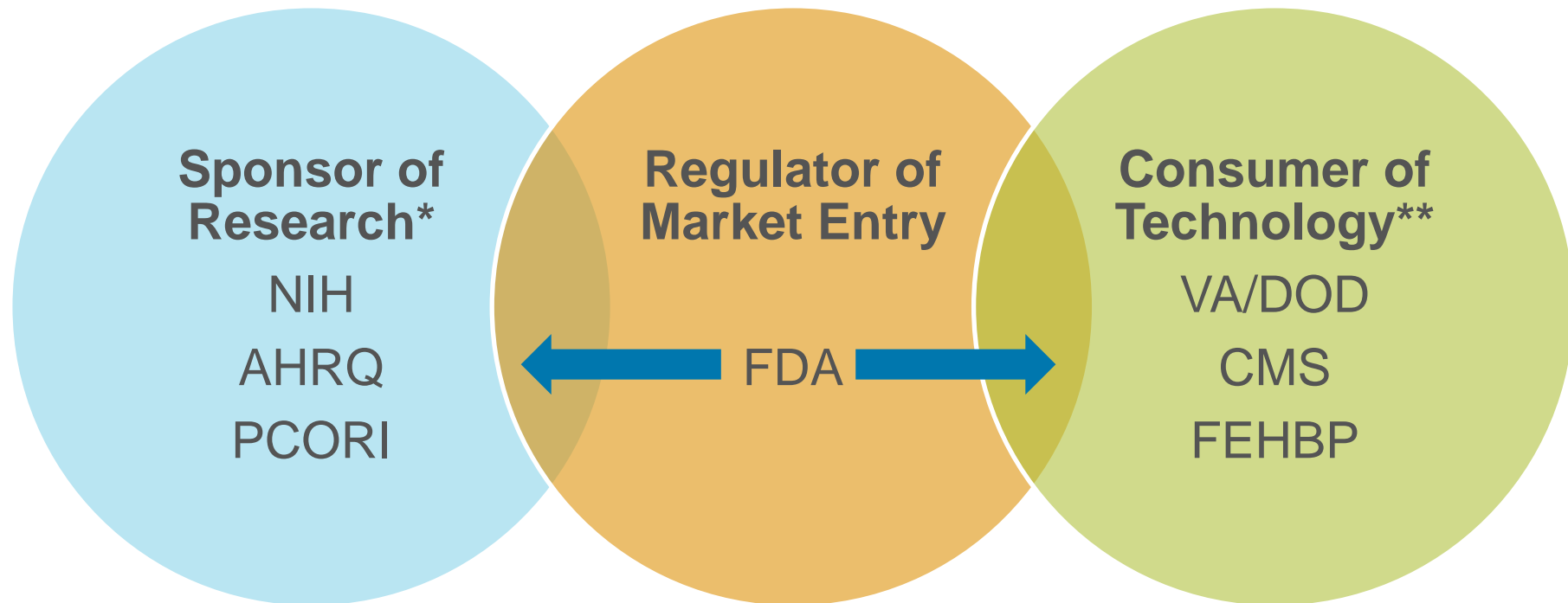




FDA Policy Forecast 2012

January 2012
Avalere Health LLC

FDA's Role Is Evolving Beyond Its Traditional Product Regulatory Function



FDA's role in the health policy and regulatory landscape is evolving to include additional and deeper collaborations with other federal agencies and the broader policy community, presenting potential engagement opportunities beyond traditional regulatory discussions

* Non-federal research sponsors such as academic institutions, CERTs, Critical Path Institute and Reagan-Udall also collaborate significantly with the FDA.

** Graphic reflects federal government consumers; managed care is also a significant consumer of technology and data.

FDA Strategic Priorities Demonstrate the Agency's Attempt to Engage More in Public Health Endeavors

Cross-Cutting Strategic Priorities:

Advance
Regulatory
Science and
Innovation

Strengthen the
Safety and
Integrity of the
Global Supply
Chain

Strengthen the
Compliance and
Enforcement
Activities to
Support Public
Health

Expand Efforts to
Meet the Needs
of Special
Populations

Advance Medical
Counter-
measures

Strategic Goals and Long Term Objectives:

Advance Food
Safety and
Nutrition

Promote Public
Health by
Advancing the
Safety and
Effectiveness of
Medical Products

Establish an
Effective Tobacco
Regulation,
Prevention, and
Control Program

Manage for
Organizational
Excellence and
Accountability

The priorities demonstrate FDA's desire to be a more engaged stakeholder and develop innovative processes to support scientific developments

FDA User Fee Negotiations Will Affect FDA's Agenda for 2012 and Beyond

Congress Will Legislate Independently-Negotiated User Fee Programs

Devices

**Originator Drugs
& Biologics**

Generics

Biosimilars*

- Common themes may overlap/blur the programs, including review transparency and standard risk/benefit profiles
- In addition, several issues may come under debate as add-ons to User Fee programs:

Drug Shortages: Requirements around notification, potential incentive realignment

