EDITORIAL: SAFE USE CONDITIONS PROPOSED BY FDA MAY RE-OPEN DOOR FOR SWITCH IN US: HAS THE OTC DRUG FACTS LABEL FALLEN VICTIM TO THE PETER PRINCIPLE?

R. WILLIAM SOLLER, PHD

Professor and Executive Director, Center for Self Care, University of California San Francisco School of Pharmacy

On March 22 and 23, 2012, FDA convened a public meeting on “Utilizing Innovative Technologies and Other Conditions of Safe Use To Expand Access to Nonprescription Drugs.” This is a landmark meeting for FDA and US OTC drug developers, and potentially marks a path of lesser resistance for switching more complex prescription medicines to over- and behind-the-counter access.

Why is this coming about at this time? What have the principle thought leaders conveyed to FDA on this matter? What are the implications for other countries?

To answer these questions, the journal SelfCare will bring commentary and other information to readers through two upcoming editions. We seek to solidify in the searchable literature those provocative yet grounded views from the FDA meeting. In so doing, we will further engage the international stakeholder dialogue on expanded evidence-based access to new self-care medicines and technologies.

Among topics to be covered in the next two issues:

• FDA View from the Top – Commentary by Senior FDA staff
• Core Principles for the New Paradigm for Nonprescription Conditions of Safe use
• The Selection and De-selection Self Care Algorithm
• A Scan of the IT Solutions for Self Care
• Switch Candidates for the U.S. – Pharmacist or IT
• Implications for the UK and Europe
• And more

US OTC Drug Facts Label falls victim to the Peter Principle

Most of the low hanging fruit for switching medicines from Rx-to-OTC access was picked by US companies during 1990’s to early 2000’s, resulting in many OTC new drug products for general pain relief, migraine, baldness, allergy prevention and relief, heartburn, dandruff, and a host of combination brand name line extensions. Good for business, but also good for the individual as many of these medicines improved the quality of consumer self care.

More complex switches fared less well in this period, perhaps the most notable being lovastatin for cholesterol control. The main barrier was the current OTC Drug Facts label. The decision making process consumers would have to use based on the proposed OTC label for lovastatin in order to properly select the product, or as importantly properly choose not to select the product, was just too
complex. Had the OTC Drug Facts label simply fallen victim to the Peter Principle – i.e., risen to its level of failure?

The answer seems to be ‘yes.’

Lovastatin was the ‘poster child’ for movement of more complex chronic disease medicines from prescription to nonprescription status. The proposed label stretched the bounds of conventional approaches to presenting OTC Drug Facts, the required labeling on all nonprescription medicines. The inclusion and exclusion criteria for self-care that would be represented in proposed levostatin OTC labels medicines were too complex, too novel in the context of the types of labels that consumer had previously been exposed to, and/or just looked too tiresome for the average consumer (including me) to want to read completely.

Yet, in the future canvas that FDA is now painting, maybe not!

For example, if the OTC Drug Facts label is deconstructed into an App used on an i-pad, kiosk or similar interactive display to allow better consumer education and decision-making through a logical flow of easy to read, layered information, what then? Certainly, the system can document whether the consumer was informed by virtue of storing responses to the sequence of questions leading the App to select or deselect the product for the consumer. When the consumer completes the product selection survey on at the kiosk, she would receive a confirmatory print-out, find the OTC product on the shelf and take both to the register. Or, perhaps the message for the consumer is to check with the pharmacist for more information, maybe a referral to a physician, or a clarification of information the App decided was poorly understood. Such a system could allow for documentation, post-marketing safety surveillance and efficiency in pharmacy workflow. A brave new world!

Other medicines for emergency use might find their way to behind the counter without a prescription, such products as injectable glucagon for persons with diabetes prone to severe life-threatening attacks of low blood sugar, injectable epinephrine for life-threatening allergies (e.g., anaphylaxis), emergency asthma medicines, and injectable or inhaled naloxone for narcotic overdose. All are potentially safe, likely to not be subject to abuse, and essential for saving lives. Why not make it easier for people to get what they need, with less hassle. Why not still allow pharmacy plan coverage and low copays? Again, FDA’s plan would be a game changer.

IT and pharmacy-based solutions in this area have profound ramifications for proponents of a pharmacy only class of medicines, and not just for the US but in other countries where this channel of distribution is usually the default first step for Rx-to-OTC switch. Yes, in the US new medicines might be made available over-the-counter in pharmacies, but so too international regulatory bodies would be compelled to re-evaluate whether the IT solution for product selection is more appropriate for consumer access and pharmacy work-flow efficiency.

With FDA’s move to carve a regulatory principle of “nonprescription conditions of safe use,” research into IT solutions to selection and deselection and pharmacy solutions for urgent care products should be encouraged to move forward rapidly. Both US and international regulatory authorities will then have to look hard at conventional processes and ask what is really best for the consumer?