

# Risk Communication

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FDA Public Hearing

Washington DC Dec 7-8, 2005

Cherif Benattia, MD

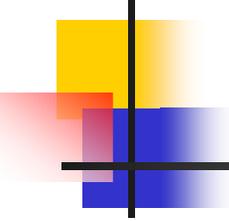
President & CEO

**APhaRC, LLC**

2008 Stone Ridge Lane  
Villanova, PA 19085 USA

Tel. +1 610 410 5291

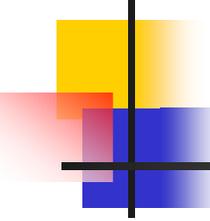
E-Mail: [cherifb@apharc.com](mailto:cherifb@apharc.com)



# Agenda

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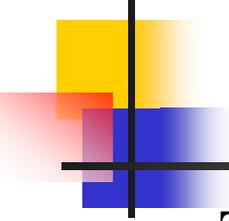
- Introduction
- Why Risk Communication?
- Strengths and Weaknesses of FDA Risk Com
- Opportunities
- Recommendations
- Conclusions



# Risk & Safety Communication

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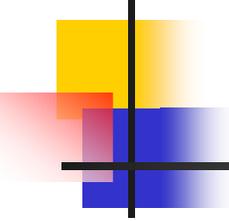
- Communicating about drug risks from any source to any audience is a challenge
- There is an urgent need to change the ways safety information is communicated.
- Shift from “information” to “**communication**” and “**education**”
- Use the same strategies and the same tools used in marketing and promotion.
- Provide the right information on the **benefits** and the **risks** of a treatment to allow HCP and patients to make “**informed**” decisions.



# Why Risk Communication?

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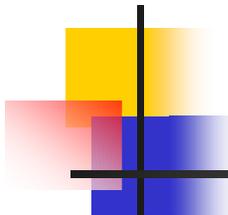
- There cannot be safer drugs until there are better ways to **communicate and educate all audiences about drug risks and benefits.**
- Communicating risks or about risks is still a challenge from any source to any audience, despite advances in information technology.
- Public is inundated by information from various sources (media, mail, internet). Too much information is available and it confuses.
- During crisis, confusion is aggravated by sensationalistic and unreliable information:
  - whom to trust?



# Why Risk Communication?

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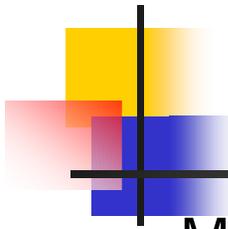
- FDA provides safety information under different formats
  - patient information sheets, press releases, public health advisories, website
  - but **it is not publicized** enough.
- Uncertainty about what kind and how much of information to communicate to patients in a format most of them could understand even with low health literacy skills.
- Gap in HCP knowledge about risks and about safety in general.



# Why Risk Communication?

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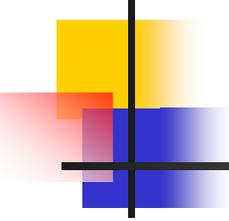
- **Safety information is not always translated into practice**
- The traditional risk communication tools (labeling, DDL, etc) have shown their limits:
  - recent withdrawals of cisapride and terfenadine and others
  - *“These drugs were removed from the market or restricted in their use because they continued to be prescribed in an unsafe manner, even after multiple changes of labeling were communicated and the manufacturer and FDA sent multiple warning letters to health care professionals. (Adapted from CERT Educational Module 1: Preventable Adverse Drug Reactions: A Focus on Drug Interactions)*
- FDA *“had to withdraw drugs from the market that would have been safe if used according to label instructions”*



# Why Risk Communication?

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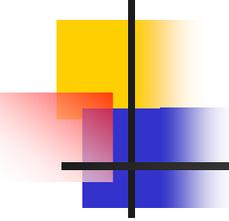
- McNamee in 1996 editorial in the Lancet:  
*“Transparency in the dissemination of risk-benefit information is the ultimate goal, to empower consumers to make **fully informed choices** about what drugs they take”*
- Communication and Education:
  - Transparency is not enough
  - We need to communicate better and to educate HCP, patients, media to use drugs in the most appropriate and safest ways.
- More than 50% of ADR are preventable!
- FDA is using the same criteria of
  - *“informed discussions to make informed decisions”*



