

THOUGHT LEADERS OF SELF-CARE

Announcing A New Program of Leading Public Commentaries on Self-Care

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SelfCare provides evidence and critical commentary on self-care practices, including medications, lifestyle and behavioral approaches, and medication use and management to inform and promote self-management of both acute and chronic conditions.

A new program for stakeholders of self-care: This issue of *SelfCare* represents a new initiative for the journal, in bringing together a searchable library of selected seminal presentations by self-care stakeholders at government and other public meetings. While transcripts of such meetings may be available on public web-sites, they are not necessarily easy to retrieve using common web search engines. Through key word linkages of our published presentations, searching for the views of thought-leaders on self-care will be easier. And, these searches will bring those interested in self-care to the journal's website, where the publications collected under this new program are freely available.

SelfCare has a keen interest in facilitating dialogue on advancing self-care and related considerations of product availability, safe use and novel technologies. We will be seeking public and other meeting presentations on self-care medications, practices and technologies, to develop this library as a useful repository of self-care knowledge and opinion.

In this issue: On March 22-23, 2012, the Food and Drug Administration (FDA) held a two-day public hearing to help the agency address two critical issues that were hurdles to certain past Rx-to-OTC switch proposals. The first of these stemmed from difficulties encountered with the more complex switch candidates, where complicated written algorithms, intended to enhance consumer self-selection, performed less well than expected in mandatory label comprehension studies used to predict medication safety in the OTC setting. The second was a regulatory hurdle, and centered on how FDA would enforce novel approaches to overcome Drug Fact labels that had fallen victim to the Peter Principle¹.

Through dialogues between industry and FDA to seek common ground on how to address these critical issues, the rationale and agenda for a public hearing on the matter was conceived. The meeting on '*Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription*' thus represents an important step in government-industry collaborations focusing on applying novel approaches and new technologies to facilitate nonprescription drug development and ensure public safety.

In this issue, we present the first of a series of articles on this subject, including:

- The public announcement of the March 2012 meeting, with a list of key areas of interest to FDA in addressing novel conditions of use for nonprescription medicines;
- Opening remarks at the meeting by FDA Center director Dr. Janet Woodcock, showing her commitment to supporting exploration of a wide range of possible solutions to the critical issues;
- Remarks from The Self Care Collaborative on foundational principles for considering novel conditions of nonprescription drug use
- An industry presentation on how simple technologies might be used in the retail setting to help consumers appropriately self-select – and self de-select – nonprescription medicines.

A call for papers ... and dialogue: We encourage readers to suggest ideas to expand and develop this new initiative for *SelfCare*, including identifying public and other meetings that might serve as a source for commentaries by self-care thought leaders. We also encourage government, industry and consumer and patient advocates in other countries to consider the open forum approach taken by FDA to help expand access to safe and effective medicines for nonprescription use.

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REFERENCE

1. Soller, R William. Safe use conditions proposed by FDA may reopen door for Rx-to-OTC switch in the U.S.: Has the OTC Drug Facts label fallen victim to the Peter Principle? *SelfCare* 2012;3(2):19-20.