAN: I'm sorry, should I know who                  7 that is? Oh, we were going to get the list during the                  8 break.                  9 Jennifer Nowak, could you just identify                  10 yourself and your affiliation please. Thank you. I                  11 think I'm going to get yelled at after the meeting.                  12 PUBLIC COMMENT                  13 MS. NOWAK: Good morning. My name is                  14 Jennifer Nowak and I'm speaking today on behalf of the                  15 Biosimilars Forum. The Biosimilars Forum is a non-                  16 profit organization whose mission is to advance                  17 biosimilars in the United States with the intent of                  18 expanding access and availability of biological                  19 medicines and improving healthcare.                  20 The forum works on a consensus basis to                  21 develop policy positions to insure the United States                  22 has a competitive, safe, and sustainable biosimilars</p>

Page 38	<p>1 market providing more options to patients and                  2 physicians. The biosimilars forum whose founding                  3 members represent the majority of companies with                  4 significant U.S. biosimilars development portfolios was                  5 please to take part in the 2016 negotiations for the                  6 biosimilar biological product user fee program or BsUFA                  7 II the results of which are reflected in the biosimilar                  8 biological product reauthorization performance goals                  9 and procedures fiscal years 2018 through 2022 which is                  10 commonly called the commitment letter.</p> <p>11 Insuring that the Agency has the manpower and                  12 expertise needed to support a robust and efficient                  13 product review process is critical to the success of                  14 biosimilars in the marketplace and was a key                  15 consideration during recent user fee negotiations                  16 between FDA and stakeholders.</p> <p>17 As reflected in the commitment letter the FDA                  18 and industry negotiators agreed to implement changes to                  19 the review program for biosimilars which will improve                  20 communications between biosimilar product sponsors and                  21 the FDA and increase the level of transparency                  22 associated with the review process. A key feature of</p>	Page 40	<p>1 report identifies critical gaps and inefficiencies and                  2 sets a baseline upon which to measure improvement                  3 through the duration of BsUFA II and beyond.</p> <p>4 The report's findings are consistent with                  5 concerns voiced during discussions between FDA and                  6 industry during the BsUFA II negotiations process. The                  7 gaps and inefficiencies in hiring and retention                  8 processes directly impact the capacity and capability                  9 of the FDA to adequately support the biosimilars                  10 program. By identifying major root causes and                  11 providing recommendations for a path forward the                  12 initial assessment constitutes a significant first step                  13 towards meeting the BsUFA II hiring and retention                  14 commitments.</p> <p>15 The Forum understands that staffing of the                  16 biosimilars review program continues to be a challenge                  17 and urges the FDA to continue this forward momentum                  18 with all deliberate speed. The Forum appreciates the                  19 efforts made by the Agency and its continuing                  20 implementation of the biosimilars program.</p> <p>21 We look forward to continued collaboration and                  22 respectful working relationship with the FDA.</p>