# Why Risk Communication?

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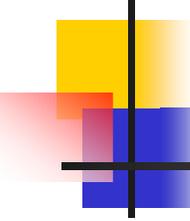
- To make informed judgments and informed decisions there is a need for independent and different reliable sources of information
- Patients want to be provided with comprehensive and truthful information about their medicines, including a clear description of possible ADRs.
- In order to make informed decisions, patients need to understand the risks but also the **benefits** of the treatment options offered to them



# Why Risk Communication?

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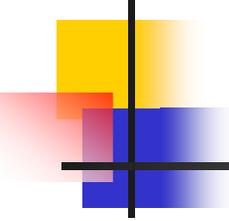
- EU Directive & Guidelines (1998)
  - Requires a patient information leaflet with description of all side effects listed in the SPC
  - ADRs incidence should be conveyed using one of 5 verbal descriptors: from “very rare (<0.01%)” to “very common (>10%)”
- EMEA Risk Mgt Guidelines (Oct 05)
  - Risk Communication



# Strengths of FDA's current Risk Communication

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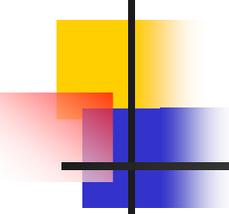
- FDA is a trusted and credible body
- The information provided by FDA is reliable, based on strong data from clinical trials, pharmacoepidemiology studies and spontaneous ADR reporting system.
- FDA has resources and easy access to media for rapid information and communication.
- FDA documentation and information resources are excellent.
- FDA has the power of enforcement laws



# Weaknesses of FDA's current Risk Communication <sup>(1)</sup>

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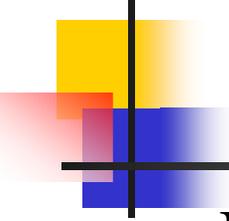
- FDA roles and responsibilities are not clear in public eyes
- “*Approved by FDA*” means “*safe*” in people’s mind
- FDA goals and objectives in Risk Communication are not clear. Is it to:
  - Inform?
  - Educate?
  - Influence and change behaviors?
  - Reassure?



# Weaknesses of FDA's current Risk Communication (2)

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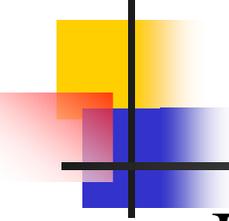
- Access to FDA's information:
  - Does public know how to access FDA information and FDA tools?
  - DTC campaigns usually refer to the prescribing physician or the manufacturer but not to FDA website
- FDA website is not friendly user. It is not easy to figure out how to find information inside it.
- FDA conveys almost the same information to all audiences (HCP, patients, media).
  - It might be confusing for some patients
  - It might not be easy to understand for patients with low literacy skills



# Weaknesses of FDA's current Risk Communication (3)

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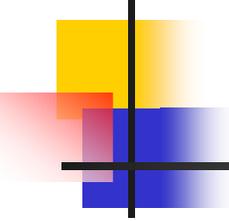
- Labeling:
  - too long, too much information
  - difficult to understand
  - not easy to identify key information
  - It is an information tool perceived to be **“a legal tool made by lawyers for lawyers”**.
- Black Boxes' impact and efficiency have not been proven and are quite challenged now
- It is not sure FDA has formal mechanisms to evaluate response process to safety communication
- FDA does not have resources for on going public safety education



# Some Opportunities

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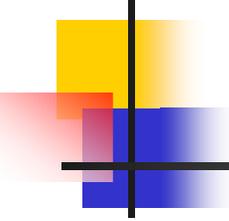
- It is a unique opportunity for FDA to obtain resources for safety education and to play a key role in public and HCP education
- FDA could gain more **trust and credibility** by improving Risk Communication content and tools.
- FDA could lead Regulators and pharmaceutical companies' efforts worldwide to change risk communication strategies.
- FDA could start a **Good (Risk) Communication Practices** initiative.



