PUBLIC MEETING ON FINANCIAL TRANSPARENCY and EFFICIENCY of the PRESCRIPTION DRUG USER FEE ACT, BIOSIMILAR USER FEE ACT, and GENERIC USER FEE AMENDMENTS

June 7, 2019

9:00 a.m. - 11:30 a.m.

White Oak, Great Room

Section A (1503A)

A P P E A R A N C E S

Monica Ellerbe, Director of Business Management Services, Office of Finance, Budget and Acquisitions, Begin Meeting, Page: 4

Patrizia Cavazzoni, M.D., Deputy Director for Operations, Office of the Center Director/CDER, Welcome and Introduction, Page: 4

David Miller, Director of Division User Fees, Office of Finance, Budget and Acquisitions, General Overview of 5-Year Financial Plans, Page: 7

Andrew Kish, Director, Office of Program and Strategic Analysis/CDER and Josh Barton, Director of Resource Capacity Planning Team, Resource Capacity Planning (RCP) and Modernized Time Reporting (MTR) Implementation Progress, Page: 22

Jim Taylor, Grant Thornton, LLP - Health FFRDC, Financial Management Evaluation for Human Drug User Fees, Page: 50

Jay Tyler, Chief Financial Officer, Office of Finance, Budget and Acquisitions, FDA Response to Financial Management Evaluation, Page: 58

MS. ELLERBE: Good morning. My name is Monica Ellerbe. I'm the Director of Business Management Services in the Office of Operation, Officer of Finance, Budget, and Acquisitions. I will be your meeting facilitator today.

Welcome to the Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments Public Meeting.

Dr. Patrizia Cavazzoni will have opening comments and remarks and go through today's agenda. Thank you.

DR. CAVAZZONI: Good morning, and welcome to this public meeting. My name is Patrizia Cavazzoni. I am the Deputy Director for Operations in the Center for Drug Evaluation and Research.

As you're likely aware, under PDUFA VI, BsUFA II, and GDUFA II, the FDA made several commitments to enhance transparency in management of user fee resources.

These commitments include developing a resource capacity planning capability and modernizing our time reporting, publishing five year financial plans for each program, and contracting and independent third party to conduct an evaluation of program resource management during fiscal year 2018.

In addition to promote transparency, FDA committed to hosting an annual public meeting in the third quarter of each fiscal year beginning in 2019, which is the meeting that brings us together today.

Together, these commitments represent a significant amount of work that the Agency had undertaken to further strengthen our ability to efficiently utilize available program resources.

The resource capacity planning capability, once fully established, will help the Agency utilize data in a more systematic and proactive manner, to help ensure the most efficient and effective deployment of resources.

The publishing of the five year plans provides us with an opportunity to communicate more clearly to stakeholders the likely financial position of each program over the current authorization cycle. And the resource management evaluation, while highlighting much of the progress that has been made over the last few years, has identified additional opportunity to refine some of our processes and internal coordination.

We have a full agenda for today's meeting. First, David Miller, Director of Division of User Fees in the FDA's Office of Financial Management, will present an overview of the five year plans for PDUFA, BsUFA, and GDUFA.

Andy Kish, Director of CDER's Office of Program and Strategic Analysis, and Josh Barton, Director of the Resource Capacity Planning Team in CDER, will provide an overview of the vision and progress towards implementing the Resource Capacity Planning Capability, and the Modernization of Time Reporting.

Jim Taylor from the MITRE Grant Thornton Health FFRDC Team will provide a summary of the findings from their evaluation of the User Fee Financial Program Management Evaluation.

And Jay Tyler, FDA's Chief Financial Officer will provide the Agency's perspective and response to the Financial Management Evaluation.

There will be time for public comments at the end of the meeting. If you wish to sign up to speak for the open public comment meeting, please do so at the registration table.

There is also a public docket that is open until July 8th to which the public can submit comments.

A few brief housekeeping items; we will have a ten minute break at approximately 10:20, and bathrooms are down the hallway in the lobby and to the left.

I will now turn over to David Miller to provide an overview of the five year financial plans.

MR. MILLER: Thank you. Again, my name is David Miller. I'm the Director of the Division of User Fees within the Office of Financial Management, which is a part of the Office of Financial, Budget and Acquisitions, and I'm going to be going through a general overview of the five year financial plans.

So, the first thing I'd like to do is just go through some of the basics for the fee setting for the

Prescription Drug User Fee Program.

As you can see on the chart, the fee setting goes through FY18 through FY22, the full timeframe for PDUFA IV, and we start with the statutory base in FY18, which is set in statute. This is the only amount actually set in statute as a number; it is the $878,590 -- or I’m sorry -- $878,590,000.

The next piece is the inflation adjustment, which is an adjustment to maintain the purchasing power of these user fee funds. This is a blend of CPI and pay increases seen at the Agency.

Then you have the capacity planning adjustment, which is intended to adjust the PDUFA target revenue for changes in workload. Currently we are utilizing an interim capacity planning adjustment until the final methodology for the capacity planning adjustment is completed, which may begin in FY21.

The interim adjustment is very similar to what we were doing in PDUFA V, but there were some key changes that were made. One of those key changes is that it's focused more on the time invested in those activities, instead of it being focused more on the standard costs for each one of those activities.

So, what we're doing is we're adjusting for workload on a weighted three year average over the initial base period, which is also three years, and that amount of change is applied to the amount from the statutory base, and then inflation that's been adjusted for that year.

The next line that we have is the additional dollar amount set in statute. Those dollar amounts are inflated independently on a yearly basis. Those enhancement dollars are for FTE for the program, and you can see that they're going to be rolled into the base for the next fiscal year.

The Operating Reserve Adjustment is an adjustment that's set forward to maintain no more than 14 weeks of operating and carryover balance. It was utilized in the first year, coming from FY17 when the balance was higher than that 14 weeks. That was a reduction of roughly $33.3 million. Those funds were utilized in FY18 to, basically, make the total revenue for that fiscal year whole.

The additional direct cost adjustment is the last line of the fee setting methodology for PDUFA. It was $8.7 million in FY18, as you can see from the table. That amount was for operating dollars for specific contracts and is not rolled into the base in the early basis. It is, actually, inflated from FY18 to FY22 independently.

