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National Council on Patient Information and Education
Rockville, MD

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American Society for Automation in Pharmacy
492 Norristown Road, Suite 160
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Long / Winding Road: A Brief History

1995/1996: Federal government (HHS) invites 34 orgs to collaboratively develop Action Plan for “useful” written Rx information for new & refill Rx from retail pharmacies. Legislation allows 10 years to meet target goals.

At year 5: FDA assessed CMI -- distribution at 90% (target 75%); content, readability / usefulness at 55% (target 75%)

At year 10: FDA conducts final assessment -- distribution at 94% (final target 95%); content, readability / usefulness **FAILS @ 75%** (target 95%)



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July 2006: 9 years & 7 months into the 10-Year Keystone *Action Plan for the Provision of Useful Prescription Medicine Information*, FDA publishes its final Guidance: Useful Written Consumer Medication Information (CMI). .

2005 – 2006: NCPIE, as convener, brings together FDA, publishers, system vendors, and pharmacy groups on four occasions to explore feasibility of electronic Medication Guide (*e-MedGuide*) to be affixed to existing CMI.



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June 2008: FDA receives CITIZEN'S PETITION Requesting FDA Action on a "One-Document Solution" for all pharmacy-based communications (based on "Counseling Highlights" section of PI)

Submitted by:

- National Association of Chain Drug Stores
- National Community Pharmacists Association
- Food Marketing Institute
- National Consumers League
- National Alliance for Caregiving
- National Alliance for Hispanic Health
- Healthcare Distribution Management Association
- Catalina Health Resource

Dec. 2008: FDA final Assessment of CMI released. Results fall short of a mandated goal that 95% of all Rx's be accompanied by useful



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January 2009: FDA calls in stakeholders for post mortem:

- Consumer & Patient Groups**
- Publishers**
- Healthcare Professionals (Pharmacists, Physicians)**

Q: Why did the CMI Initiative fail?

Q: What needs to be fixed to make it succeed?

February 2009: FDA's Risk Communication Advisory Committee (RCAC) convenes 2-day meeting on Written Medicine Information, including CMI, Medication Guides, and PPIs.

Stakeholders press for "single document solution" to replace today's multiple, lengthy, sometimes contradictory & unbalanced written information. Also --consider electronic distribution options (email).

Researchers press for regulated, standardized, numeric risk- quantified Rx drug label.

RCAC unanimous vote: Recommends FDA adopt a single, standard document for communicating essential Rx patient information to be developed through appropriate consultative process, and it would replace current CMI, Medication Guide, and PPI.

If adopted by FDA, would result in regulated, single-document consumer drug information labeling for all prescription drug products.



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May 2009:

FDA meets with NCPIE Board of Directors about convening a Fall '09 workshop on written medicine information: Intent is hands-on/interactive” meeting. FDA says they have heard “common themes”:

- Multiple documents don't work (CMI, PPI, MedGuides);**
- Whatever evolves should be evidence-based; consumer tested;**
- Need a single document (consistent, reliable);**
- Drug sponsors should develop content (regulated program);**
- Whatever evolves should contain both benefits and risks.**

FDA says workshop will focus on four specific issues:

- CONTENT**
- FORMAT**
- DISTRIBUTION**
- EVALUATION**



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September 2009: FDA convenes public workshop to explore potential approaches to achieve comprehensible, accurate, easily accessible information.

- Seeks input on four FDA prototypes of written information**
- Asks participants to configure most useful prototype**

Stakeholder Panels Address:

What Should Written Information Look Like? (Research-Based Discussion)

- Assessing the Adequacy of Specific Leaflets**
- Patient Access to Information @ Point of Prescribing**
- Distribution of Patient Leaflets from Pharmacy**
- Distribution and Access of Information to Pharmacies**
- Electronic distribution of information to pharmacy and clinics**

Workshop details: <http://www.fda.gov/Drugs/NewsEvents/ucm168106.htm>



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2009: Evolving Risk Evaluation and Mitigation Strategies (REMS) Program and Burgeoning Medication Guide Program add to the mix.... How do these programs factor into a “one document solution?”

Nov. 2009: FDA Announces SAFE USE INITIATIVE -- *Collaborating to Reduce Preventable Harm from Medications*

*** FDA seeks to partner & collaborate with relevant stakeholders to measurably reduce preventable harm from medications, thereby improving patient health.**

*** FDA calls out NCPIE in SAFE USE INITIATIVE report:**

The National Council on Patient Information and Education (NCPIE) seeks to advance the safe, appropriate use of medications through enhanced communications... .. The Council is an umbrella coalition comprising a large number of health-related organizations... FDA believes that through a

SAFE USE INITIATIVE -- continued

“FDA has already launched (or is planning) several medication risk reduction projects that could benefit from collaboration with relevant stakeholders. The following efforts are only a small sampling of the types of problems that could benefit from Safe Use Initiative support.”

Consumer Medication Information (CMI):

“Many stakeholders have asked FDA to modify the current system for CMI to ensure that all patients receive a single, brief, standardized leaflet about their medications, as is the practice in many other countries.

However, this step would significantly affect established medication use processes in the out-patient setting. It is clear that any new approach to CMI will require a collaborative effort across most of the stakeholders in the ambulatory medication use process.”

FDA Next Steps: SAFE USE INITIATIVE

- Develop a general list of candidate cases for collaborative analysis and intervention.**
- Based on public input and the best available data, work with interested partners to select specific candidate cases for analysis, intervention proposals, and evaluation metrics.**
- Implement a small number of interventions. Each intervention will have an explicit plan for measuring impact. Interventions may involve FDA regulatory actions in concert with actions by other stakeholders.**

Wrap – Up:

“This session will provide an update on the current status of written medicine information stemming from the now federally-directed effort led by FDA that kicked off in September 2009 at a two-day workshop in Washington, DC.”

Current Status – As Noted

Next Step(s):

- FDA pronouncements subsequent to Sept. 2009 Workshop → ?
- Will Written Rx information = An initial Safe Use Initiative undertaking?
- Other?

CONTACT INFORMATION

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NCPIE Educational Web Sites

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