Page 39	<p>1 this program enhancement is FDA's commitment to hire an                  2 additional 15 FTEs to support the biosimilars review                  3 program within the first year of BsUFA II.</p> <p>4 During the negotiations process FDA also                  5 pledged to fill a large number of positions before the                  6 start of BsUFA II to support the biosimilars review                  7 program, an effort which was to be funded from carry-                  8 over fees that had not been expended under BsUFA I.</p> <p>9 Further the Agency agreed to set clear hiring                  10 goals and to complete the establishment of a new                  11 dedicated unit within the office of medical products                  12 and tobacco. This unit will be charged with the                  13 continuous recruiting, staffing and retention of                  14 scientific and technical staff for the review of                  15 products under PDUFA and BsUFA in order to ensure that                  16 the FDA is staffed with the talent required to keep                  17 pace with rapid innovations and the development of new                  18 therapies.</p> <p>19 The forum applauds the FDA's fulfillment of                  20 its commitment to publish an initial assessment report                  21 and hold this public meeting before the end of 2017.                  22 The initial assessment of FDA hiring and retention</p>	Page 41	<p>1 Thank you.</p> <p>2 DR. SHERMAN: Thank you for your comments.                  3 I believe Dr. Mullin has a comment.</p> <p>4 DR. MULLIN: So thank you for the -- I'm very                  5 excited OSP is my office so we are in the pilot. It is                  6 very exciting.</p> <p>7 So I have a question or just maybe you could                  8 say more about it. I mean one of the things and as I                  9 looked at the slide I think Tania presented on                  10 corporate recruiting and the various non-MD, non-                  11 Dentist disciplines that are there. And it is great                  12 that those are going to be undergoing corporate                  13 recruiting. And I wonder if you can say more about                  14 another dimension of this which is a challenge for us                  15 because these are very competitive fields. What can we                  16 do? Do we have any flexibilities with the starting                  17 salaries, what we can offer people to be competitive                  18 because there is a lot of competition? The drug                  19 industry represented by our colleagues here are non-                  20 slackers when it comes to offering nice packages to                  21 people. So what can we do or is there much we can do                  22 in addition to the process innovations that you have in</p>

Page 42	<p>1 mind to try to do something with salaries, either both</p> <p>2 in the recruiting phase and retention which is quite</p> <p>3 critical and part of that office as well, that</p> <p>4 scientific staffing office is to look at the market and</p> <p>5 the salaries. Can you say more about what we might be</p> <p>6 able to do there? What you might be looking at?</p> <p>7 MS. TSE: Absolutely. Melanie and I will tag</p> <p>8 team that response. So under current government</p> <p>9 regulations we have some tools that give us some</p> <p>10 limited flexibility that we leverage frequently.</p> <p>11 Something called above the minimum appointment. But</p> <p>12 that is not enough for some of these very tough</p> <p>13 scientific positions and helping us fill those. So</p> <p>14 while we're currently leveraging tools available to us</p> <p>15 as well as offering retention allowances for those very</p> <p>16 key positions, the Cures initiative will really help us</p> <p>17 on the compensation level. And Melanie is leading that</p> <p>18 effort as well. So I will punt the rest of that to</p> <p>19 her.</p> <p>20 MS. KELLER: Thanks, Tania. So I agree I</p> <p>21 think we're really excited and working feverishly</p> <p>22 behind the scenes on implementing the hiring provisions</p>	Page 44	<p>1 imperative that we continue to work as a team as well</p> <p>2 as with our external partners who are gathered here</p> <p>3 today and our internal partners.</p> <p>4 As Melanie said the 21st Century Cures</p> <p>5 addressing Dr. Theresa Mullin's question is important</p> <p>6 to FDA. That will avail itself the opportunity to</p> <p>7 retain some of our very good people and also make sure</p> <p>8 that we offer competitive packages because some of you</p> <p>9 in here are cherry picking some of our best staff too.</p> <p>10 So we need to be able to retain our people to be able</p> <p>11 to do and be forthright with the FDA mission and vision</p> <p>12 which are Dr. Gottleib is on the Hill fighting for us</p> <p>13 every day.</p> <p>14 So I want to thank you and as well as thank</p> <p>15 Dr. Rachel Sherman for sponsoring this.</p> <p>16 Thank you.</p> <p>17 DR. SHERMAN: Thank you. And Dr. Gottleib</p> <p>18 would have been here but he's actually on the hill</p> <p>19 testifying. So that dragged him away.</p> <p>20 Any other comments or questions.</p> <p>21 Well, first on behalf of everyone we'd like to</p> <p>22 thank you for coming, spending the time this morning.</p>
