CDER New Drugs Program: 2019 Update

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Deputy Director for Operations
Office of New Drugs, CDER/FDA

FDA/CMS Summit
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Data and analyses presented to reflect latest information, although usual QC for official FDA reports has not occurred. Presentation content should be considered preliminary.

Pay close attention to fiscal year (FY), academic year (AY) and cut-off dates on data presentations; denominators are important too!

Talented staff at FDA provide the data and analyses for this talk each year. Special thanks and acknowledgement to:

- Nader Qassim, Nancy Maizel, and Reza Kazemi-Tabriz in CDER’s Office of Program and Strategic Analysis
- Mike Lanthier in the Office of the Commissioner
Topics to be covered

- New drug review process efficiency: a historical look and ongoing changes in PDUFA VI
- New drug activity in 2019: approvals, workload, international comparisons, and profiling the 2019 class of NMEs/BLAs
- Development phase activity: IND workload, the breakthrough program, meeting workload and continued changes in PDUFA VI
- A look ahead to 2020: New Drugs Regulatory Program Modernization efforts
CDER New Molecular Entity Approval Rates by PDUFA Cohort

Projection estimates account for actions to date and elapsed time to date for non-approvals

Data as of 9/30/19
New Drug Activity in 2019

- In FY 2019*, CDER has approved 45 NMEs, including 23 orphan drugs
  - 32 Priority Reviewed NME approvals
  - Roughly half of the NMEs approved are orphan drugs to treat rare diseases
    - More than half of the orphans (12 of 23) are for cancer/cancer imaging
    - 4 for neuropsychiatric drugs for: LEMS, polyneuropathy of hereditary transthyretin-mediated amyloidosis, and two for excessive daytime sleepiness (EDS) in adult patients with narcolepsy
    - 3 orphans are for inherited genetic conditions: polyneuropathy of hereditary transthyretin-mediated amyloidosis, primary hemophagocytic lymphohistiocytosis (HLH), Adenosine Deaminase-Severe Combined Immunodeficiency (ADA-SCID)
- 2019 has a unique blend of therapeutic areas
- U.S. continues to lead the world in first approval of NMEs
- Several Notable Approvals, including:
  - Trikafta
  - Recarbrio and Fetroja
  - Spravato
  - Scenesse

* This information is accurate as of September 30th, 2019. In rare instances, it may be necessary for FDA to change a drug's new molecular entity (NME) designation or the status of its application as a new biologics license application (BLA). This note applies to all references to NME/Original BLAs in this presentation.
Notable Approvals: Not Only Quantity but Quality for 2019

- **Trikafta** - the first triple combination therapy to treat patients with Cystic Fibrosis (CF) who have the most common form of the CF gene mutation, which is estimated to represent 90 percent of the cystic fibrosis population for some patients with CF, but many patients have mutations that are ineligible for treatment.

- **Recarbrio and Fetroja** - two new antibiotics effective against certain Gram-negative infections --- important advances because Gram-negative bacteria represent a growing danger of serious and potentially life-threatening infections.

- **Spravato** - closely related chemically to the drug ketamine, originally approved in 1970 under the trade name Ketalar as an injectable anesthetic for certain diagnostic and surgical procedures. Esketamine was approved in 2019 as a nasal spray, to be used in conjunction with an oral antidepressant, for the treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression).

- **Scenesse** - to increase pain-free light exposure in patients with phototoxic reactions (sensitivity to sunlight) due to erythropoietic protoporphyria, a rare condition resulting from excess accumulation of a chemical that normally helps red blood cells deliver oxygen to the body.
† Multiple applications pertaining to a single new molecular/biologic entity are only counted once. Original BLAs that do not contain a new active ingredient are excluded.

* This information is accurate as of September 30th, 2019. In rare instances, it may be necessary for FDA to change a drug’s new molecular entity (NME) designation or the status of its application as a new biologics license application (BLA). This note applies to all references to NME/Original BLAs in this presentation.