An important thing to notice, for the Operating Reserve Adjustment, is it has not been utilized again since it was utilized in FY18, and the Agency does not plan on needing to utilize it again for the remainder of PDUFA IV.

The statute base for FY19 is a combination of the statutory base for FY18, the inflation adjustment for FY18, the Capacity Planning Adjustment for FY18, and then the additional dollar amounts for FY18. Those combined together equal the $935.9.

Jumping to the next slide, I'm going to do a quick overview of what you're looking at right now, because I know it's a lot to take in.

The chart in front of you is three tables combined. The top chart is the budgetary resources available to the Agency. It is made up of target revenue, cash collections, recoveries, and the carryover balance, available carryover balance in the previous year.

The important thing to note is we are also utilizing for FY18 an estimated figure coming into the year, and then what we ended up with. The target revenue is not changed, but you can notice that the cash collections do change, so we will projecting to have $911,346, and we collected, $908,000.

The recovery line -- recoveries, just to give you a general description of what they are, recoveries are funding that were utilized for contracts in prior years. Once that contract is complete, if there's any dollars remaining on that contract belonging to the program, they go back to the carryover balance in the program, so we don't lose those funds.

The reason why the projection was zero dollars in FY18, was we didn't have enough data to be able to project what that number would actually be.

But you can see going forward, we do have enough data at this point where we believe that we can project it, and that number for FY19 is estimated to be #10 million, and we've taken that $10 million and spread it out through FY22.

And the reason we're doing that is so we can have a better estimate of what our budgetary resources would be on a yearly basis, and at the same time have a better prediction of what our carryover balance would be at the end of the fiscal year.

The second table is on user fee obligations. The user fee obligations are broken down by pay and operating by center, and you can walk down through that; do have an estimate and an actual for each one of the centers. It also has a cost for rent and for shared services.

Shared services at the Agency, at this point, is also referred to as the work in capital fund. The work in capital fund contains several offices within the Agency that provide general services to all FDA employees.

Just to give an example; my office of FBA is a part of the work in capital fund, as well as human resources, and facilities management.

The bottom chart is on carryover. So,

carryover provides you with several numbers. One is the total carryover balance at the end of the year, and also provides you with an unavailable balance. That unavailable balance right now is made up of funding from prior PDUFA authorizations that were not appropriated; it's roughly $79 million, along with a set-aside amount that we hold for refunds.

The total comes out to $83.8 million, which provides us with a carry-around at the end of the year that would be available for the following fiscal year at the very bottom of the chart.

So, again, we are showing an actual and an estimate here for FY18, and you can see that we projected to have, at the very bottom, $127.3 million at the end of the year available, and we ended up with $125.3, so you're seeing that we're pretty accurate with our projection of how much we thought we were going to have going into the next fiscal year.

Another thing you'll notice is cash collections. Cash collections were over 90 percent, 99 percent, accurate from what we had projected to collection, to what we actually did collect.

Part of that is due to the impact that we've had from the change in our fee structure. The fee structure did change from PDUFA V to PDUFA VI, and one of the big factors there is we were able to reduce the amount of burden on the application fees coming into the Agency by shifting it from 33 percent to 20 percent.

Applications are very volatile; they're very volatile to predict, and relying on them less, in terms of our revenue coming in, is a good thing, and you're seeing the results.

Another thing that is really important to us is the fact that the administration burden on coming up with some of the older fees has been eliminated. That would be the establishment fee, where there's a lot of back and forth with industry trying to figure out exactly how many establishments would be charged, per company. It was very burdensome. We no long have that fee in PDUFA, so that burden had drawn down.

In addition to that, we also eliminated the need to have a large cleanup billing after the fiscal year ended.

So, after we had already finished FY18, for example, we would be shifting into when are we going to bill for the cleanup billing for FY18, and that's a whole different billing process. So, we've eliminated that, as well.

And as you can see, the results are we're collecting 99 percent of what we believe that we're going to.

The Agency wants to collect exactly what it predicts; we don't want to collect less; we don't want to collect more.

Another thing you're going to notice from this chart is the carryover balance. The carryover balance projected, or available to us in the beginning of FY18, was $232 million. That total has dropped to what's available to us in FY19, is $125 million.

That is a substantial drop in carryover from one year to the next, and that can be attributed to the $33 million offset that we needed to do in FY18. That drop, plus some additional targeted investments in the PDUFA program, brought us down to an available balance of $125,372,000 in FY19.

You can see that that drop is going to continue. The available balance in FY19 is $125.3; we're projecting to drop $202.4 by the end of the fiscal year. But then you're going to notice that it's going to stabilize over the next three years.

So, we're projecting that we're going to be dropping the carryover balance again to the $104 -- I'm sorry -- the $102.4, and then it will remain relatively stable over the next three years, ending in FY22 at $104.7 million.

BsUFA. So, you can see BsUFA has some of the same elements as PDUFA in this chart, from target revenue. The base amount in statute is $45 million. There's an inflation adjustment, capacity planning adjustment, and operating reserve adjustment, and a normal, regular, adjustment for FY18, which is being utilized to enable us to reduce our carryover balance into the future years.

Again, the program, in BsUFA II, with a large carryover balance, and we did commit to reducing that balance over time below the 21 weeks of operating, which is set in statute, through the operating reserve.

One of the big things to note for BsUFA, is it's still a relatively new program, and it's extremely volatile. This is the first authorization for the program that it has its own fee structure, with fees mapped out in statute that are not attached to a fee related to the PDUFA program.

So, in BsUFA I, you were paying a percent -- your fee was a percentage of the PDUFA fee, and now BsUFA is completely independent of itself.

One of the important things, also to note in the program, is there's not a lot of fluctuation in inflation capacity planning. What you're seeing here is a normal inflation adjustment going from 18 to 22. Capacity planning is in the same boat as PDUFA. We're waiting for that methodology to be developed and approved, and once that happens, we could, potentially, have a Capacity Planning Adjustment in FY21.

So, I'm glad I did the walkthrough on the budgetary resource obligations and carryover; you're going to see this table one more time after this.

The biggest things to note for BsUFA, again, is that the program is extremely volatile, and you're going to see that several times over this chart. The first being in its cash collections.

Cash collections for BsUFA was projected and targeted to be $40,214,000. We ended the year with $29,238,601. That is an $11 million drop in collections. It's a gigantic loss in revenue, and so as a result, you're going to be able to see at the bottom, that the carryover balance dropped significantly.