# Recommendations to FDA <sup>(1)</sup>

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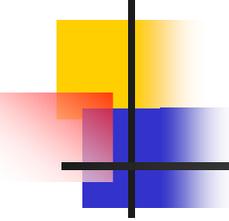
- FDA needs to:
  - have clear goals and objectives
  - develop risk communication strategies and Risk Com Plans
- Risk Communication is an important tool in Risk Mgt and should be included in Risk Management requirements
- FDA should engage partners for synergies:
  - Patients associations, Academia, CME providers, Communication professionals, agencies, Pharmaceutical companies
- FDA should publicize and advertise their communication tools
- DTC adds should direct patients to FDA website too



## Recommendations to FDA (2)

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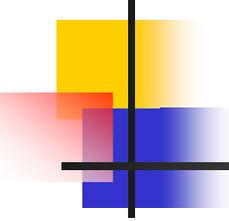
- Marketing departments have used communication tools for a while
  - Billions spent every year in “Promotion” with the best communication tools and strategies and great results
  - it is still a new area in drug safety with only few specialists
- Pharma have developed a strong expertise on How To:
  - Prepare, test and pilot messages and strategies
  - Develop messages that translate into practice (sales)
  - Target audiences: MDs, Pharmacists, Patients (DTC)
  - Evaluate the efficiency of messages.



## Recommendations to FDA <sup>(3)</sup>

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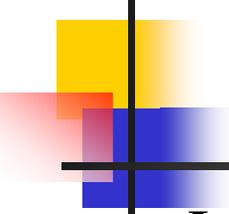
- Take advantage of this strong expertise and **use the same communication strategies and tools** to communicate about safety and risks
- Communicating right about drug safety could also be “good business” and become a competitive advantage (DTC) in the pharmaceutical market.
- Communicating safety to patients could pay back



# Recommendations to FDA (4)

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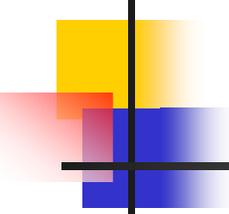
- FDA needs to:
  - Shift from “Information” to “**communication**” and even to “**Education**”
  - Develop mechanisms to ensure the information was received, processed, remembered and has been translated into practice.



# Recommendations to FDA (5)

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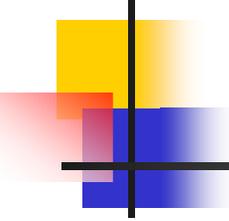
- Information: News channel.
  - The same information is made available to all people, audiences
  - There is no mechanism to ensure the information has been even received
- Communication:
  - A two way process based on trust and credibility.
  - There are mechanisms to ensure the information was received, processed, remembered and has been translated into practice.
- Education:
  - An ongoing process and a proactive tool to ensure audiences (HCP, Patients, etc.) have acquired the right reflexes
  - The communication has been translated into practice and has induced a profound change of behavior to use medicines in the safest and most appropriate way *all the time*



# Recommandations to FDA (6)

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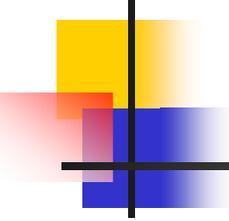
- FDA should
  - communicate risk information in a **format and a vocabulary, patients could understand** even with low health literacy skills
  - avoid the use of medical or technical terms.
  - adapt messages to audiences in terms of
    - **content** (low literacy level)
    - **format** (size of the fonts, presentation, choice of tools,)
  - identify the different audiences
  - choose the right channel for the right audience
  - pilot and tests messages and communication strategies



# Conclusions

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- There cannot be safer drugs until there are better ways to **communicate** and **educate all** audiences about drug **risks** and **benefits**.
- If HCP and patients have the **right information** to make **informed decisions**, there are chances they will change their behaviors
- Risk Communication is a shared responsibility between Regulators, Pharma, HCP, politicians and media.
- Concept of **Good Risk Communication Practices**



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*for a **Better Use of Medicines***

*The ultimate goal*

Should be

The **Right Product**

For the **Right Patient**

In the **Right Indication**

With the **Right Information**

# References

upon request to the speaker

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**Cherif Benattia, MD**

**AP*ha*RC, LLC**

**A**dvanced **P*ha***rmaceutical **R**egulatory **C**ompliance

2008 Stone Ridge Lane

Villanova, PA 19085 USA

Tel. +1 610 410 5291

E-Mail: [cherifb@apharc.com](mailto:cherifb@apharc.com)