AMCP Webinar

Enabling the Exchange of Clinical and Economic Data Pre-FDA Approval

December 15, 2016

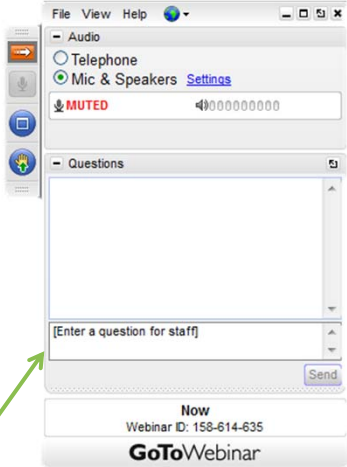AM CP | Academy of Managed Care Pharmacy®

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How to Ask a Question

Type your question in the 'Questions' area

Today's Speakers

Mary Jo Carden, RPh, JD
Vice President, Government and Pharmacy Affairs
Academy of Managed Care Pharmacy

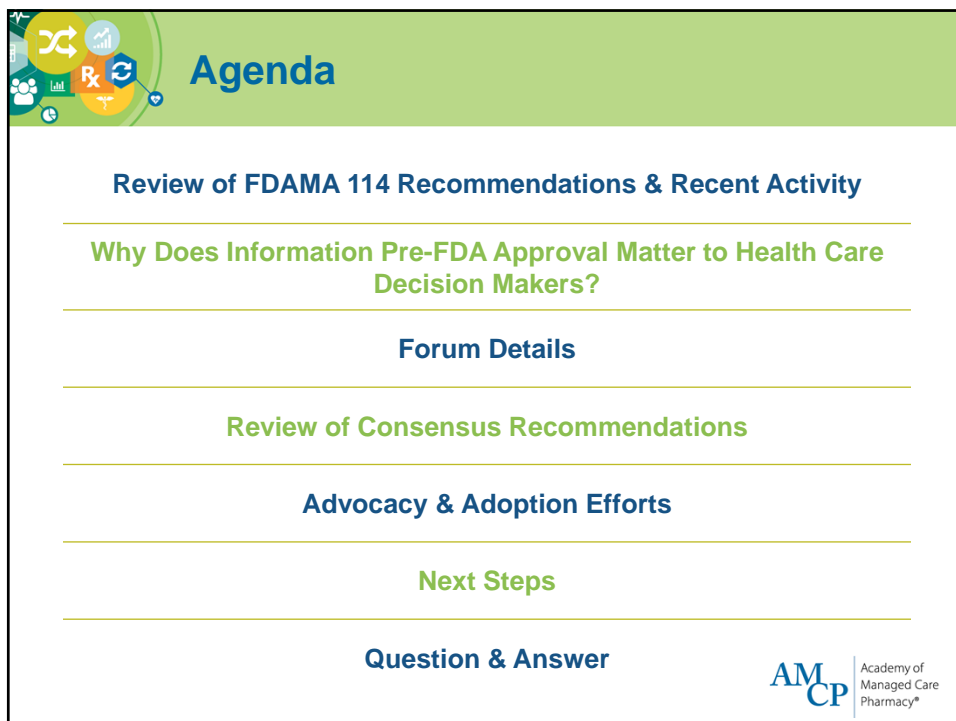**Amy Duhig, PhD**
Senior Director, Outcomes Research Team
Xcenda