Since applications are received and filed throughout a calendar year, the filed applications in a given calendar year do not necessarily correspond to an approval in the same calendar year. Certain applications are within their 60-day filing review period and may not be filed upon completion of the review.
NME Actions and Approvals by FY

*Data as of 9/30/2019

Includes discrete actions on a given date for an active ingredient which, if approved, would constitute a new molecular entity. Actions for original submissions and resubmissions as well as actions for new BLAs are included. Multiple actions which occur on the same date for multiple dosage forms or indications are counted as a single regulatory action.
NME FILINGS BY FISCAL YEAR AND THERAPEUTIC AREA

- Oncology
  - FY 2005-2009: 28
  - FY 2010-2014: 44
  - FY 2015-2019: 63

- Infectious Disease
  - FY 2005-2009: 22
  - FY 2010-2014: 24
  - FY 2015-2019: 35

- Neurology
  - FY 2005-2009: 11
  - FY 2010-2014: 9
  - FY 2015-2019: 32

- Metabolism and Endocrinology
  - FY 2005-2009: 20
  - FY 2010-2014: 21
  - FY 2015-2019: 18

- Hematology
  - FY 2005-2009: 8
  - FY 2010-2014: 7
  - FY 2015-2019: 15

- All Others
  - FY 2005-2009: 81
  - FY 2010-2014: 69
  - FY 2015-2019: 87

* Data as of 9/30/2019
**CDER NME NDAs/BLAs**

**First Action Approval Rate by FY**

* There are 3 Pending FY 18 applications as of 9/30/19

† Multiple applications pertaining to a single new molecular/biologic entity (e.g., single ingredient and combinations) are only counted once. Therefore, the numbers represented here for filings are not indicative of workload in the PDUFA V Program. Original BLAs that do not contain a new active ingredient are excluded.
CDER Orphan Drug Approvals by FY

* Data as of 9/30/2019
USA Share of New Active Substances Launched on World Market Remains High

Data as of 9/30/2019

## Snapshot of FY 2019
### NME NDAs/BLAs† Drug Approvals (1/2)

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<tr>
<th>Trade Name</th>
<th>Met PDUFA Goal Date*</th>
<th>Approved on First Cycle</th>
<th>First in Class</th>
<th>Approved First in the U.S.</th>
<th>Breakthrough Therapy</th>
<th>Priority Approval</th>
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Data as of 9/30/2019

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* A PDUFA Goal Date is marked as met if the NME is acted upon within its approval cycle due date.
## Snapshot of FY 2019
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Data as of 9/30/2019

† Multiple submissions pertaining to a single new molecular/biologic entity (e.g., single ingredient and combinations) are only counted once. Therefore, the numbers are not indicative of workload in the PDUFA V Program. Original BLAs that do not contain a new active ingredient are excluded.

* A PDUFA Goal Date is marked as met if the NME is acted upon within its approval cycle due date.
In FY 2019, CDER Continued To Ensure The Efficiency Of First Cycle Review

- All of the (100%) NMEs/BLAs approved in FY 2019 met their PDUFA goal dates

- All but three (93%) of the drugs approved in FY 2019 were approved in the first review cycle
Utilization of Expedited Development and Review Programs Remained High in 2019

- Almost three-quarters (71%) of the drugs approved in FY 2019 were approved under Priority Review.
- About one out of four (24%) of the drugs approved in FY 2019 received Breakthrough Therapy designation.
- About three out of ten (31%) of the drugs approved in FY 2019 received Fast Track designation.
2019 Continues A Strong Track Record For Drug Innovation

- Just over half (51%) of the drugs approved in FY 2019 are orphan drugs
- Four out of ten (40%) of the drugs approved in FY 2019 are the first in their class
- Almost two-thirds (64%) of the drugs approved in FY 2019 were first approved in the U.S.
Snapshot of FY 2020
NME NDAs/BLAs† Drug Approvals