So, we planned on spending $40,465,000, we spent $40,279,000; we did a pretty good job on what we said we were going to do, but nonetheless, the program didn't collect as much as we were hoping, so the carryover available at the end of the year, which we were projecting, was around $48 million, and we ended up carrying over $38 million.

So, again, the big issue with BsUFA is it's extremely volatile, it does rely on several fee bands, but one of them is applications and you can see from the table, and the notes on the side, that the fee applications were 56 percent lower than anticipated. And the Agency hopes that that volume will kick up, but it's still a very volatile program and cash collections will vary from year to year.

Another thing about the volatility of the program is the impact that the spendature (ph) has on the program. BsUFA needs a conservative spending approach, and it needs a conservative spending approach not only because collections vary from year to year, but also because we're committed to spending $20 million in non-user fee budget appropriations every year, plus an inflation factor that's set forth in the statute.

I have the numbers in here for FY18; that trigger was $21,711,380. We cleared that trigger by $600,000 last year. So, $600,000 is only three percent.

So, this is all dictated by the program time reporting. So, how much time is being spent on the BsUFA program, in relation to how much money is being spent at the centers, and you can see that that is just not a very large gap between the trigger itself.

Now, BsUFA does have a threshold that we can miss that trigger by; it's 15 percent. So, the three percent cleared from the actual trigger, which is where we want to be above. We do have the ability to be below it by roughly $3.9 million.

So, we could miss the trigger; we could have been lower by 18 percent, and still have made the trigger, but that is extremely important to have in the program, if we're going to be able to move forward and meet that trigger on a yearly basis, considering the volatility.

So, the next program, you'll notice, is a little bit more straightforward. This is the Generic Drugs Program. It doesn't have a Capacity Planning Adjustment. There's no Operating Reserve Adjustment.

Now, the Agency does love to hold between eight to ten weeks of carryover to mitigate risks. Those risks would include risk of government shutdown, or enhancements that need to happen in the program, to have some dollars available. Or, you know, cash collections not coming in where we need them to be.

But we don't have an adjustment here, which means we can hold over the eight to ten weeks over the 14 weeks, if need be. The base amount is set in statute, was $493,600,000 and you can see that that's inflated on a yearly basis just by inflation.

Now, one important thing to note here on the chart is cash collections. We did collect over 99 percent of the GDUFA funding that we -- actually, more than 100 percent. It was just over 100 percent. So, it's $493.6 is what we wanted to collect; we collected $493.6. $55,000 -- $56,000 over our target revenue. It was extremely close. It was an excellent job, by the Agency, of being able to predict its collections for the year and estimating the fee bands.

There is some volatility in those fee bands, but those fees are relatively new, and refinements will be made.

Like I said before, we don't have an operating reserve in GDUFA, but we do maintain an eight to ten week carryover balance. That balance, you'll see from this chart, is actually a little higher than the eight to ten weeks; it's closer to 14 weeks and one of the reasons for that is the estimates for obligations in FY19 have been lowered from last year.

They were lowered from last year because we've having some issues with hiring. You'll see from the chart. You can have -- we have hiring challenges in FY19, and it's expected -- we're still expected to decrease this balance over the next four years, but that is impacting the total of the program.

That was it. Thank you.

MR. KISH: All right. I know it's always good to start the morning with consolidated financial statements. If you need more coffee, I don't blame you, but thank you for David, for going over it.

We're all very familiar with it. I know it might take some time to get familiar with those statements, so please do review them, and the five-year plans that are now out publicly.

I’m going to briefly introduce Capacity Planning. Josh, to my left, is really going to dive into it and give you, not the most detailed overview, because it is a very detailed topic, but hopefully, a deep enough dive to help understand what that commitment is, and where we are with implementing it.

So, this really came out of PDUFA negotiations, and then it continued over to BsUFA and GDUFA.

When we were discussing Modernized Time Reporting and Capacity Planning, the negotiations, the Agency really saw a lot of value in this capability and bringing it into the Agency.

It primarily comes out of R&D operations in the pharmaceutical industry, and it -- at its simplest, it's using data to figure out what resources you need, before you need them, to complete a performance of certain unit of work, in a certain period of time.

We committed to three major commitments across the three programs. One is to publish an implementation plan for Modernized Time Reporting Capacity Planning. That is completed. It was out last spring.

If you haven't read it yet, it's on the website. Feel free to read it. It's a fairly good read. Maybe don't read it right before you go to bed.

We also committed to staffing our Capacity Planning Team to implement and manage the system. I would say, we've got team established in CDER and in Headquarters. We still need to add folks to that team, and bring in more capability, but we do have it in place, and we're continuing to build.

Another commitment that Josh will dive into a bit more, is around conducting a third-party assessment to recommend a new methodology to adjust fee revenue amounts. That's based on capacity needs. That applies only to PDUFA and BsUFA.

That evaluation will be completed around next spring or published around next spring. Public comment, once we receive public comment, we do have the capability to add a new revenue adjuster, capacity adjuster, to PDUFA and BsUFA. That would be in time for setting fees for '21.

So, we spent a fair amount of time planning how to implement Capacity Planning. We actually started in 2016 on this work, in terms of planning.

At its simplest, the vision we've established is to maximize our operation to deliver on our public health mission. I'll go through this a bit slowly because it's a lot of words, but we went through a consensus process to come up with this across all medical products, to develop a unified and trusted resource management capability to foster innovation, maximize our operational performance, facilitating the flow or products to patients first in the world, in order to protect and promote public health, and meet our commitments to the American public.

So, it's a mouthful. If you get asked about the vision of Capacity Planning, probably the top's the easiest; FDA is trying to maximize operations to deliver on its mission.

So, on that I'll hand it over to Josh. He's going to do a deeper dive into Capacity Planning and where we are in implementation.

MR. BARTON: Thank you, and testimony. As Andy mentioned, we've been really working on this since 2016. So, I really appreciate your interest today, in joining us, so we can talk through all the work that we've been doing here, and the work to come.

So, Andy mentioned the plan that we published last spring, at the end of March, as well as that vision statement. In the text of the commitment for that plan, it required us to bring third-party consultant contractor to help advise us on how we design the implementation plan for this capability.