Enabling the Exchange of Clinical and Economic Data Pre-FDA Approval

AN AMCP PARTNERSHIP FORUM

SEPTEMBER 13–14, 2016
TYSONS CORNER, VA

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Agenda

Review of FDAMA 114 Recommendations & Recent Activity

Why Does Information Pre-FDA Approval Matter to Health Care Decision Makers?
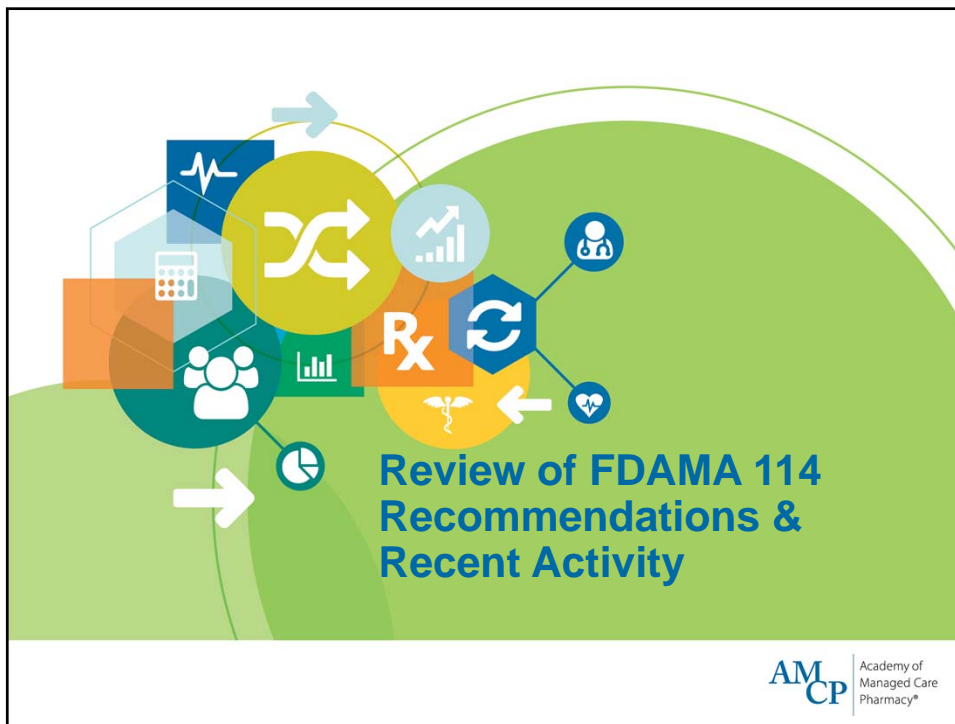
Forum Details

Review of Consensus Recommendations
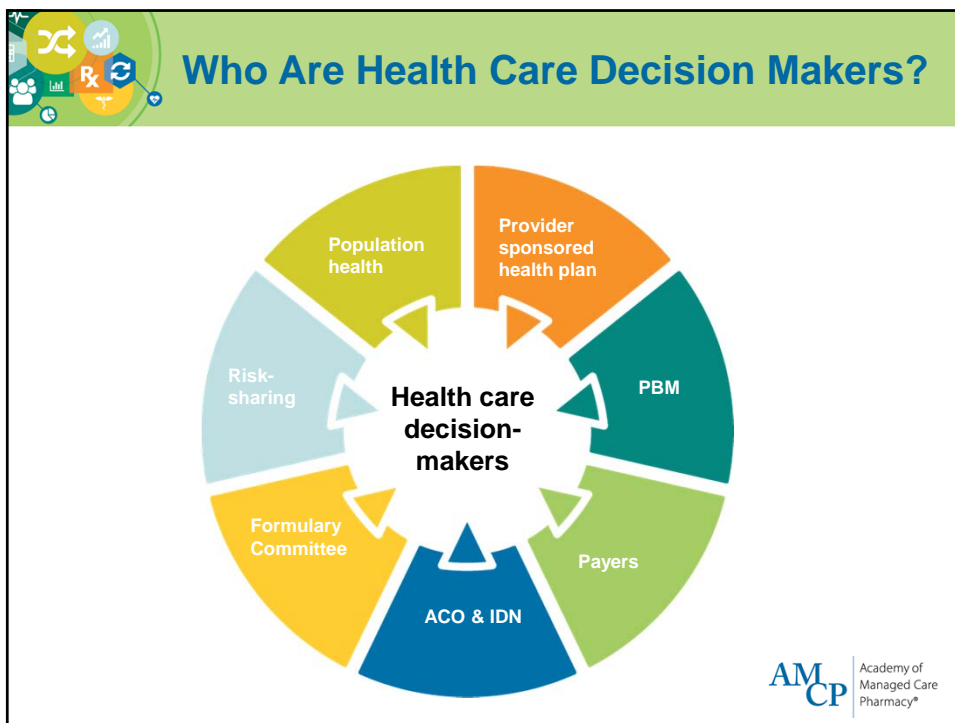
Advocacy & Adoption Efforts

Next Steps

Question & Answer

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Review of FDAMA 114 Recommendations & Recent Activity

Who Are Health Care Decision Makers?

