

Submission of the  
**National Council on Patient  
Information and Education  
(NCPIE)**

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[www.talkaboutrx.org](http://www.talkaboutrx.org)  
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to the Food and Drug Administration's  
**Nonprescription Drugs Advisory Committee  
(Risks of Acetaminophen)**

September 19-20, 2002  
Silver Spring, Maryland



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\*Non-voting liaison

August 23, 2002

Sandra Titus, Ph.D.  
Advisors and Consultants Staff  
Food and Drug Administration / CDER  
5600 Fishers Lane, HFD-021  
Rockville, MD 20857

Dear Dr. Titus:

On behalf of the National Council on Patient Information and Education (NCPIE), I am pleased to submit comments to the FDA's Nonprescription Drugs Advisory Committee as they consider benefits and risks of acetaminophen and other non-prescription medicines. Formed in 1982, the National Council is a non-profit coalition committed to improving health professional-patient communication about the safe, appropriate use of prescription (<http://www.talkaboutrx.org>) and non-prescription medicines (<http://www.bemedwise.org>). Our 135-member coalition includes national consumer and patient advocacy organizations; health professional associations representing pharmacists, prescribers, and nurses; voluntary health associations; prescription and non-prescription manufacturers; and the FDA, Agency for Healthcare Research and Quality, and other government agencies.

While these comments may not necessarily reflect the opinion of each organization in the NCPIE coalition, there is universal support among the NCPIE membership for the vital role that high-quality healthcare provider-patient communication, public awareness and education play in promoting safe and appropriate use of medicines and better health outcomes.

The purpose of this document is to (1) share the results of recent research we commissioned examining consumers' attitudes and behavior regarding non-prescription medicines, including common pain relievers; and (2) provide a brief overview of our "Be MedWise" public education campaign promoting the wise use of over-the-counter (OTC) medicines, along with the new "Drug Facts" label on most OTC products.

NCPIE's research, the basis for our "Be MedWise" campaign, indicates that many consumers do not recognize the potential for harm if they: take more than the recommended dose; take more than one product containing the same active ingredient; inappropriately combine OTCs and prescription medicines; or inappropriately combine OTCs and dietary supplements.

As this committee knows, non-prescription medicines account for six of the top 10 medicines taken by Americans, according to the “Slone Survey,” a one-week prevalence study (see “Recent Patterns of Medication Use in the Ambulatory Adult Population of the U.S.,” Kaufman, D. et.al., JAMA, Vol. 287, No. 3, Jan. 16, 2002, pps. 337-344 <http://jama.ama-assn.org/issues/v287n3/abs/joc11123.html>). Acetaminophen, ibuprofen and aspirin represented, respectively, the first, second, and third most commonly used medicines in the U.S. (Multiple-ingredient preparations accounted for 45% of acetaminophen and 26% of aspirin. See: *ibid.*)

These prevalence data, combined with the FDA’s emphasis on promoting consumer understanding of medicines’ benefits and risks, the new OTC “Drug Facts” label, and NCPIE’s two decades of experience in medicine communication campaigns, led NCPIE to develop its first-ever campaign promoting safe use of OTC products, entitled “**Be MedWise.**”

NCPIE envisions the “**Be MedWise**” campaign as a multi-year effort to support and enhance consumers’ informed self-care decision-making when selecting and using OTC medicines. The campaign is also intended to stimulate consumer – healthcare provider communication about appropriate use of OTC medicines. Campaign activities are described on pages 4-5.

### Consumer Research Findings

In late 2001, NCPIE commissioned an extensive telephone survey of both consumers and health care professionals to learn about their attitudes, behavior, and interventions involving non-prescription medicines. Key findings from our consumer survey included:

- Of the respondents who had taken an OTC product in the past six months, 78% had taken one for pain relief.
- Only 34% of respondents who used an OTC product for their headache could correctly identify that product’s active ingredient.
- When purchasing an OTC product, 34% of respondents said they read the product’s active ingredient; 10% said they read about possible side effects; seven percent said they read about possible interactions with other non-prescription medicines; and six percent said they read about possible interactions if taken with alcohol.
- One-third of respondents said they had taken more than the recommended dose of an OTC medicine. Of that subset, 69% said they had taken more than the recommended number of pills at a single time; 63% said they had taken the next dose sooner than directed on the label; and 44% had taken more than the maximum doses per day as directed on the label.