13
NME Approvals
To date in FY 2020

7
Priority

6
Orphan

4
Breakthrough

4
Fast Track

Data as of 11/21/2019
† Multiple submissions pertaining to a single new molecular/biologic entity (e.g., single ingredient and combinations) are only counted once. Therefore, the numbers are not indicative of workload in the PDUFA V Program. Original BLAs that do not contain a new active ingredient are excluded.
Development Phase Work Continued to Grow in 2019

Data are from the PDUFA Workload Adjuster and represent an Academic Year (12 month period of July 1st - June 30th)
CDER Breakthrough Therapy Requests by Division

Oncology, Hematology, and Neurology account for over 50% of Breakthrough Requests.

Some notable conditions for FY 19 include:

- Ebola Virus Disease
- Fragile X Syndrome (Cannabidiol)
- Chronic Hepatitis D

793 Requests since BT Program Inception in July 2012

Data as of 9/30/2019
CDER Breakthrough Therapy Grants by Division

Of 793 BT Requests CDER issues a BT Grant about 38% of the time.

Oncology, Hematology, and Antiviral account for the majority of Breakthrough Grants.

Data as of 9/30/2019
CDER Breakthrough Therapy Approvals by FY

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* Data as of 9/30/2019
CDER Active Breakthrough Development Programs

* Data as of 9/30/19. Figures includes total # of granted breakthrough designations for drug/indications under active IND development but have not yet received marketing approval or rescission decision.
Data as of 9/30/2019
BLAs were transferred to CDER in FY2004
*2019 Data is preliminary
CDER Denied Meeting Requests By FY

Data as of 9/30/2019
# New Drugs Regulatory Program Modernization

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Guiding principles for modernizing the new drugs regulatory program</th>
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| **Scientific Leadership** | **We will grow our scientific expertise and clarify pathways to regulatory approval.**  
- Expanding the armamentarium to address unmet medical needs is an important part of our public health mission.  
- Towards that end, we will proactively collaborate with academic medical scientists and patient/disease advocates, evaluate scientific gaps, and strategically foster drug development. |
| **Integrated Assessment** | **We will critically, collaboratively and consistently assess whether information in submissions meets statutory and regulatory requirements.**  
- We will take a new approach to document our assessments, developing a more integrated, cross-disciplinary document to foster collaboration and reduce redundant information.  
- Our assessments will be rigorous, risk-based, and clinically relevant; focus on the key issues; and incorporate the patient perspective. |
| **Benefit-Risk Monitoring** | **We will establish a unified post-market safety surveillance framework.**  
- To effectively protect the American public, we will systematically monitor the benefits and risks of approved drugs across their lifecycles. |
| **Managing Talent** | **We will attract, develop, and retain outstanding people.**  
- We will use 21st Century Cures Act authorities to recruit and retain technical, scientific and professional experts, and eliminate our backlog of vacant positions. |
| **Operational Excellence** | **We will have a dedicated focus on operational excellence.**  
- We will enhance our ability to address OND’s large volume workload through greater process standardization and better defined roles and responsibilities.  
- This will improve operational efficiency and enable our scientists to focus on science, not ancillary tasks. |
| **Knowledge Management** | **We will facilitate knowledge management.**  
- Vast and diverse information is submitted to and generated by the New Drugs Regulatory Program.  
- We will make it easy for our staff to find and use scientific and regulatory precedents.  
- This will reduce manual work time, increase the speed and efficiency of submission assessment, and increase the consistency and predictability of regulatory decision-making. |
### The New Drugs Regulatory Program has 6 active initiatives