Health care decision-makers

- Population health
- Provider sponsored health plan
- PBM
- Payers
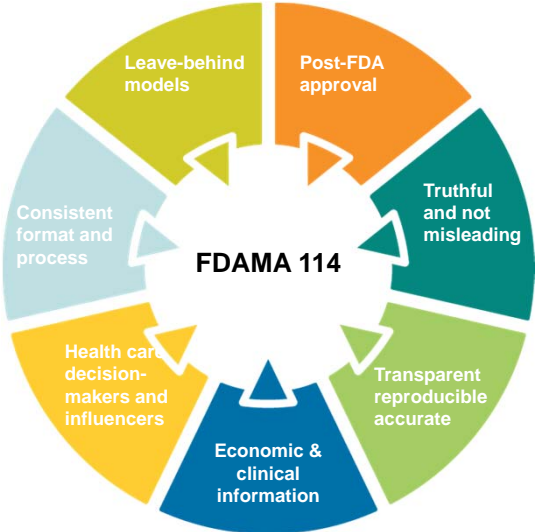- ACO & IDN
- Formulary Committee
- Risk-sharing

Why Does This Matter to Health Care Decision Makers?

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Review of FDAMA 114 Recommendations

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21st Century Cures (Pub. L. 114-255) Includes FDAMA Sect. 114 Revisions

- Legislation approved by the House & Senate
  - Sent to President on December 8, 2016 and signed into law on December 13, 2016
  - Section 3037. Health Care Economic Information includes revisions to FDAMA Sect. 114
    - Provisions identical to those that passed the House in July 2015

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Summary: 21st Century Cures Law FDAMA Sect. 114 Revisions

- *Updates definition* of "formulary committee" by defining it as "a payor, formulary committee or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs or reimbursement

- *Strikes* "directly relates" and inserts "relates"

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Summary: 21st Century Cures Law FDAMA Sect. 114 Revisions

- *Strikes* "and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph"

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Summary: 21st Century Cures Law FDAMA Sect. 114 Revisions

- *Inserts*: "is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 505 or under section 351 of the Public Health Service Act...." and,
- *Defines* the term 'health care economic information" as
  – An analysis (including clinical data, inputs, clinical or other assumptions, methods, results and other components underlying or comprising the analysis)
  – That identifies, measures, or describes the economic consequences that may be based on separate or aggregated clinical consequences of the represented outcome, of the use of the drug

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Summary: 21st Century Cures Law FDAMA Sect. 114 Revisions
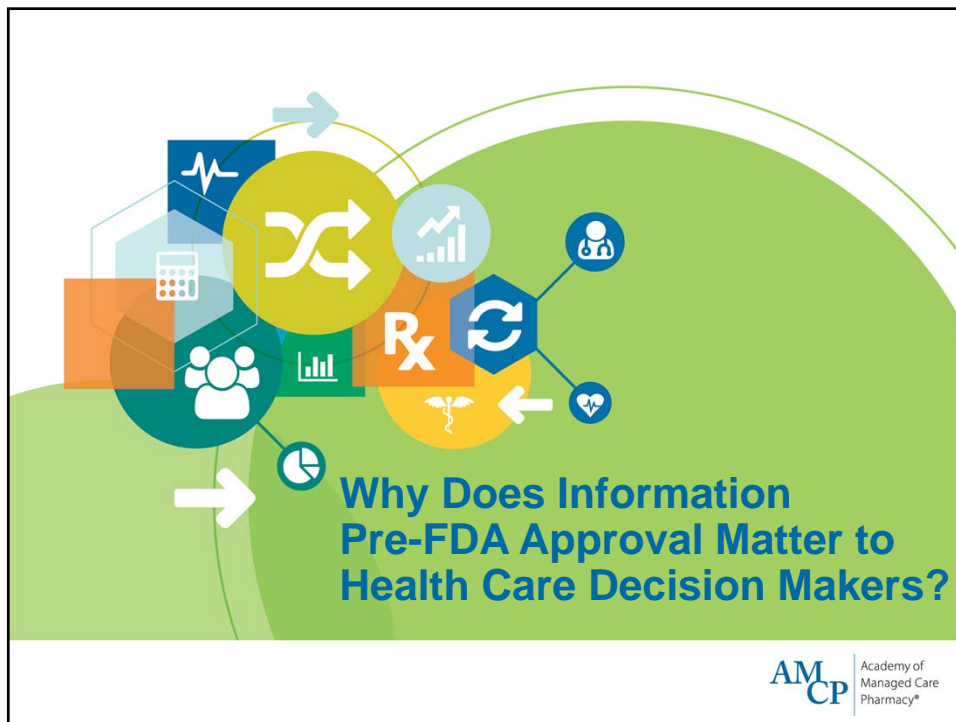
- *Includes* analysis comparing the use of another drug to another health care intervention or to no intervention
- *Does NOT include* any analysis that relates only to an indication that is not approved under section 505 or 351 of the Public Health Service Act