510(k): Process to approve devices of “substantial equivalence” being reformed

Diagnostics: Significant diagnostics legislation is pending

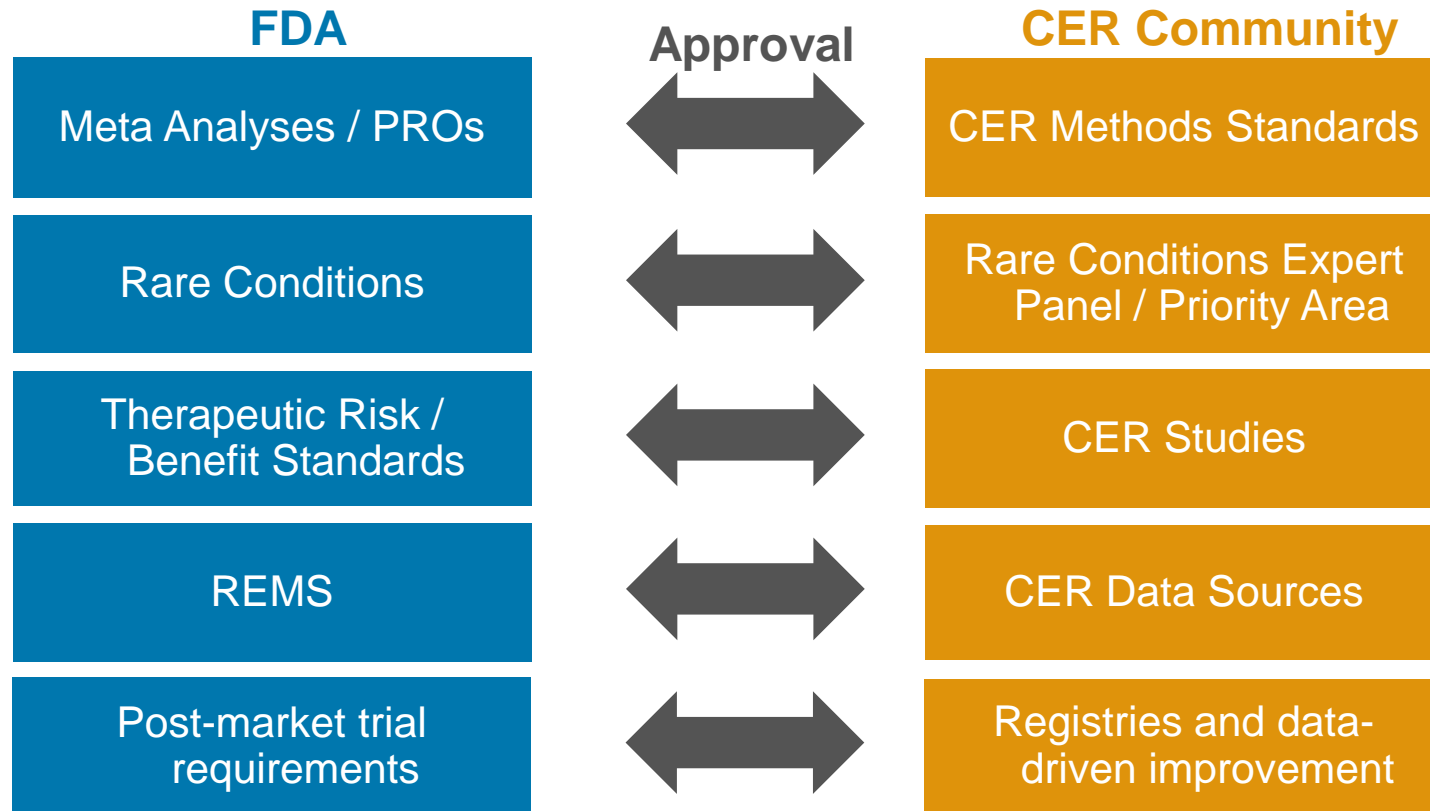
Progressive Approval: Streamlining review pathway for unmet medical need

Post-market data resources: Focus on standardization of requirements e.g., REMS

* FDA has standing authority for Biosimilars User Fees; draft agreement released December 2011.

REMS = Risk Evaluation and Mitigation Strategies

As Proposed, PDUFA V Would Define Evidence Standards and Solidify the FDA's Role Post-Approval



FDA's ongoing initiatives in pre- and post-market data collection may affect evidentiary standards, trial design, and time to market. Alignment with the CER community may be necessary to meet payer demand and industry ability to communicate "real-world" benefit

Forthcoming FDA Policy Regulation/Guidance Present Several Opportunities and Risks for the Healthcare Industry in 2012

Emerging

Impending

Regulation of HIT

FDA proposing to expand oversight over a broader range of medical software products

Draft guidance on regulating mobile applications intended for use as a medical device would classify based on potential risk and regulate through the 510(k) process

Solicited public feedback on a regulatory framework for standalone clinical decision support (CDS) software

Personalized Medicine

Guidance forthcoming on co-development opportunities for drugs/biologics with a companion diagnostic

Recognized need to optimize evidence development and engage public on study methodology for diagnostics

Payers recognize biomarker value in targeting therapies, but difficulties in development, validation, regulatory, and commercialization processes hinder their true acceptance as predictive tools

Biosimilars

Many details about the pathway and review/approval requirements left to the FDA discretion, guidance forthcoming

Payers need to determine approaches to coverage, coding, formulary management, and payment

Uncertainties remain on pricing and marketing practices for biosimilars and reference manufacturers

FDA's Evolving Policy Role Will Affect Market Access for Medical Technologies, Necessitating Strategic Refinement

FDA Regulatory Strategy

- Pre-clinical/clinical trial design
- Regulatory applications
- Evidence submission and evaluation

Approval

Novel FDA Policy Initiatives

- Investment in CER infrastructure
- Post-market data collection & surveillance
- Evidence standards harmonization
- Regulation of communication
- CMS/FDA parallel review

Ongoing Inputs

