

Risk-Benefit Uncertainties

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Disclosures (past year)

- Rofecoxib litigation: testimony for plaintiff's attorneys
- Pfizer: research funding

Limitations Current Approval Process

1. No requirements for crucial data
2. Conflicts of interest
3. Translating data into practice

Case Studies

	Salmeterol	Muraglitazar
Data gaps	Safety: available drugs Signal ignored Clinically relevant comparisons	Relative efficacy Surrogate endpoints Long-term safety
Conflicts of interest	Trial design Data analysis	Trial design Data analysis

An Improved Process

1. Mandatory, tailored post-approval studies; RCTs whenever possible
2. Independent conduct and analysis of these studies
3. Phased release