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AMCP Activity and Next Steps FDAMA Sect. 114 Revisions
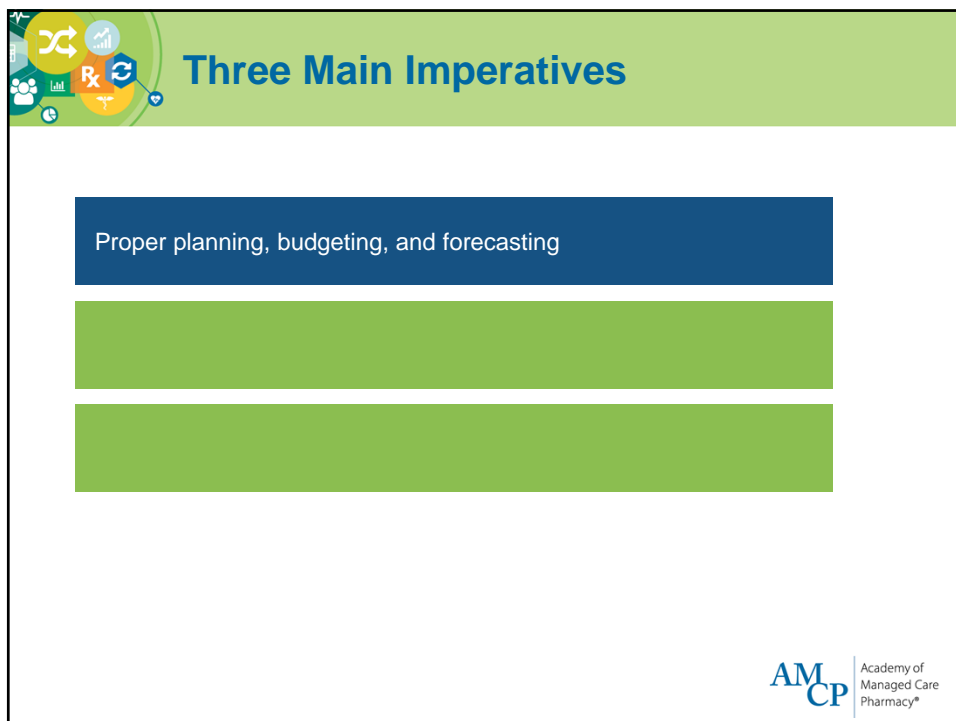
- AMCP Activity on 21st Century Cures
  - 11/29: sent letter supporting revisions to House and seeks issuance of FDA guidance
    http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=21655

- Next steps on the "FDAMA Communications"
  - Work to support release of FDA guidance document including recommendations from FDAMA Partnership Forum

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Why Does Information Pre-FDA Approval Matter to Health Care Decision Makers?

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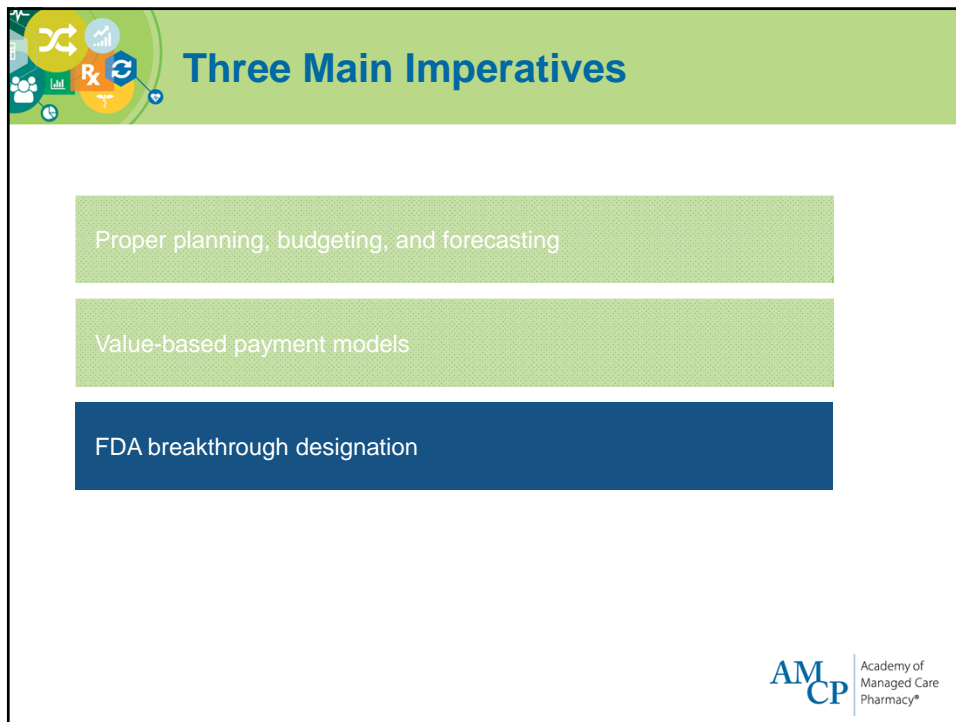
Three Main Imperatives

