



FDA and Communication about Regulated Products

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FDA's Mission

- Protect public health
 - assure safety, effectiveness, security of regulated products
- Advance public health
 - speed innovations
 - help public get accurate, science-based information needed to use medicines and foods to improve health





Evolution of FDA Communication

- Regulation of sponsor communication about marketed products
- Inform regulated industries about decisions, actions, guidance
- Inform public about activities
 - workshops, meetings, esp. Advisory Committee meetings
 - outreach to assure stakeholder input
- Consumer education for certain products (especially foods)





Recent Additional Focus

- Explain context of regulatory actions
 - approvals are relative – cannot assess benefit (effectiveness) in absence of risk (safety)
 - innovations, just because they are new, generally create their own challenges
 - removals may be absolute or relative – typically cannot assess risk in absence of benefit





How Does FDA Communicate?

- Indirectly through
 - regulation of labels and labeling
 - regulation of some promotional activities for some products
- Directly through
 - press activities, variety of communication vehicles about specific products and product classes, stakeholder outreach, direct response to inquiries, public education campaigns





A Different Way to Slice the Pie

- Ongoing information
 - education – web, print, TV; FDA and FDA + partners
 - facilitating access to product labeling
 - stakeholder outreach – web & phone
- New information
 - typically safety (risk) related
 - various titled vehicles focused on emerging risks, labeling changes, recalls – web, email, podcasts, MedWatch distribution





Communication Effectiveness?

- December 2005 hearing on drug risk communication strategies
- IOM 2006 report on Future of Drug Safety
- Upcoming September 2008 hearing on use, effectiveness, consumer perceptions of allergen advisory labels on foods





RCAC Establishment

- FDA Amendments Act of 2007 established advisory committee
 - “to advise on methods to effectively communicate risks” of regulated products
- Initial meeting “set stage” for continuing discussions of FDA risk (and benefit) communication





Stage Setting

- February 28, 2008
- Overview of laws and regulations affecting FDA communications
- Overview of current communications programs and vehicles





Purpose: Day 1 of 2/08 AC Meeting

- Provide initial legal and regulatory context for early committee discussions
- Parameters for legally defensible communication
- Parameters for research relevant to communications





Presentations: FDA Communication Activities

- Specific direct communication vehicles and activities presented from across various FDA components
- Fleshed out specific activities and vehicles to communicate
 - ongoing information about regulated products
 - new information





Selected Committee Comments

- Design communications in at start
- Track response to communication products
- Empirically test messages before release
- Increase effort to reach vulnerable groups
- Communicate about benefits, not just risks
- When putting out early communications about possible new risks, explicitly address uncertainties in a scientifically sound way





Patterns of Recommendations

- Wide range
 - some sweeping recommendations – significant task to find where and how to implement
 - even specific recommendations present challenges in where and how to accomplish
- Recurring recommendations
 - simplify language, chunk information
 - test before releasing





Focus of Today's Discussion

- Further exploration of FDA direct communications
 - focusing on new information
- What do/should we do?
- How do/should we decide what/when/with whom, to communicate?
- How should we evaluate our effectiveness?





Categorizing Communications?

- By purpose
 - inform, persuade, explain
- By decision maker
 - individuals, sponsors/producers, FDA
- By audience
 - healthcare providers, lay public (consumers and patients), press, industry, advocacy groups