So, we were working with Price Waterhouse Cooper's PWC, the R&D Advisory Services, and that’s a practice that typically works with R&D operations within the bio-pharmaceutical sector.

So, we were working with them. That vision statement that Andy just read was part of the consensus process that we organized across the Agency, as part of that planning effort with PWC.

And really, the logic of bringing in, you know, a third-party expert in this field, is really to help the Agency so that we can benefit from established best practices in this field, and we're not building this -- making this up on our own.

But, obviously, the way that our human medical product programs work, is -- the operating paradigm is a little bit different, obviously, than the way industry works. And so, we've adapted this

Resource Capacity Planning vision to really match our paradigm.

So, what's up on the screen here, this is perhaps over-simplistic but hopefully, really emphasizes kind of the key difference between the way industry and FDA would work in this space.

So, in -- you know, maybe again, an over-simplistic, sort of industry model, if there's an idea for a new project, that might go through a process of reviewing a strategy, if that project fits into the strategy and/or priorities of the organization. If so, there might then be a review of, do we have the people with the volume and the types of skills that we need to deliver on this project? And if yes, great, if no, you might be able to find additional resources, i.e., bringing on contract resources, you could look at re-prioritizing other work within the portfolio, or perhaps delaying the initiation of the project until the appropriate resources are freed up.

Within FDA, when we're talking about our UFA (ph) programs and the performance goals that we have around those programs, when we get a new submission that if there's a performance goal, we get that done within the timeframe that's required, with the resources we have available.

So, if we get -- if we were to get a large bellist (ph) of NDA's today, they're going to get reviewed by the staff what are here today.

So, what that means, in order for us to really be able to adjust our staffing levels to meet the resource demand, with enough lead time, we need to have a forward looking proactive capability, that can really begin to understand where work is headed, so that we can identify the resources before we actually need them, so we can get them in place when we do need them.

So, how do we plan on doing that? Again, this is very high level, and perhaps simplistic, but hopefully pulls together the main concepts.

So, we have a couple of different capabilities that are in play here. The first is our time reporting. So, the commitment letter talks about our Modernized Time Reporting. We've rebranded our Time Reporting as Insight Time Reporting. It's really about providing insight into our resource needs. So, you know, the branding's a little bit better than Modernized Time Reporting.

But the Insight Time Reporting, that provides us, you know, we're now doing 52 weeks a year of time reporting, where up until -- you know, we had historically been doing eight week -- a total of eight week samples across the year.

So, we have a much -- we are working towards collecting a much greater volume of time reporting data and have a much better picture of our -- how our operations are being invested.

But that provides us much better data on level of effort for different types of work. But that's also combined with our workload forecasting capability.

And when we say workload forecasting, we're really talking about developing advanced analytics to really model what's happening in medical product development, and translate that into forecasts of likely incoming work, i.e., regulatory submissions.

That is then pulled together to translate likely regulatory submissions, into resource need. And this can be used in a number of different ways, including balancing available resources today, being able to adjust the revenue for PDUFA and BsUFA, which Andy talked about a little bit, being able to develop more proactive hiring plans, and help to better inform our financial forecasting, and how we are executing our spending triggers, which David talked about a little bit, throughout the course of a fiscal year.

So, how are we going to do this? And this is from the report we published. So, if you're read that report, this might look familiar.

We've established very high level five phases of implementing this full capability, and we're still very much in phase one, which is really building the foundation.

So, this phase one includes our 100 percent time reporting, developing our initial workload and resource forecasting capabilities, and we're very much progressing through this.

Our next phase, which we're beginning to engage in, is really developing the support model and the organization, as well as the business processes to really integrate these capabilities into decision making within the organization.

Once that is accomplished, phase three is really about doing the close loop planning. So, this is where we'd have our forecast of our resource needs, we'd be able to track our actuals to those forecasted needs, and we'd be able to refine our forecast, as well as begin to make informed decisions about how to adjust, if and as necessary, our resource deployment.

From there we have this planned business case refinement and stage gate review. So, these first three phases are really taking us through the current authorization period, and -- but we want to keep this idea of this longer term vision, this longer term integration, as something that is possible.

And once we've completed, gotten through the three phases of the initial implementation, you know, the organization can consider the cost and benefits of continuing to further integrate with our project management and our corporate analytics and reporting capabilities.

In working with PWC, you know, one of the things that they communicates is, if you're going into an organization that has, sort of, a green field of systems and capabilities, you'd really first focus on developing a project management capability, and then you'd build these time reporting and resource planning capabilities on top of that.

But because we really have -- we have a variety of project management workflow and management tools in place, that are being updated, we've really flipped this to focus on the capabilities we committed to establishing within the authorization period, the Time Reporting and the Capacity Planning, but we really wanted to keep the vision of the longer term integration as something that is possible in the longer term.

So, this next slide is also from the -- our published plan. I wanted to just dive a little bit more in-depth about what we would accomplish and the benefits we would have at certain phases within that five phased plan.

So, at the completion of phase three we would have -- we would expect to have the ability to forecast our user fee program cost and be able to track our actuals to those costs.

This would be a little bit more of a macro level, looking programmatically across the board, and we built on -- we see here the operational backbone. This would be integrating data from across the enterprise, as necessary, to be able to inform these projections.

So, we'd have a more systematic and consistent Resource Capacity analysis across the organization, we'd have our forecasts that would be -- resource forecasts that would be more integrated with our financial planning processes. We'd have a more emerging proactive ability to identify resource gaps, and develop tactics to address those gaps, and we'd have this emerging holistic and more comprehensive view of our resource needs across our book of work within the organization.

Then phase five, this would be the full implementation of the long term capability, should we decide to continue towards that full implementation.

This would -- you'll see here, the operational backbone here is really based on this integrated project management data.

So, the idea here, the real, sort of, enterprise difference here is that our project management capability would be closely integrated, fully integrated, with our time reporting and our capacity planning capabilities.

What that would provide us would be a much more microlevel understanding of resource utilization and have that closely integrated with workflow processes.

So, you'd be able to see, at a much more granular level, any bottlenecks within processes, and be able to identify opportunities for continual improvement around our processes.

So, this would provide a much more authoritative source of planning data, provide key technical resource capacity information to frontline management, a much more robust and flexible portfolio of reporting, based on a holistic book of work, and provide improved tools to support operational strategies and prioritization of work, and an ability to deliver authoritative portfolio and Resource Capacity Planning data as needed across all levels of the organization to support strategic and operational decision making.

