

## Speech that FDA Generates

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## Scope of FDA's Communication

- FDA communicates with stakeholders in a variety of ways through a variety of mediums.
- FDA's communications cover a wide range of topics, including risk information.

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## Scope (cont'd)

- FDA uses several methods to communicate risk information to the public.
- Certain forms of communication are targeted to specific audiences, such as health care professionals and the public

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## Methods for communicating risk to the general public:

- Public Health Advisories
- Press releases
- Partnerships/Information Networks
- Patient Information Sheets
- Public Service Announcements (PSAs)

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## Methods for communicating risk to healthcare professionals

- Healthcare Professional Sheets
- Partnerships/Information Networks
- Professional labeling for prescription products

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## Other means of communication

Sometimes FDA is also involved in the communication of risk by sponsors:

- "Dear Doctor" letters
- Voluntary product recalls

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[ Factors that impact FDA's message: ]

- Reliability of the data at issue
- Plausibility of a causal relationship between product and the evidence on which the risk is based
- Magnitude of the risk
- Medical necessity of the product(s) at issue
- Extent of exposure

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[ Factors (cont'd) ]

- Effect on clinical practice
- Disproportionate impact on particular populations
- Facts versus advice (i.e., should FDA educate practitioners about an emerging risk or actually advise them not to prescribe a drug while the risk is further evaluated)
- Trade secrets and confidential commercial information (CCI)
- Personal privacy

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