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<tr>
<th>Initiative</th>
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<td>Integrated Review for Marketing Applications</td>
<td>Developing a streamlined interdisciplinary review process and template to support the new integrated review for assessing NDA/BLAs</td>
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<tr>
<td>IND Review Management</td>
<td>Streamlining the IND scientific review processes for managing IND applications, beginning with 30-Day Safety Reviews and Protocols</td>
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<tr>
<td>Post-Market Safety Management</td>
<td>Creating a standardized, consistent, and effective approach to post-market drug safety</td>
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<td>Assessing Talent</td>
<td>Developing an effective and consistent process for hiring, onboarding, developing and evaluating new Clinical and Pharm/Tox reviewers</td>
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<tr>
<td>Reorganization and Transition Management</td>
<td>Planning, coordinating, and implementing modernization and organization changes at the future Office and Division levels across the New Drugs Program</td>
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<tr>
<td>Administrative Operations</td>
<td>Optimize administrative and clerical staff roles, structure, and functions to enhance customer focus and employee engagement</td>
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Re-org will therapeutically align offices and divisions to support scientific exchange and improve consistency across OND

Approved

OND Immediate Office

OND Director

Deputy Director (Clinical)

Pharm/Tox ADs

Office of Drug Evaluation Sciences

Clinical Outcomes Assessment

Biomedical Informatics, Biomarker Qualification and Research

Clinical offices (x8)

Therapeutically aligned to support scientific exchange

Clinical offices (x8)

Office of New Drug Policy

Clinical Policy Division

Regulatory Policy Division

Office of Program Operations

Executive Operations Staff

Business Process Operations Staff

Program Development, Implementation and Mgmt Staff

Learning and Talent Development Staff

Office of Admin. Operations

Financial Services Staff

Admin. Analysis Staff

Admin. Operations Staff (x5)

Office of Regulatory Operations

Divisions of Regulatory Operations (x8)

Ensures "unit" size optimizes leaders ability for detailed supervision and involvement in regulatory work, as well as external development

1 Regulatory Operations Divisions align to each clinical office

Details to follow
1 ONPD P/T staff in the ONPD IO given the small current size of P/T staff. P/T staff will grow into a division from OMUFA;
2 Single P/T division with staff supporting both ORPURM and OSM; PT DD will have dotted line reporting to ORPURM and OSM for P/T issues, and solid line to ORPURM Office Director for PMAP, etc.
Integrated Review of Marketing Applications

- Effort attempts to design a streamlined issue-based integrated review process and template that reduces silo reviews, by
  - Creating **a template and a process** that are issue-based, foster interdisciplinary collaboration, reduce redundancy and low-value work, and enable better knowledge management
  - Developing a **tracking tool** to be utilized from pre-NDA through end of review cycle, allowing for systematic tracking of review issues for the entire review team
  - Adding **new roles** to allow reviewers to focus on the science and regulatory aspects of the application: (1) Clinical Data Scientists to support safety analysis and (2) Medical Editors to provide editing and formatting services
  - Incorporating **purposeful scoping working meetings** with early involvement of leadership to discuss known benefit and risk issues; and **joint assessment meetings** focused on specific review issues

Currently in Phased Implementation. All divisions to begin using the new process and template in 2020.
IND Review Management

- Effort attempts to address variable practices across divisions and reduce redundant documentation practices
- Creating templates that are issue-based, foster interdisciplinary collaboration, reduce redundancy and low-value work, and enable better knowledge management
- Establishing procedures that standardize the review process, clearly define roles and responsibilities and improve our ability to provide high-quality feedback to sponsors in a timely manner
- Developing a risk based approach to categorize incoming protocols and amendments and identify the protocols that should follow a higher priority process to review more expeditiously

Currently in Phased Implementation. All divisions to begin using the new process and template in 2020.
Post-Market Safety Management

Create a standardized post-market drug safety framework that will include:

▪ Cross-disciplinary, collaborative, science-focused assessments
▪ Clear roles, responsibilities, and governance
▪ IT-enabled processes to enhance knowledge management and fit-for-purpose analytic tools to promote optimal evaluations
▪ Policies and processes (i.e., via SOPs, charters, templates) that support this framework

Anticipate beginning implementation in 2020