Where we are today; like I said, we've been doing a lot of work since -- for almost three years, at this point.

This is organized broadly in four different areas. The first being the initial planning effort to get -- you know, get the ball rolling in this capability development, and that was really organized around the plan that was published last March.

We've had a lot of work around the Time Reporting Implementation. CBER implemented full time reporting beginning in FY18, and CDER just completed the Insight Time Reporting implementation -- we had this ready to go in January, but due circumstances beyond our control, that was delayed a little bit, and so we completed between March and April the Insight Time Reporting Implementation across CDER. So, now all CDER offices are doing full time reporting, from here on out.

All that Time Reporting work required a lot of work; we spent about a year taking our existing Time Reporting categories and really reviewing what would make sense in the new paradigm and doing a lot of the technical development.

So, the Insight Time Reporting tool, which is intended to be used across the enterprise, within the FDA, as needed, is developed on a Sales Force platform. So, this is an application we configured to meet our needs.

We did a lot of work thinking about, you know, can we use something off the shelf for time reporting? And we really thought it made a lot of sense to be able to have a lot of control over the interface and the data model, so that we can really make sure it's adaptable and flexible to meet our Time Reporting requirements.

So, that was actually one of the first agile development projects that has occurred in the FDA, and so that's been working really well for us.

We've also been focused on developing the broader RCP capability, and really -- this has really been a large focus since about the September timeframe. We've established another engagement effort with PWC and established a number of different workstreams around the various capabilities that need to come together to support the broader RCP capability.

We, of course, have also been working on the organizational development, bringing the staff we need to implement this capability, and you know, that’s always an ongoing effort.

We also have the Adjustment Methodology Study, which I'll talk about a little bit as well.

In terms of how we're running this internally, this is the program structure we've established within the Agency. We have a steering committee, which is connected to our User Fee Governance Committee, and establishes the broad vision and reviews the direction of the program.

We have a core team, which really organizes and runs the program. We have extended teams within certain parts of the organization; we have focused in

CDER, because we've really focused on the Insight Time Reporting Implementation over the last year, and we have a Cross center Extended Team, and that's really to keep stakeholders from across -- you know, outside of CDER as part of the program, as well, to help prepare them for their own Time Reporting Implementations.

We have a set of delivery teams, which are focused on the various areas, including the Time Reporting, the Workload Forecasting, which I'm going to talk about a little bit in the next couple of slides.

The Resource Forecasting, which again, is translating the Workload Forecasts into the resource needs.

We also have a Training, Communications, and Change Management Team, which supports all three of those delivery teams, as well as a Business and Technical Integration Team, which helps really make sure all the technology is working.

So that, very much, has been focused, initially, on the Insight Time Reporting, but as we move towards the broader Resource Capacity Planning and analytical capabilities, and bringing that together to support the organization, there will be a lot of additional technical integrations that will need to occur to implement that full capability.

So, I want to talk a little bit more about our Workload Forecasting. This is a pretty interesting aspect of our work, in my opinion. So, I alluded to this a little bit already, but this is, really, understanding where our work is headed.

So, what we're doing, in a sense, is to -- using internal FDA data, as well as relevant external data, and -- working to develop models and understanding what's happening with drug development, so we can develop predictive analytics around the likely regulatory submissions we expect to receive.

So, we have a wealth of internal data, which has been really helpful in this regard. A lot of it tends to be unstructured, so there's a lot of work, in terms of, you know, identifying relevant text within various documents, and pulling that together in a systematic way. That can then be used for analysis.

We're looking at other data sources, including things like ClinicalTrials.gov, as well as other commercially available external data sources that can help supplement the picture we can develop from internal data.

So, we have laid out here timeframes for initial model development. Before I say anything more, I want to highlight initial model development.

So, like I talked about in the slide with the five phases, we're still really very much building a foundation here, and what we really want to do is to focus -- we're, at this point, developing initial predictive analytics.

We're exploring the data, we're exploring methodologies that are helpful to -- and predictive, and really focusing on some of these more -- some of these more major submission types, like NDA's -- the original NDA/BLA's, the number of IND's we're receiving, the number of supplements receiving, the number of NDA's, originals and supplements we're receiving.

Of course, this is only -- this is a

significant aspect of our work, but this is not, obviously, the full portfolio of the work that we do.

But we're really very much trying to develop this foundation, focus initially here, and these models will evolve over time. We see this as being a very iterative process, and as we learn more about, you know, effective methodologies, as well as we get more data from the actuals, the predictive analytics here will evolve and you know, this will be an ongoing process. This is always something that will be managed and iterated upon and improved upon over time.

We’ve laid this out in a couple of waves over the next year, or so. The first focusing really on the NDA and BLA originals, as well as their resubmissions, and then the new IND's we may receive, as well as the workload generating active IND's that the Agency is overseeing, and we're making a lot of progress through that wave.

Wave number two is focused more around the efficacy supplements, manufacturing supplements, labeling supplements, as well as the formal industry meetings, which have been increasing significantly over the last few years.

Then wave three is really looking -- you know, taking a first look at the -- some of the GDUFA relevant work around the ANDA's, both the originals and the supplements.

So, in essence, we're really trying to model a large portion of activity in the pharmaceutical industry; we're translating that into how that impact the Agency.

What I have here on this slide; this is a very preliminary analysis, and is really only here to help, you know, illustrate, sort of, the -- some of the concepts here around Workload Forecasting.

But the example that we're showing is that by looking at activity within IND phase, the hypothesis is that we can use that to then predict NDA or BLA submission.

So, in the example here, which again is very preliminary, and still very much a work in progress, we've used a survival random forest model. This is a machine learning technique, which involves developing a large number of covariates and pulling together a large amount of data and utilizing a machine learning algorithm to develop predictions.

But what you see here is that looking at -- so there's basically two examples. In the first one we have a IND that had an end of phase two meeting between three and four years ago. It's had a proprietary name request; something related to a proprietary name request within six to twelve months prior, and it's had some type of meeting request six to twelve months prior.

So, in those -- in an IND, with those types of characteristics, in this very preliminary and conceptual model, that would have -- according to the initial preliminary results, would have roughly about a 60 percent chance of becoming an original NDA or BLA within about one and a half years.