Page 43	<p>1 of 21st Century Cures and that was enacted in January</p> <p>2 and I think very soon we'll be able to start</p> <p>3 implementation of those additional hiring and pay</p> <p>4 flexibilities. That Act enables the commissioner to</p> <p>5 set pay up to \$400,000, but not everyone can make that.</p> <p>6 So but we are excited that we really have contracted</p> <p>7 with experts to build that new pay structure. And I</p> <p>8 think the kinds of occupation that you are referring to</p> <p>9 Theresa are very in in line with the authorities that</p> <p>10 are granted in Cures and can be used in a targeted way.</p> <p>11 DR. SHERMAN: I see our Deputy Chief Operating</p> <p>12 Officer; would you like to say anything?</p> <p>13 CLOSING</p> <p>14 MS. HEBERT: Hi, good morning everyone. My</p> <p>15 name is Angel Hebert and as our fearless leader Dr.</p> <p>16 Rachel Sherman pointed out I am the Deputy Chief</p> <p>17 Operating Officer who is very glad to be here this</p> <p>18 morning. Fortunately a meeting got cancelled and</p> <p>19 fortunately I was able to come.</p> <p>20 I want to thank Melanie as well as Tania Tse</p> <p>21 for all the work they've been jointly doing to help us</p> <p>22 move this process and project forward. It is</p>	Page 45	<p>1 We look forward to comments into the docket.</p> <p>2 I'd like to acknowledge first team hiring that or as</p> <p>3 Melanie dubbed it hashtag team hiring for working to</p> <p>4 put this meeting together.</p> <p>5 I'd like to emphasize a couple of points that</p> <p>6 were just made. There's really no higher priority and</p> <p>7 we are taking this very seriously. We are very</p> <p>8 appreciative of the authorities or nudges whatever and</p> <p>9 the resources that were provided by the user fee</p> <p>10 agreements. That gives us a tremendous platform to work</p> <p>11 with. And we have every intention of changing that 12%</p> <p>12 flipping it around, maybe we will make it to 100</p> <p>13 satisfy hiring managers. But we are going to do our</p> <p>14 best. I think that this was just pointed out coupled</p> <p>15 with the FDARA or the Cures hiring authorities really</p> <p>16 can change the paradigm our hiring.</p> <p>17 This is a great place to work. And we want to</p> <p>18 continue to recruit and retain the best. And I think</p> <p>19 Melanie's two plus decades in government are paying</p> <p>20 off, again we appreciate CDER sending her to us and</p> <p>21 supporting her and the enthusiasm is infectious. I</p> <p>22 think we are all very excited about hiring. And I</p>

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1 never thought I'd use those two words in a sentence  
 2 together but I do it a lot now.  
 3 So please look forward to additional updates  
 4 from us in the future and please send your comments to  
 5 the docket.  
 6 And have a good afternoon or actually morning.  
 7 Take care.  
 8 [APPLAUSE.]  
 9 (WHEREUPON, the Assessment Meeting was  
 10 concluded.  
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1 CERTIFICATE OF TRANSCRIBER  
 2 I, CHERYL LaSELLE, do hereby certify that this  
 3 transcript was prepared from audio to the best of my  
 4 ability.  
 5  
 6 I am neither counsel for, related to, nor  
 7 employed by any of the parties to this action, nor  
 8 financially or otherwise interested in the outcome of  
 9 this action.  
 10  
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 12 12/4/2017  
 13 DATE CHERYL LaSELLE  
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1 CERTIFICATE OF NOTARY PUBLIC  
 2 I, IRENE GRAY, the officer before whom the  
 3 foregoing proceeding was taken, do hereby certify that  
 4 the proceedings were recorded by me and thereafter  
 5 reduced to typewriting under my direction; that said  
 6 proceedings are a true and accurate record to the best  
 7 of my knowledge, skills, and ability; that I am neither  
 8 counsel for, related to, nor employed by any of the  
 9 parties to the action in which this was taken; and,  
 10 further, that I am not a relative or employee of any  
 11 counsel or attorney employed by the parties hereto, nor  
 12 financially or otherwise interested in the outcome of  
 13 this action.  
 14  
 15 December 12, 2017  
 16  
 17 IRENE GRAY  
 18 Notary Public in and for the  
 19 State of Maryland  
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