Proper planning, budgeting, and forecasting

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Health Insurance Rate Filing and Approval Process[1]

1. Eli Lilly and Company and Anthem. Facilitating Open Communication About Emerging Therapies. January 29, 2016. (pg 6-9) https://lillypad.lilly.com/WP/wp content/uploads/LillyAnthemWP2.pdf

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Proper planning, budgeting, and forecasting

Value-based payment models

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FDA breakthrough designation

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Forum Details

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AMCP Partnership Forum

Objective: To convene a Partnership Forum for stakeholders to define AMCP's role in meeting the needs of managed care pharmacy with respect to dissemination of health care economic information (HCEI) pre-approval

Key Stakeholders: Pharmaceutical industry, managed care industry, health care providers, pharmacoeconomic experts, health policy experts, and patient advocates

Date: September 13-14, 2016 in Tysons Corner, VA

Moderator: Susan Dentzer, President & CEO of NEHI

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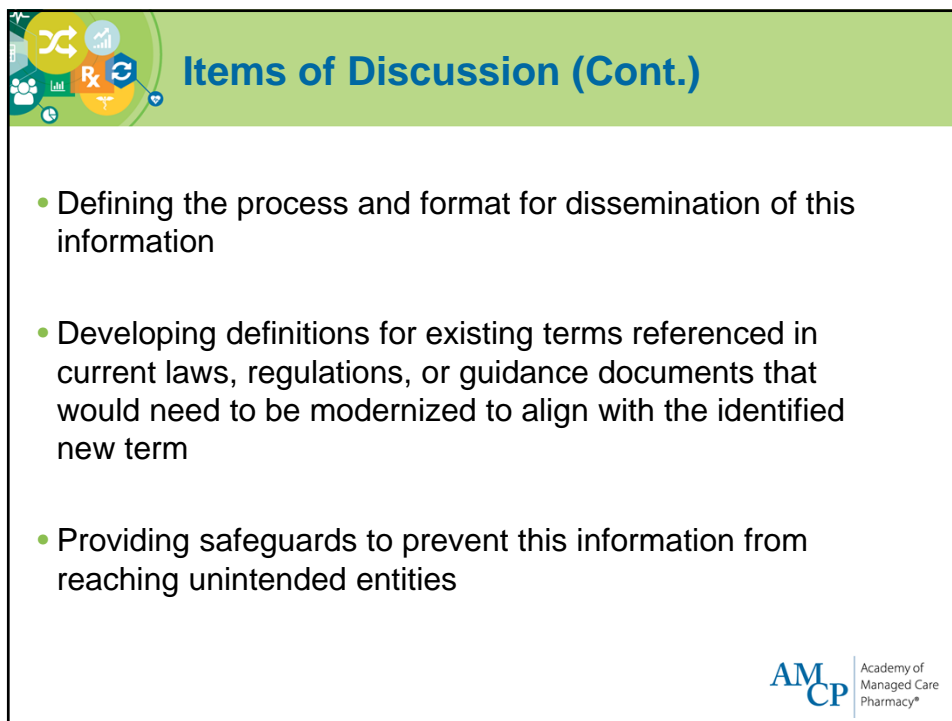
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Items of Discussion

- Creating and defining new terms for how biopharmaceutical manufacturers may provide both clinical and economic information 12-18 months prior to FDA approval

- Defining clinical and scientific standards that this information should meet

- Determining which entities should have access to this information and the value to each

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Items of Discussion (Cont.)