As opposed to the example on the right; an IND what does not have any of those three things, does not have a phase two meeting, does not have anything related to proprietary name request, or a meeting request. In the same timeframe, about 1.5 years out, has a less than one percent change of becoming an original NDA or BLA.

Of note, if you're comparing these graphs, the scale on the left is different. So, that -- just for your awareness. Visually, it's really one percent on the right and it's 60 percent on the left.

Again, this is just a very simple and early example of the type of work we're looking to do to develop these predictive analytics. The survival random forest is, like I talked about, is a machine learning algorithm. We're looking at the application of other types of machine learning algorithms, as well, as traditional statistical techniques, and as well as, you know, where appropriate, using other time series or moving averages, where appropriate.

What we're really trying to do is not to limit ourselves, preemptively, to any specific techniques, but when we approach a problem, and approach a need to develop a predictive model, really keep everything in play, and then see which types of techniques work -- seem to develop the best and most accurate types predictive forecasts.

So, again, this is just an example, but it's

-- you know, hopefully helps to make this a little bit more real.

I want to talk a little bit about next steps, in terms of adjustment methodology. So, this is a fee adjustment that could be applied to PDUFA and BsUFA.

So, as David talked about, PDUFA has an interim Capacity Planning Adjustment Methodology, which is really an extension of the -- what had been the PDUFA Workload Adjuster, that had existed prior to PDUFA VI. BsUFA II does not have, currently, any sort of adjustment to the fees for capacity needs.

But what is shown here is the language from the PDUFA section of the statute that outlines how we can go about implementing a new Capacity Planning Adjustment methodology, and this is similar for BsUFA. But that involves conducting another third-party evaluation, and this evaluation would be specifically focused on what should the Fee Adjustment methodology look like and developing ideas and recommendations around that. Options or recommendations.

That evaluation must be published for public comment, and then once that's done, once that's published for public comment, once FDA reviews public comment, we do have the ability to implement a new adjustment methodology.

So, the -- we had planned an expect to have that third-party evaluation to start early in the next fiscal year, so of course, our fiscal year start in October. We would expect to have that published for public comment around the springtime. So, roughly, around March of next year, 2020, in order to meet that -- the possibility of the FY21 adjustment.

So, if you're familiar with how our fees our set; we publish the fee notices at the beginning of August, so you know, we'd be working back from there if -- you know, in terms of implementing a new adjustment methodology.

So, that's the process. Just to highlight a little bit; so, this is -- summarizing a little bit, some of the current state of the PDUFA Capacity Planning Adjustment that is used today, which as I mentioned, is really an outgrowth of the PDUFA Workload Adjuster, prior to PDUFA VI.

The background here is a PDUFA Workload

Adjuster is something that was developed beginning back in 2003 with PDUFA III. There's been -- some adjustments have been made over the years, but it's really intended to -- it was always intended to adjust the top line total target revenue in a fiscal year to meet our trends and workload.

It does present some structural adjustments. So, if you're familiar with it, you'll know it's based on three year averages. So, it's -- in instances where we have growth, it's a lagging indicator. So, it's -- if there's trends, whether they're up or down, it's going to -- you know, it's going to take time for those numbers to catch up.

So, it's a lagging indicator, which means it compensates us for increases that occurred in the past. It's based on submission counts and it's -- the timing is higher -- is compounded by hiring timeframes.

So, based on submission counts -- it's simply looking at things like the number of NDA's and BLA's submitted over the -- you know, the previous three year period, versus the current three year period.

So, it doesn't translate -- so, if I were to say, hypothetically, you know, we have ten percent more NDA's, it doesn't translate that in terms of resource need. It doesn't translate that into, you know, ten percent more NDA's means X number of medical officers, or Y number of project managers, etcetera.

The timing compounded by hiring frames, since it's a lagging indicator, and if you have a growth, you know, a period of growth, it does take the Agency time to hire and to train regulatory review staff, so you know, when you're in a growth period, using the adjustment as is to provide the resources you need, it's -- there's always going to be a -- you know, a gap that we would be struggling to catch up to.

So, there's kind of a structural issue with the way that the adjustment currently works, which is why we see a lot of value in developing a more forward looking revenue setting methodology.

Of course, this is based around forecasts. So, there's always uncertainty when you're developing a forecast, and we'd have to, you know, be very thoughtful about how we're adjusting within, you know, any sort of forecast range.

But a future state adjustment, you know, would -- it would be very helpful for it to be a forward looking adjustment. It could, with our Resource Capacity Planning capability, help compensate us for likely sustained increases, so we don't want to staff to, you know, temporary peaks or spikes in submissions, but really -- because we have a very, sort of, fixed labor pool, we want -- really need to plan to, you know -- the sustained workload levels.

With our Resource Capacity Planning capability, we'd be able to translate that submission activity into likely sustained resource demand. So, like I said, instead of just ten percent more NDA's, what does that mean in terms of the number of medical officers, etcetera.

And this could provide us with the opportunity to optimize the timing of our planning for resources to account for hiring and training timeframe, so we can get folks ready to do the work, you know, when the work is coming in.

So, this will really be elicited through that third-party study that we talked about, but these are some initial ideas about some of the opportunities around a new more forwarding looking fee revenue setting methodology.

So, the graphs on the right, if you can read that, that's really -- what that's trying to do is really say, okay, if -- you know, these are the number of -- in this example -- active commercial IND's we're expecting, what does that mean in terms of our RPM's in Office A, or medical officers in Office B?

And with that, I think that's my material, so I'm going to -- but I, again, very much appreciate your interest and your time here with us today. Thanks.

MS. ELLERBE: Thank you, Josh. Given the current pace of the meeting and in an interest of saving time, we would like to forego the ten minute break and continue on with the presentations. Great.

Jim Taylor, thank you.

MR. TAYLOR: Good morning. Now, there's a danger of skipping this break; the agenda was very carefully construed so that you'd have a chance to get coffee, because now the accountants are going to start talking. So, I hope you have enough coffee in you to continue to get this going.

My name is Jim Taylor and I'm a Managing Director with Grant Thornton, and I'm really pleased to be with you here today representing the FFRDC, the Health FFRDC, the MITRE GT Team, and well as to present to you our just released Financial Management Evaluation of the Human Drug User Fees for FDA.

