

Risk Communication Advisory Committee

Discussion Topics and Background Information

This committee meeting of April 29-30 will be discussing 3 different agency topics;

- 1) *Standing out in a competition rich communications environment*
- 2) *Safe Use Initiative Communication and Collaboration*
- 3) *MedWatch: Communication and Education to the Public*

Listed below are the agency's proposed questions for the committee. Where relevant, examples or links are provided to briefly describe or illustrate the discussion topic or key concepts that may assist the committee in better understanding some of the agency's perspectives and challenges.

Monday, April 29, 2013

Discussion Topic 1:

Standing out in a competition rich communications environment

Background Info:

Health News Review.org

Presentation #1:

Managing FDAs message in a competition rich communication market
Steven Immergut, MPH, Assistant Commissioner

Committee Questions and Discussion

Discussion Topic 1: Standing out in a competition rich communications environment

- How can the FDA compete better and develop a more targeted voice in its communications?
- What are the best practices for combatting misinformation and overcoming powerful personalities?
- How should the agency work with/respond to competing/conflicting messages from celebrity spokespeople?

Presentation #2:

Guest Speaker: Dr. Harold J. DeMonaco, M.S., Clinical Advisor, Health News Review

Background Info:

Health News Review.org <http://www.healthnewsreview.org/>

Committee Questions and Discussion

Discussion Topic 1 continued

- How can the FDA redefine the agency's relationship with traditional media and with intermediate sources to better inform the public about scientific findings?
- What are some immediate methods to measure influence of a message, for real time/short term rewrites and edits?

- What are some strategies that the agency can employ to sustain its messages longer in this communication rich environment?
- How can the agency enhance the value of scientific knowledge in the public?
- How can the agency better influence how the public understands public health/scientific information?
- What types of strategies can the FDA employ to confront early stage non-scientific anecdotes with much slower verified scientific data?

Discussion Topic 2:

Safe Use Initiative Communication and Collaboration

Background Info:

FDA Safe Use Initiative, <http://www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/default.htm>

Safe Use Initiative Criteria Worksheet

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM349514.pdf>

Presentation:

Safe Use Initiative Communication and Collaboration

Dale Slavin, Ph.D., Acting Director, CDER

Committee Questions and Discussion

Discussion Topic 2: FDA Safe Use Initiative

- Are there other ways that the Safe Use Initiative can use to gain greater information and or data from outside of FDA on the occurrence of preventable drug harm issues?
- Safe Use uses decisional criteria to evaluate whether a preventable drug harm issue should become a Safe Use project. Of the criteria listed on the worksheet, provided, do you consider that some criteria might have a higher priority or ranking than others? Are there other criteria Safe Use should consider?
- There are numerous stakeholders and stakeholder organizations that can become collaborators on different Safe Use projects. With that in mind, what processes can Safe Use develop and utilize to appropriately select and specifically target those stakeholders for further engagement?
- Those tools and interventions that come out of the collaborative process are implemented voluntarily by healthcare providers (individual clinicians, as well healthcare entities) and patients. Based on the Safe Use project examples provided are there ways (processes, communication formats etc.) that might help us better manage the discussions and gain broader input and stakeholder buy-in?
- After a tool and or intervention is developed, Safe Use continues the collaborative process to gain consensus regarding dissemination, adoption and testing of the agreed upon tool and/or intervention. What processes can we use to facilitate this step in development of a project?
- We understand that there are general methods for assessing the progress and impact of an intervention. Nevertheless, based on the projects we have outlined today are there other methods we might use to assess the impact of the intervention?

April 30, 2013

Discussion Topic 3:

MedWatch: Communication and Education to the Public

Background Info:

MedWatch: The FDA Safety Information and Adverse Event Reporting Program
<http://www.fda.gov/Safety/MedWatch/default.htm>

MedWatch Consumer Voluntary Reporting Form (FDA Form 3500B)

MedWatch Adverse Event Reporting Form
<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM349516.pdf>

MedWatch Consumer Voluntary Reporting Form
<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM349518.pdf>

Presentation #1:

MedWatch: Communication and Education to the Public
Anna Fine, Pharm.D., MS, Office of Health and Constituent Affairs

Committee Questions and Discussion

Discussion Topic 3 MedWatch Communication and Education to the Public

- Please describe how you would enhance our education activities on awareness and availability of the MedWatch program.
- Describe additional ways to promote the availability of voluntary consumer reporting form for MedWatch.

Presentation #2:

MedWatch Practice Portal/Science of Safety
Heidi C. Marchand, Pharm.D., Assistant Commissioner, Office of Health and Constituent Affairs
Norman Marks, MD, MHA, Medical Advisor, Office of Health and Constituent Affairs

Background Info:

MedWatch: Adverse Event Reporting Program Practice Portal
<http://accessdata.dev.fda.gov/scripts/MedWatchPracticePortal/default.htm>

Committee Questions and Discussion

Discussion Topic 3 continued

- Are there academic audiences you think would benefit from the availability of the MedWatch Practice Portal beyond pharmacy?
- As we prepare to launch the practice portal, does the committee have further recommendations for increasing awareness of its availability?

