

PROMOTING EFFECTIVE DRUG
DEVELOPMENT PROGRAMS:
OPPORTUNITIES AND
PRIORITIES FOR FDA'S OFFICE
OF NEW DRUGS

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PURPOSE

The purpose of the meeting is to solicit specific, actionable policy suggestions for the review staff of the FDA's Center for Drug Evaluation and Research, Office of New Drugs regarding opportunities to promote effective drug development while maintaining the FDA's regulatory standards for the assessment of safety and effectiveness of new drug products. Of interest are efforts that could be implemented in the near-term and that cut across multiple therapeutic areas.

ENTHUSIASM IS COMMON, BUT COMMITMENT IS RARE

- Per the FDA, “Modernizing our operations helps us perform our mission effectively in an environment of rapidly evolving science, changing stakeholder expectations, and new statutory authorities and responsibilities.”

BUT THE STATUS QUO IS A HARSH MISTRESS

- What senior agency management says publicly about the value and urgency of regulatory innovation has yet to permeate through its review divisions
- This disconnect is causing a lack of faith within the broader healthcare ecosystem that FDA can be a potent ally in advancing patient access to new and important medical technologies
- There must also be a similar review of the disconnect between the pronouncements from the upper echelons of the biopharmaceutical industry and the actual research and development programs undertaken by their companies

INCREASING REGULATORY VELOCITY: THE OFFICE OF NEW DRUG POLICY

- The 21st Century FDA requires greater regulatory certitude (i.e., that similar situations are treated in similar ways across divisions)
- This is as much a scientific issue as it is one of social and cultural alignment across therapeutic review divisions
- This new policy function can help enhance the knowledge and comfort of reviewers so that new initiatives (use of real world evidence, basket trials, adaptive clinical trials, master protocols, synthetic trials, etc.) are more regularly accepted as part of the FDA review process
- This means nothing less than accelerating an OND-wide review of the current and dangerous stasis of the regulatory status quo

INCREASING REGULATORY VELOCITY: THE OFFICE OF NEW DRUG POLICY

- The most potent way that FDA can enable innovation is by being a partner in advancing new approaches to both drug development and regulatory science and this begins at the conceptual policy level
- Regulatory ambiguity doesn't instill confidence in an already high-risk developmental environment
- The OND policy shop must provide closer coordination between senior agency leadership views on advances in regulatory science and those of divisional line reviewers

“REGULATORY VELOCITY” MEANS GENERATING LIGHT RATHER THAN HEAT

- The intent is to provide greater consistency and nimbleness regarding, the appropriate use of new tools and techniques for drug development
- This is as much a scientific issue as it is one of social and cultural calibration across therapeutic review divisions.
 - Sometimes even brilliant scientists have a hard time viewing new ideas without being threatened by them
- FDA must be a leader in regulatory science -- the science of developing new tools, standards, and approaches to assess safety, efficacy, quality and performance -- through true expertise rather than for simply “being the FDA”



5 WAYS TO ACHIEVE REGULATORY VELOCITY

A GENERAL REVIEW OF THE CURRENT AND DANGEROUS STASIS OF THE REGULATORY STATUS QUO

1. The dangers of heterogeneous approaches to regulatory policy and the need for closer coordination between senior agency leadership views on advances in regulatory science and those of divisional line reviewers
2. The need for greater regulatory “certitude” (i.e., that similar situations should be treated in similar ways)
3. The need for additional resources for and better training of divisional review staff in new regulatory science techniques
4. The need for a more flexible approach to agency/sponsor communications that does not compromise review integrity or sponsor resources
5. The need for additional resources for and better training of divisional review staff in new regulatory science techniques

**ARE FDA INITIATIVES
BEHIND THE EIGHT BALL?**



EVERYTHING STARTS WITH POLICY PREDICTABILITY

- The best way to avoid resistance to change is to try to uncover it before implementing change. The FDA's reorganized Office of New Drug Policy can act as a regulatory MapQuest for advancing regulatory science
- Is this achievable?

“SIGNS POINT TO YES.”



THANK YOU

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