Before I talk about the conclusions of the study, let's maybe take a step back and give you a little bit of background.

The seamless alliance to modernize healthcare, the Health FFRDC, is the first federally funded research and development center dedicated to strengthening the nation's healthcare system. It's sponsored by the Centers for Medicare, Medicaid Services, CMS, and the other divisions of the Department of Health and Human Services.

The MITRE as an objective, a not for profit organization, operates the Health FFRDC in partnership with CMS to implement innovative ideas to solve our nation's toughest health problems.

The Health FFRDC is composed of an alliance of partners and members who are committed to providing conflict free objective expertise to HHS and its divisions, and as one of those partners, Grant Thornton is really proud that we were asked to participate in this and bring our expertise in federal and commercial financial management, and user fee evaluation, to the team.

Now, FDA collects over $1.4 billion in human drug user fees annually. The Prescription Drug User Fee Act authorized FDA to start charging user fees from sponsors of new drug products back in 1992, and the subsequent new user fee programs, including GDUFA and BsUFA, have increased financial management complexity, which I think is pretty obvious from the prior presentations.

Through authorization agreements for Prescription Drug User Fee Act for the three programs, included FDA's commitment to engage in independent third-party to conduct an evaluation of its financial management practices, and as a result, FDA asked the

Healthcare FFRDC to develop a comprehensive evaluation focused on five specific areas of FDA's financial management capability for the three programs during fiscal year 2018, and to provide recommendations based on best practices to help ensure that FDA's User Fee Financial Management capabilities are consistent with the best practices in the federal government.

So, the five areas that we were asked to specifically look at, included the resource planning and request allocation and user fee administration, administration of user fee programs, oversight and governance, technical capabilities, and the user fee estimating methodology.

So, our full report has been posted online by the FDA, and I feel compelled to tell you that the next slide is actually the spoiler slide. So, for those of you who are going to go and are anxious to read that full report, I'm about to give you the conclusion, and after spending the whole last season of Game of Thrones with my kids, I'm worried about spoilers, and I want to make sure that you're very clear on this before you go read this report.

What we did conclude is that FDA's financial management maturity is appropriate for the governance management, and the oversight of its Human Drug User Fee programs. We concluded that FDA is fully compliant with financial management requirements, and that they're within two percent -- it think David had one percent -- I think it's a timing thing -- of target revenue across all Human Drug User Fee programs, with no over-allocation of user fees, and that FDA is on a path to improve its policies, procedures, and processes, as well as its technology systems, to meet the increasing complexity within the Human Drug User Fee program.

So, I think -- that's the key takeaway from this, is that this is -- and it's a highly technical evaluation term, but this is a good news story overall.

We think that FDA, while they're fully compliant, and obviously, you see today they're moving forward trying to anticipate future problems and make their selves more efficient, more effective, we think that they are also well placed to take advantage of some opportunities that we identified as part of this process.

Here I'll focus on the opportunities, instead of going through all the key -- all the takeaways. We'll just look at the right side.

We found that FDA didn't really have a fully integrated User Fee Management Policy and Procedures framework, resulting in localized processes. The resulting variation of practices leads to a lack of standardization.

Bottomline is that we're recommending that the FDA have procedures and policies that goes soup to nuts, all the way throughout the whole organization, so that you have more standardization.

In addition, centers and offices rely on distributed tools and systems that require a manual reconciliation and validation, which can lead to process inefficiencies, and FDA is planning on extending the central system to the centers and offices.

Here it's good to note that -- I emphasize that we took a snapshot of 2018, and what you're looking at today is that this is a moving target. That while we looked at things as of 2018, FDA was continuing to improve in their system, and their processes, so that they're already addressing some of the concerns we identified.

And here we're talking about that there's a lot of centralized systems that provide the information that the FDA needs. We think that there's still a lot of manual activity, a significant amount of manual activity, at center level that could benefit from similar technology and the FDA is looking to address that.

Under administration of fee program resources, we found that further efficiency gains can be realized through center level automation, like electronic billing for PDUFA and BsUFA, use of automated workflow tools, and to streamline waiver and exemption process, and we noted that efforts are already underway to leverage existing FDA customer service technologies to streamline customer service and request processing for the three programs.

In terms of oversight and governance, we thought that FDA would benefit from the creation of high level strategic objectives that cut across all the user fee programs and describe the plans to achieve the negotiated individual program before those commitments.

This would help user fee oversight bodies align their investments to projects that achieve optimal long term outcomes and performances.

Technical capability is really looking at the staffing, and the capabilities of the staff that implement these programs. Here we found that, based on supervisors desired proficiency, the FDA and financial management staff should increase proficiency in decision support, problem solving, and analytical skills, and improve training in financial and related systems, and enhance organizational structure knowledge.

Under the fifth category, user fee estimating methodology, we thought that while the portfolio performed well in FY2018 overall, that FDA could improve the forecasting accuracy of individual fee units, based on federal best practices for predictive modeling.

We gave them some examples of that, and the research alternative methodologies, quality data, and policies with the help of stakeholders, and applied metholodgical approaches, to leverage industry inputs, external market data, and subject matter expert opinions.

In conclusion, what I'd like to thank FDA for all the cooperation. They asked for a very in-depth review, and this goes along the category of be careful what you ask for. We spent a year going through FDA's financial management activities and estimating methodologies. They made their staffs available on multiple occasions.

We had a lot of spirited conversations, and we had a lot of data requests that they constantly were willing to fulfill, and so, we just really appreciate all the cooperation. Thank you.

MR. TYLER: Well, good morning. We're going to keep moving along. I'm Jay Tyler, I'm the Chief Financial Officer here at FDA, and also the Head of the Office of Finance, Budget and Acquisitions.

So, this morning I want to talk to you about how FDA's going to address the findings from the Grant Thornton MITRE study. We appreciate the collaboration, as Jim said, very detailed approach to this, and we worked very close with MITRE, as well as the centers and offices, to identify all the areas that we need to address.

So, I'm going to go through this focus area by focus area; as Jim indicated, there were five focus areas.

So, starting with focus area one, Resource Planning Request and Allocation and User Fee Administration Process. I think the key take away here, for FDA, and what we're going to do to address this area, and next steps, if you will, and the action plan that we're going to put in place, we took to heart very much, through these discussion, these detailed discussions over the past year, that the level of knowledge, in terms of how we administer these user fees here at FDA, certainly varies.

