Enhancing Post Market Regulation and Enforcement: An Industry Perspective

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A Perspective on Risk Management: **Continuous Improvement of Benefit Risk**

- Patients, providers, regulators and industry have a vested interest in optimizing the benefit:risk of therapeutic molecules.
- Continuous assessment and improvement of the benefit:risk of new therapies will require partnerships across the health care spectrum to be effective.
- Governance, roles and responsibilities of partners in this alliance are fundamental to achieving the goal.
- Regulatory guidance issued by the FDA and expectations regarding risk management should be designed to optimize overall benefit:risk from a public health perspective in a cost effective manner.

Recommendations

- Distribution conditioned on compliance with agency-initiated changes in drug labels:
  - Must include dialogue with industry.
  - Process should be transparent.
  - Changes made should meet the perceived safety need.
- Restricted distribution to certain facilities, pharmacists, or physicians with special training or experience:
  - FDA already has some authority in this arena.
  - Restrictions must be applied in the appropriate circumstances.
  - Must consider access for the patient. For the patient in rural areas restriction may result in lack of access. Accommodations must be made as necessary for public health and patient care.

Further Recommendations

- FDA needs increased enforcement authority and better enforcement tools:
  - Industry benefits from a strong FDA which is scientifically based and transparent.
  - Guidance must be developed and process must be transparent.
  - Industry takes the safety of their products very seriously wants to work proactively and scientifically together with the FDA. Concepts of risk:benefit must be communicated to the public.
  - FDA should have authority to withdraw products with due consideration that the benefits to patients are outweighed by the identified safety risks.