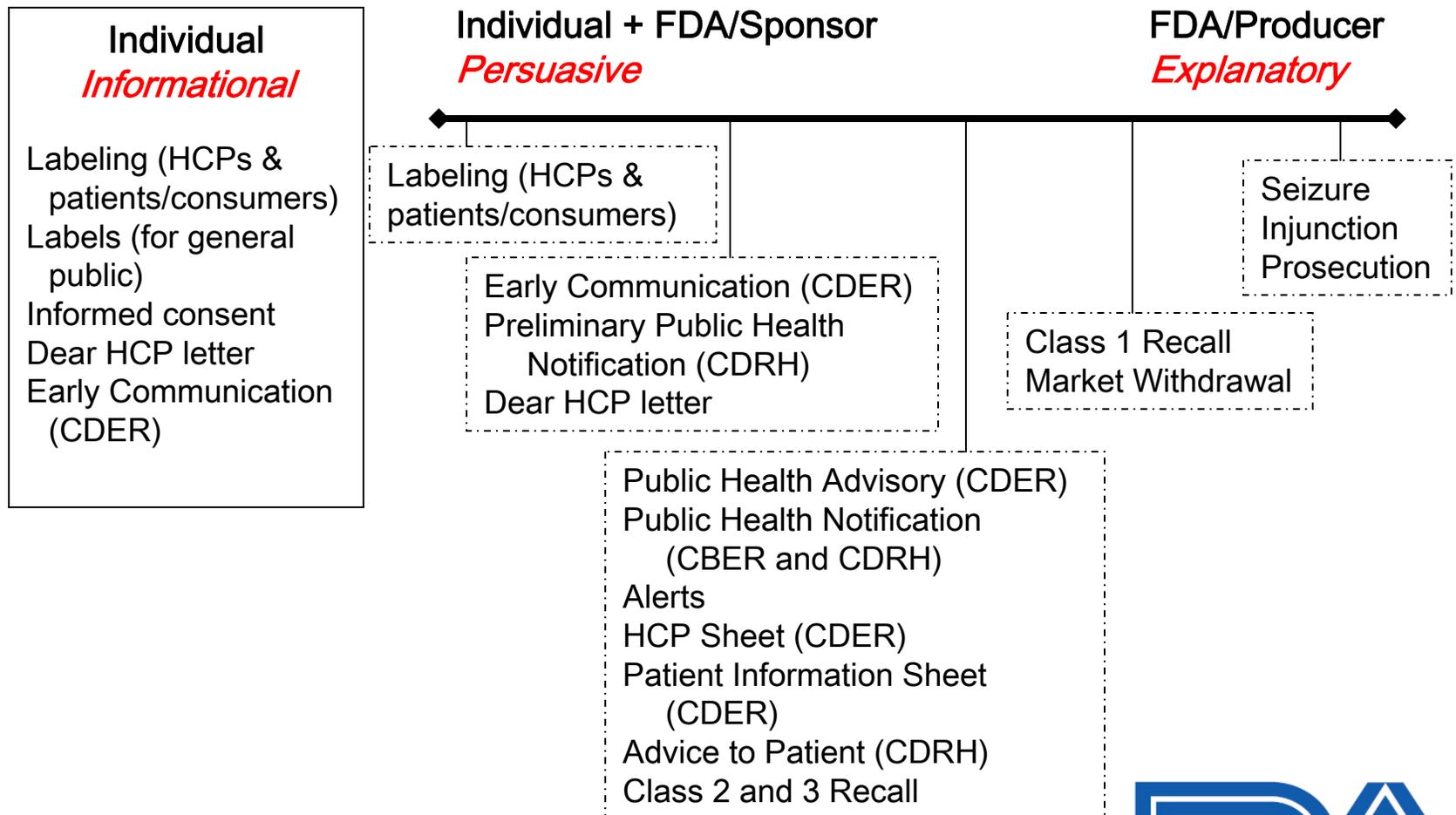


FDA Communication: Purposes

- Non-persuasive
 - inform decision-making, where best course of action may vary
- Persuasive
 - recommend a course of action
- Explanatory
 - explain an action FDA has taken
- Often, more than one purpose is addressed



FDA Communication Vehicles by Decision Maker and Purpose





Information to be Communicated?

- Product benefits
 - degree of relief
 - severity of condition/disease
 - type of affected population
 - size of affected population
- Product risks
 - severity of consequences
 - likelihood of consequences
 - type of affected population
 - size of affected population





Information to be Communicated?

- Quality of data associated with risks and benefits
- Quantity of data associated with risks and benefits
- Availability of alternatives





Information to be Communicated as a Checklist? (I)

Decision Factors	<i>Inform</i>	<i>Persuade</i>	<i>Explain</i>
Product Benefits			
Degree of relief			
Severity of condition/disease			
Type of affected population			
Size of affected population			





Information to be Communicated as a Checklist? (II)

Decision Factors	<i>Inform</i>	<i>Persuade</i>	<i>Explain</i>
Product Risks			
Severity of consequences			
Likelihood of consequences			
Type of affected population			
Size of affected population			



Information to be Communicated as a Checklist? (III)

Decision Factors	<i>Inform</i>	<i>Persuade</i>	<i>Explain</i>
Quality of data associated with risks and benefits			
Quantity of data associated with risks and benefits			
Availability of alternatives			



Topics for Discussion – I

- In light of information presented by the RCAC members and the FDA panelists, please discuss what scientifically supportable, empirically-based, steps FDA should take to improve the effectiveness of communications.





Topics for Discussion – II

- As noted in the FDA presentations, FDA's communications may be drafted for a range of objectives and for a range of audiences. Please discuss how the success of a communication may be evaluated for different objectives.





Topics for Discussion – III

- FDA has adopted, especially in regard to drug products, a policy of increased transparency about early or emerging (possibly still uncertain) risk information. From the perspective of your communities and experience, what might be the effects of this policy? How might the FDA learn more about such effects, if necessary?





Topics for Discussion – IV

- FDA uses certain terms that have special regulatory meaning and importance (example: product X has been shown ***safe and effective*** for its intended use). From the perspective of your communities and experience, what might be conveyed by such terms? How might the FDA learn more about such key terms, if necessary?





Order of Proceedings

- FDA Center Representatives
 - Dr. Frank Torti, FDA Chief Scientist
 - RCAC Member Presentations
 - Discussion...
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- Thanks in advance to all the FDA and RCAC speakers!