The further that staff get away from, sort of, the day to day administration of these fee programs, the less knowledge, of course, that they have, and we know that that's a gap that we need to close.

There are many participants in these programs, and we want everyone to have a level playing field, in terms of their knowledge in how these programs are administered.

And so, one of the things that we're going to do, key things that we're going to do, with respect to focus area one, is make sure, as Jim indicated, that we have a soup to nuts policy and procedures framework. Today I call it a playbook; we may call it something else when we actually put this into play and in action.

But we will have a comprehensive set of policies and procedures that everyone in the Agency will follow.

The folks in my office, and in some of the more immediate sub-finance offices in the centers, understand these programs thoroughly. But we don't have a comprehensive set of policies and procedures that everyone references, down to the person in a center, if you will, that might interact once a month with one of the fee programs.

So, we want to make sure, again, that everyone's working from a level playing field.

We're also going to make sure that we have better leverage of existing tools and processes, that are available at the corporate offices. Meaning my office, the Office of the Commissioner.

We believe we have some state of the art tools, particularly, our Integrated Budget and Acquisition Planning System that is probably pretty unprecedented in the Federal Government. Meaning that we can do payroll forecasting, we can do acquisition planning, we county do budget formulation planning and justification. We produce our budget justification, click of a button; it's over 300 pages. And we, of course, can do budget execution monitoring out funds.

Now, we have these tools at the corporate level, but they haven't been deployed appropriately into the sub-centers and offices in FDA, and this study certainly pointed that out, and we're going to be making sure that we're able to leverage that tool across all of the centers and offices and be able to implement, what we call, child (ph) applications of our IBAP solution, Integrated Budget and Planning System.

So, that’s how we're going to address focus area one.

For focus area two, the finding here was that, again, the centers and offices should leverage our tools and systems better, and so I've -- with respect to how we're going to address focus area one, I've already, sort of, identified what we intend to do.

But we also want to broaden training opportunities. My office offers corporate level training in very financial management topics, anywhere from the appropriation laws, to how to track resources in our core financial system.

But we do need to develop a corporate level offering, with respect to how we manage our user fee programs here at FDA. And so, we're going to be making sure that that's offered, but that also we offer to our centers and offices more training on our existing tools and processes, our core financial system, which is a Oracle based federal financial management system, our user fee collection system, which is our accounts receivable system that interfaces with the public for fee paying, and of course industry, as well as the budgeting system that I mentioned.

So, training and access to tools, more general management training around our finances, as well as training on leveraging the tools and systems that we already have and putting those tools and systems in place more locally in the centers and offices, is how we're going to address focus area two.

For focus area three, oversight and governance; took this area or finding to heart as well. We've had a couple iterations of governance here, with respect to how we administer our user fee programs at FDA. We had a legacy User Fee Financial Council. That council proved to be effective for the time that it was in place, but during the tenure of that council, we noticed that the council was very much focused on the finances, and the financial management of our user fee programs, but sometimes there were gaps in the knowledge level of the members of that council, with respect to strategic policy direction and steering for our user fee programs.

So, we've reconstituted our user fee governance, and now it's been retitled the User Fee Financial Management Council, focused on the notion that this council is focused on the financial management of our user fee programs, that but that in order to fill the gap around a policy direction for our user fee programs, we need to leverage the top leadership of the Agency to get that guidance and direction.

And so, we are building a partnership with, what we call here, the Executive Committee, that consist of all of our center and officer directors, as well as the FDA Commissioner, to make sure that at least twice a year we engage with the Executive Committee on topics in areas that we should strategically be focusing on, in terms of the direction of our user fee programs, and making sure that there's alignment of how we allocate resources, user fee resources, to the strategic direction that is coming from the top leadership of the Agency.

So, for technical capabilities, the MITRE GT Team essentially found that for our staff they have the right skillsets, we're able to retain our financial management team, in general. We don't have a significant amount of attrition, but there is certainly opportunity to increase their knowledge and expertise around how we administer our fee programs, as well as their general financial management expertise.

So, we'll be building a greater collaboration, as I already indicated, with my office and with the budget and finance staffs in the centers here at FDA, to make sure that they enhance their skillsets. We'll be offering, as I've already indicated, more training from the central organization, as well as sharing our knowledge and offering more training around our tools and our processes and making sure that the existing corporate tools are put in place in all of the centers and offices.

Focus area five; I think Josh has already covered this a bit, but the essence of this here is that we do need to broaden our processes, our methodologies, for how we predict our fees, or revenue streams, with respect to the various human drug programs, and particularly with respect to our newer programs, and I think Josh and Andy have already indicated the volatility with BsUFA.

And so, our hope is that with the advanced predictive analytics that we'll be putting in place, under the initiative for Modernized Time Reporting and Resource Capacity Planning, that we will be able to look forward, forecast better, versus looking backward, in terms of being able to predict our fee revenue streams.

So, we're very excited about continuing along the path of Modernized Time Reporting, Resource Capacity Planning, and we think that we will be able to smooth out allowing the volatility that we're seeing in -- particularly with BsUFA, as well even further tightened what's already pretty close estimation for -- in terms of the fee streams, for

PDUFA and GDUFA.

So, that's the essence of how we're going to deal with the results from the User Fee Evaluation Study for our finances. We have not received any request for anyone to make any public comment, so we are way ahead of schedule and we're going to end the meeting.

We really thank you for your participation today. We remind you that the public docket is open until July 8th, so seeing as no comments are being made in this forum, you're certainly encouraged to provide any comments, as long as the docket is open.

So, again, thank you and we look forward to seeing you next year.

(Whereupon, at 10:18 a.m. the meeting was concluded.)

CERTIFICATE OF NOTARY PUBLIC

I, KeVon Congo, the officer before whom the foregoing proceedings were taken, do hereby certify that any witness(es) in the foregoing proceedings, prior to testifying, were duly sworn; that the proceedings were recorded by me and thereafter reduced to typewriting by a qualified transcriptionist; that said digital audio recording of said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

KeVon Congo
Notary Public in and for the
District of Columbia

CERTIFICATE OF TRANSCRIBER

I, Corinne Yanosy, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

Corinne Yanosy

d