- Defining the process and format for dissemination of this information

- Developing definitions for existing terms referenced in current laws, regulations, or guidance documents that would need to be modernized to align with the identified new term

- Providing safeguards to prevent this information from reaching unintended entities

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Consensus Recommendations

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Consensus Recommendations

Wheel diagram with "PIE" at center surrounded by: Information, not evidence; Pre-FDA approval; 12-18 months in advance; Bidirectional; Health care decision-makers only; New molecules and expanded indications.

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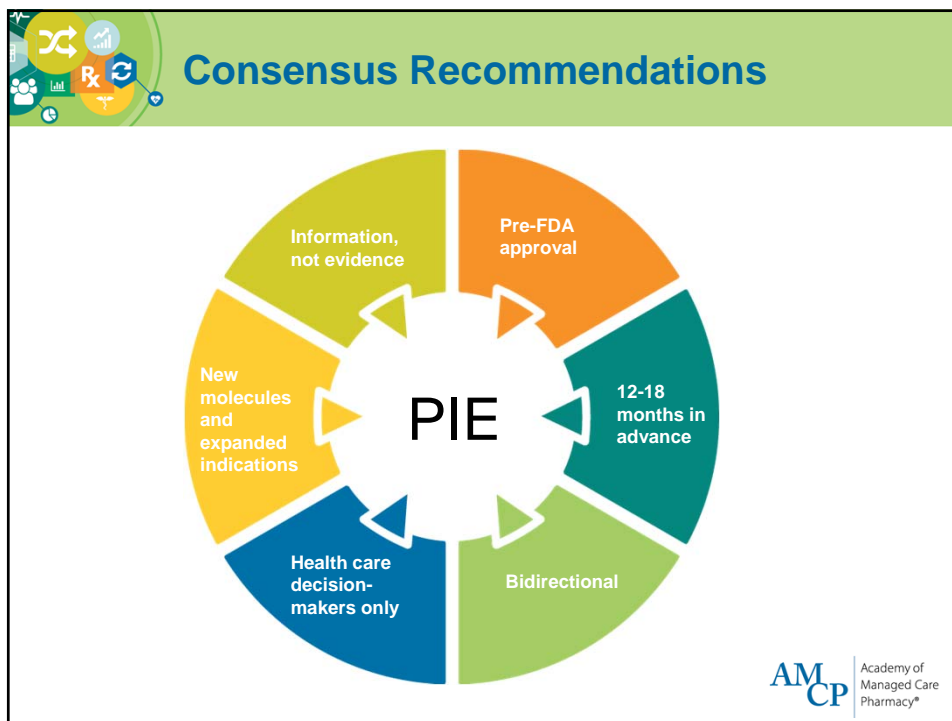
Entities and Individuals Who Should Receive Preapproval Information

- Population health decision makers such as managed care organizations (MCO), pharmacy benefit managers (PBM), integrated delivery networks (IDN), and accountable care organizations (ACO) would be eligible to receive preapproval information

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Preferred Format and Process for Receiving Preapproval Information

- Central repository vs. repositories for each manufacturer

- Standardized format vs. flexible format

- Communication and notification

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AMCP Surveys on FDAMA 114

- Objective: To understand payer and manufacturer experiences, attitudes, and perceptions of FDAMA 114

Payer (31 questions)	Manufacturer (23 questions)
• Use and importance of HCEI in formulary decision-making	• Processes for, and consistency of, approval of FDAMA 114 materials
• Unmet need for HCEI	• Types of HCEI approved
• Delivery, variation, and utility of HCEI from manufacturers	• Internal and external FDAMA 114 stakeholders
• Limitations of legislation and impact of AMCP-proposed changes	• Limitations of legislation and impact of AMCP-proposed changes
Responses: 58	**Responses: 73**

Xcenda AmerisourceBergen

http://tinyurl.com/gtv7nq3

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Advocacy & Adoption Efforts

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Adoption & Advocacy Efforts

- Congressional Staff Briefings - October 19, 2016

- FDA Hearing - November 9-10, 2016 (live meeting)
  - April 10, 2017 (docket closes for written comments, joint letter)
    - Changed from January 9, 2017

- Publication in JMCP – January 2017

- Continue work with FDA and other stakeholders regarding guidance on FDAMA Section 114 revisions

- Work with stakeholders to adopt legislative or regulatory provisions for PIE in 2017

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Questions?

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How to Ask a Question

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Contact Information

For more information, please contact:

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