

# Developing a Risk Minimization Action Plan (RiskMAP): Developing Interventions

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# RiskMAP

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**Tools** are categorized into three areas:

- Education and outreach
- Reminder systems
- Performance-linked systems to evaluate effectiveness
- Check-list approach vs. situational analysis, behavioral models, assessment and refinement
- Which tools make most sense
  - Depends on what is the problem
  - Must understand “the problem” before attending to the solution

*FDA tools: progressively impactful, progressively insensitive*

# Risk Management Irony

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Beliefs

$$\text{Safety} = \frac{\text{Benefits}}{\text{Risks}}$$

Perceptions

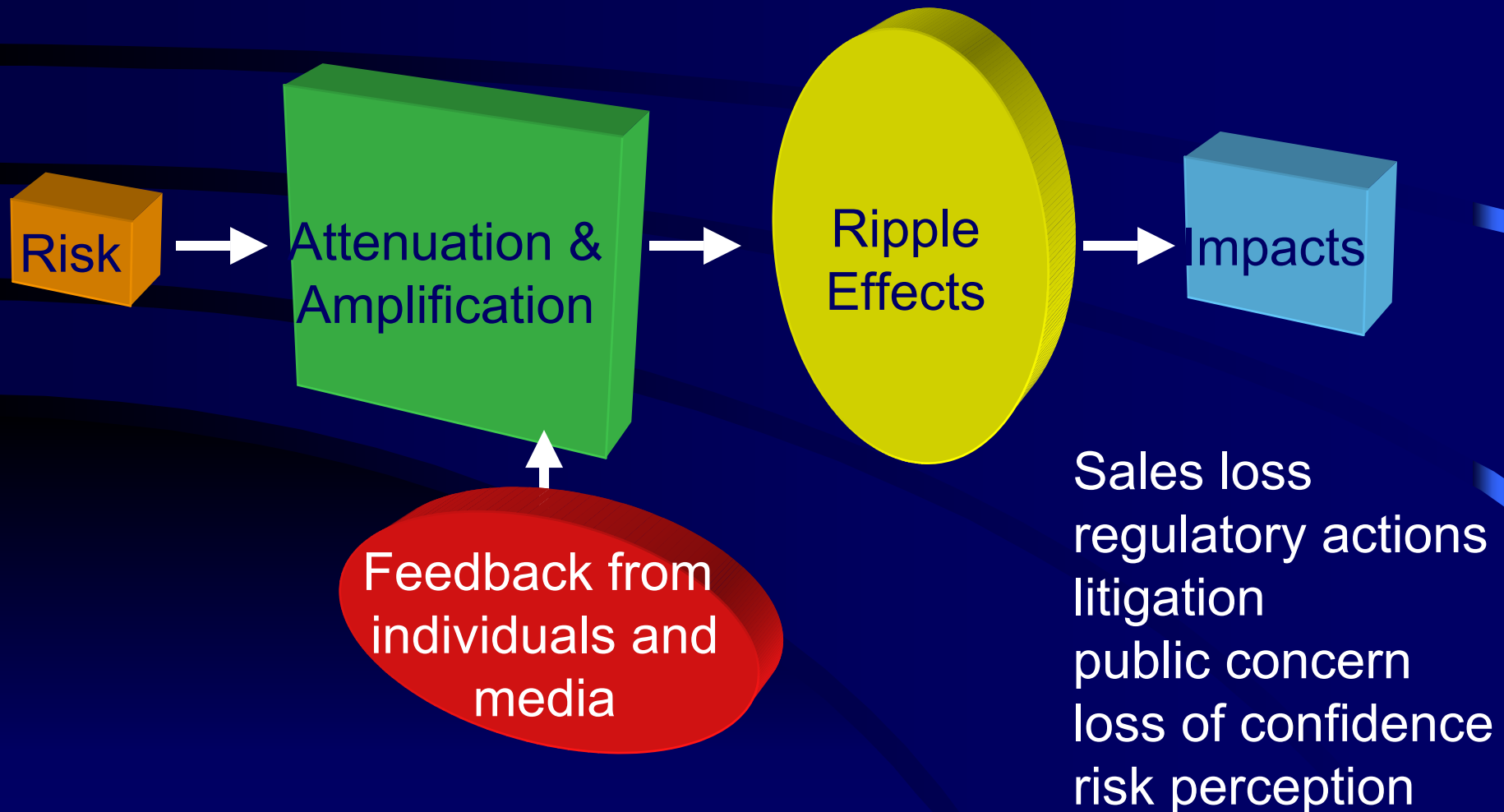
Perception  
of Risk

Willing-  
ness to  
Use

*Unintended Consequences*

# Social Amplification of Risk

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# Designing a RiskMAP (1)

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- Must clearly **specify risk to be managed**
  - Use PI (or target profile) to select and specify problems to be addressed
  - Organize and focus on problems needing RiskMAP
- **Understand the “System”**
  - Processes underlying drug prescribing, distribution and use
  - Use Root Cause or FMEA analysis to specify sources of system failures

*Correctly “framing the problem” points to the best solution*

# Failure Mode and Effects Analysis

- Develop System Steps (or subsystem)
  - Sources of Failure for each step
  - Probability
  - **Severity**
  - Likelihood Of Detection
  - Develop Index by Multiplication
- Root cause analysis is better if there is an appropriate model.
  - Be prepared to update FMEA when drug is launched
  - Difficult to anticipate underlying causes of behavior

*Research: clinical trials as a RiskMAP laboratory*

# Designing a RiskMAP (2)

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- Develop a behaviorally predictive model
  - the set of **beliefs** underlying behavioral intentions
  - the **motivations** that encourage or discourage desired behavior
  - the **environmental conditions** that facilitate (reinforce) or place barriers to compliance.

