



How Does the FDA Improve Appropriate Use of FDA- Regulated Products?

Miriam Campbell, PhD, MPH
Social Science Analyst
FDA, Office of the Commissioner

For presentation at the HINTS Annual Meeting, September 25, 2009



U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov



Dr. Kidd cures everything, late 19th century


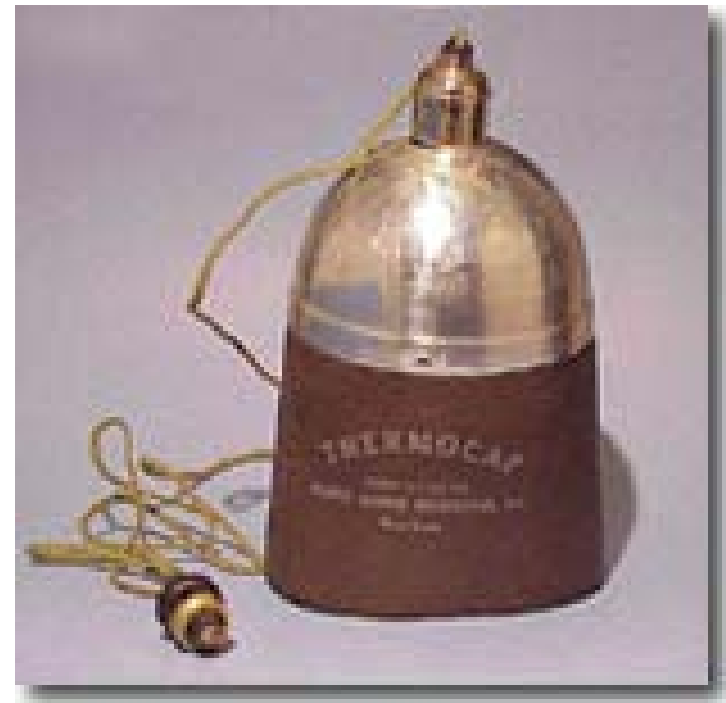
**How Easy
to take this
Treatment**

*Right at Home
in your
Spare Moments*

The action of the Thermocap Treatment is practically automatic. Just a few minutes (according to directions) whenever you have a little spare time. In the evening, for instance, before you retire just attach the plug and set the Thermocap upon your head. Don't let it bother your reading. It is better to do it just before bedtime, for it has a soothing, restful effect. This Thermocap sends just the right amount of heat into the scalp, stimulating the papillae and bulbs. Of course, the present condition of your hair roots did not come about in an instant; yet you will notice how quickly the Thermocap Treatment seems to get at the real cause of your hair trouble, and steadily continues to eliminate it, until you later will begin to see results like those told about on the other side.

**Read Remarkable Report
On Other Side**

Allied Merke Institutes, Inc. — 512 Fifth Avenue, New York City

Early 20th century: Thermocap for "hair growth"



Charles Addams, mid-20th century



1938 *Federal Register*

Drug labeling should be written “only in such medical terms as are not likely to be understood by the ordinary individual.”

DIFFERENCES BETWEEN THEN AND NOW

- Population education
- Consumer empowerment -- desire for involvement in one's own health care
- Litigious environment
- Greater attention to improving outcomes and reducing risk
- Aging population

Strengthen the *science* that supports effective risk communication

Science Strategy 1: Identify gaps in key areas of risk communication knowledge and implementation and work toward filling those gaps

Science Strategy 2: Evaluate the effectiveness of FDA's risk communication and related activities and monitor those of other stakeholders

Science Strategy 3: Translate and integrate knowledge gained through research/evaluation into practice



IDENTIFYING THE GAPS



Photograph by Barry C. Bishop





IDENTIFYING THE GAPS, Q 1

- How much and what kind of risk and benefit information do patients need to make informed decisions on appropriate use of a particular medical product?



IDENTIFYING THE GAPS, Q 2

- What is the effect of including quantitative information about the risks and benefits of prescription drugs or medical devices in information to patients and consumers?



IDENTIFYING THE GAPS, Q 3

- How much benefit information needs to accompany risk information to create a *balanced* perception of a medical product?



IDENTIFYING THE GAPS, Q 4

- What key groups are most likely to misunderstand risk and benefit communications?



IDENTIFYING THE GAPS, Q 5

- What information is needed about the risks and benefits of not using a medical product for informed decision-making?