

Communication of Risk Information

Public Hearing
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Testimony of the
Coalition for Healthcare Communication

Major Points

- Need for new policy?
- Recognize limits
- Create clear distinctions for professional & consumer communications
- Respect court requirements
- Protect FDA jurisdiction

Existing Policy Problems?

- Perhaps: Not broke; don't fix it
 - What's wrong with existing policy?
 - Should FDA take on new responsibility?
- Notes from the trenches
 - Consumers are complicated
 - Avoid mistakes
 - PhRMA Principles
 - New DTC Ads
- Example: Toprol XL DTC messages

Toprol XL Ads

- Disease education
- Stress compliance
- Clear benefit/risk messages
- Engaging creative

Reasons for New Approach

- High rates of noncompliance jeopardize patients' health and can lead to costly treatment for complications.
- According to a recent study noncompliance rates range from 30-60%.
- Patients understand the long term consequences of high blood pressure, but often don't relate it to **their** current or future health.

Research the Audience

- **Consumers respect their doctors.**
 - **Model physician/patient dialogue**
- **Consumers want to understand their medication**
 - **Fair balance must be clear, uncomplicated**
- **Messages should be reassuring, not frightening.**
 - **Fear and confusion decrease compliance.**
- **Messages should reinforce physician instructions**
 - **Physicians support compliance messaging.**
 - **Physicians like DTC that supports their messages to patients on compliance, contraindications, side effects and warnings.**

Print & TV Ads

Toprol XL

Measuring the Results

- Television/print research: (results early 2006)
 - Evaluate key message understanding:
 - Fair balance/black box
 - Intent to discuss with doctor
 - Intent to adhere to Rx
 - Understanding of value of compliance
- Tracking Study (on-going)
 - Measure message understanding
 - Behavioral change

Summary of An Effective Campaign

The Toprol XL campaign works because it:

- **Educates patients about dangers of high blood pressure**
- **Encourages patient compliance.**
- **Communicates the benefit and risk information in a format that is clear, realistic, fair and serious**
- **Communicates the availability of a patient assistance program**
- **Entertains and engages patients**

Meanwhile: Clearer Guidance Needed from the FDA

- More objective, predictable standards
- Value of consistency
- Must respect difference between
Professional and Consumer Communication

Brief Summary Reform

- Time for FDA to issue final guidance
- Need to avoid complicated messages
- Consider an approved, standard format
- Time to kill “Holy Roman Empire” analogy

Court Requirements

- Public record
- FDA has “Burden of Proof”
- Must
 - articulate need for new rules
 - know new policies work
 - consider alternatives
 - use marketing limits only as last resort

Marketing Limits in Drug Approvals

- Proposals for permanent advisory committee
- Develop Social Science Standards
- Simple rules, high profile enforcement
- Public process required

Protect Marketing Jurisdiction

- Resist inconsistent state laws, attorney general enforcement
- Participate in state cases
- Resist private actions for “failure to warn” and “false advertising”
- Resist policy expansion by HHS-IG under “false claims” jurisdiction

Summary

- Start with clear objectives, proceed carefully
- Separate professional & consumer warnings
- Follow Court mandates
- Resist attacks on jurisdiction

For Further Information

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