*What do people do, what do you want them to do?*

*Is it lack of knowledge or incorrect beliefs, how ingrained are these beliefs?*

# Appropriate Use: Marketing Both Ends

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Stakeholder  
Education

Risk Minimization



AUP



Correct Use

Incorrect Use

*Use a combination of Patient Education and Risk Minimization Processes to develop an Appropriate Use Program*



# Behavioral Models

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- Attitude Change
  - Understanding Beliefs and Persuasion
- Improving Involvement (personal relevance) or Competency (self-efficacy)
- Decision making (mental models)
  - Think and act like experts
- Field Theory (barriers and facilitators)
- Stages of Change or Precaution Adoption
- Emotional Models (fear appeals or positive affect)

*Choose the Model that best fits the problem*

# Designing a RiskMAP (3)

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- Developing Interventions
  - Selecting Tools
  - FDA three classes are descriptive but not predictive
  - Suggest two class categorization
    - Informational Tools
      - Use Communication Model to select tools
    - Distribution Controls
  - Additional classes of tools available
    - Economic Controls (incentives for compliance)'
    - Product Modifications (reformulations, system delivery)
    - Combinations and systems improvements

*Tools fit the 4 Ps of Marketing: Product, Price, Promotion and Place (distribution)*

# Information Options

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- HCPs

- PI, Label Changes (black box), Dear Doctor letters, Advertisements (medication errors), Fair Balance in ads, MedEd, brochures

- Patients

- PPIs, Medication Guide, Informed Consent, Multiple options (Accutane, Thalidomide), DTC or refrain from DTC

- Public (PR)

- FDA public announcements (talk papers, press releases), website posting, advisory committee meetings

*The message is more important than the media  
Don't forget the symbolic value of the choice: the  
dreaded black box*

# Tools Selection

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- Necessary And Sufficient for Influencing Behavior
- FDA: Selecting Tools
  - Input from stakeholders
  - Consistency with existing tools
  - Documented evidence
  - Degree of validity and reproducibility
- Nothing beats a good theory:
  - Use a behavioral model, organize tools around overcoming barriers (based on model)
  - Organize evaluations to assess progress meeting model's impact

# Communications Process

## Goal/Barrier

## Measure

- 
- |              |                            |
|--------------|----------------------------|
| • Exposure   | Distribution               |
| • Attention  | Readership                 |
| • Interest   | Willingness to Read        |
| • Understand | Comprehension              |
| • Accept     | Attitude Change            |
| • Memory     | Recall/Recognition Tests   |
| • Decide     | Decision Making Scenarios  |
| • Behave     | Intention to Heed/Behavior |
| • Learn      | Behavior Maintenance       |

*Select Vehicles to Maximize Communication Goal  
May need a combination of Vehicles*

Form (tools)	Distribution	Purpose
Brochure	Physician	General Education
PPI	Package/ RPh	Risk Communication
Medication Guide	Package	Risk Communication and Methods of avoidance
Informed Consent	Physician	Acknowledgement of Risks
Warning on Package	Package	Risk “signal”/compliance
Wallet Card	Starter Kit	Reminder
Stickers: Medication Vial or Prescription	Medication Vial or Prescription	Reminder or time sensitive control message
Patient Agreement or Contract	Physician	Behavioral Commitment
Decision Aid	Physician	Choice of Therapy
Video Tape or CD	Physician or Starter Kit	Persuasion or Choice of Therapy
Recurring Interventions (telephone calls)	Telephone	Behavioral Maintenance

# Sample Tactics Matrix

<b>Goal</b> <b>Audience</b>	<b>Awareness</b>	<b>Motivation</b>	<b>Reinforcement</b>
<b>Sales</b>	Detail Aid	Training manual	Leave behinds
<b>CRM</b>	Affirmative Scripts, Q&As	Training video	Desktop Media
<b>MDs</b>	Mailing	Sales Rep Material	Desktop Media, poster
<b>ER</b>	Sales force materials	Grand Rounds Training	Poster
<b>Patients/ Partners</b>	Waiting room placard, pharmacy printouts	Brochure/Web site, MD materials	Materials with logo

*Theme: Risk Avoidance    Involvement    Logo as Reminder*

# Distributional Controls

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How do we slot the risk-control level for any drug?



Record  
Keeping

Controlled  
Substances

Special  
Packaging

Actiq  
Fosamax

Certification

Tikosyn

Prior  
Approvals

Thalomid  
Accutane

Closed  
System

Clozaril

*Distribution Controls more impactful, more side effects*



# Conclusion

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- Understanding the problem is the key to solving it
- Information is necessary
  - Multiple interventions likely necessary to overcome communication obstacles, achieve different communication goals
- Information Not Always Sufficient
  - May need distribution or other controls
  - Be aware of the side effects, assess those as well
- Humility is a positive characteristic
  - Assessment, refinement and reapplication is essential
  - Good news; that's recognized by FDA