

The Future of Drug Safety: Regulatory Authority

Symposium on the Future of Drug Safety – Challenges for
FDA

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System



Regulatory Authority: Challenges

- Authority is unclear—interpretations of the statute are subject to change
- Authority is not sufficiently nuanced—major options are “bully pulpit” or withdrawal, actions dependent on successful negotiations with the sponsor, which may be prolonged



Regulatory Authority: Recommendations

- Congressional clarification and strengthening of agency's enforcement authority
- Congressional authorization of a flexible and enforceable “tool kit” of regulatory options that may be applied at or after approval, e.g., conditions and restrictions on promotion and distribution, postmarketing studies



Regulatory Authority: Recommendations

- A special symbol on labels and promotional materials to remind providers and inform consumers that a drug is “new” and knowledge about its benefits and risks is limited
- FDA review of accumulated data on safety and effectiveness 5 years after the approval of a new molecular entity



Regulatory Authorities: 4 recommendations

- A toolkit of conditions/restrictions on distribution to use at and after approval
- Strengthened enforcement authority
- A 5-year postapproval milestone to review all data
- A special system for new drugs



Regulatory Authority: Take Home Message

Approval should not be the “last call” for realistic and effective regulatory action on drug safety.