- Just over one-third of respondents (36%) said they were “extremely” or “very likely” to discuss the use of a non-prescription pain reliever with a health care professional. This compares with 55% of respondents who said they were “extremely” or “very likely” to discuss with a health care professional the use of an OTC medicine prior to or following surgery; with 48% of respondents who were “extremely” or “very likely” to discuss the use of aspirin for a heart condition; and with 40% who said they would discuss taking more than one OTC product simultaneously.

(Please note: NCPIE’s survey was conducted six months before the implementation of the new “Drug Facts” label.)

When these consumer findings were considered against health care professionals’ expressed concerns about their patients’ appropriate use of non-prescription medicines, our “Be MedWise” message points quickly emerged as “Remember the 3 R’s”:

**Risk:** Know your medicine’s risks and benefits.

**Respect:** Respect the power of your medicine and the value of medicines, properly used.

**Responsibility:** Take responsibility for asking questions if you need more information, and for telling your health care professionals about all prescription and non-prescription medicines you are taking.

#### **“Be MedWise” Campaign Messages**

To further expand on the “3 R’s,” the following sub points are being disseminated to the public via the “Be MedWise” campaign:

- OTC medicines are safe when taken as directed, but they are still serious medicines that can cause harm if taken incorrectly;
- Many OTC medicines contain the same active ingredient, so make sure you know the active ingredient(s) in each OTC medicine you plan to use / administer to others.
- Always read the OTC drug label carefully and always follow dosage instructions, warnings, etc.
- Compare active ingredients if you are taking multiple OTC medicines.
- Tell your doctor and pharmacist the names of all the medicines (prescription and nonprescription) that you are taking.
- When in doubt about choosing or using an OTC medicine, consult your pharmacist or doctor.

**“Be MedWise” Campaign Implementation**

Phases I and II of **“Be MedWise”** (below) were supported by an unrestricted educational grant to NCPIE from McNeil Consumer and Specialty Pharmaceuticals. Phase III is supported by an unrestricted educational grant to NCPIE from Procter and Gamble. Neither sponsor (nor their parent companies) serve on NCPIE’s Board, and no **“Be MedWise”** sponsor had any input into these NDAC comments. Additional sponsors, within and outside of the pharmaceutical industry, are being sought to support subsequent phases of the campaign.

Phase I -- Launched January 22, 2002 in Washington, DC:

1. Press conference/ release of “A Dose of Reality” survey results;
2. National TV / print advertising - - :30 second TV ad on AOL-Time Warner stations including CNN, CNN Headline News, and TNT.
3. Video News Release (VNR);
4. Launch of [www.bemedwise.org](http://www.bemedwise.org), a consumer-oriented web site.

At the invitation of NCPIE, the Food and Drug Administration and the American Pharmaceutical Association (APhA), participated in our January 22 campaign launch / press briefing at the National Press Club (Washington, DC). With permission, the FDA’s name and logo, along with NCPIE’s, appeared on the above-referenced television ad.

Phase II -- Launched May 16, 2002 in New York City:

Phase II was timed to coincide with the implementation date for the OTC “Drug Facts” label. FDA personnel again participated in the media briefing. Additional elements of Phase II included:

1. Satellite media tour with FDA officials;
2. Print ad (with NCPIE & FDA logos) in Time - (see attached);
3. Video News Release (VNR);
4. Multi-City media tour to coincide with back-to-school season (**“Be MedWise”** message to parents about children’s use of OTC medicines).
5. **“Be MedWise”** Tool Kit for NCPIE members and other interested stakeholder organizations (available by October to coincide with NCPIE’s national health observance, *“Educate Before You Medicate: Know Your Medicines.”*)

Also, NCPIE entered into a licensing agreement with the Ontario Pharmacists’ Association/ Drug Information and Research Centre, for use of **“Be MedWise”** campaign elements to support **“Be MedWise”** Canada ([www.bemedwise.ca](http://www.bemedwise.ca)), which was launched on June 20, 2002.

Phase III -- Launched August 15, 2002 in Cincinnati, OH:

At a press briefing, NCPIE announced that the next phase of “**Be MedWise**” will include development of consumer-oriented messages and materials for dissemination through community-based pharmacies and medical clinics. NCPIE will work closely with national- and state-level pharmacy organizations (many of whom are NCPIE members) to develop, produce, and disseminate such materials. Additionally, this phase will focus on reaching older adults, who purchase / use a significant percentage of OTCs, and who are particularly at risk from the concomitant use of prescription and nonprescription medicines, and dietary supplements.

Campaign Media Coverage to Date:

As noted below, since its launch on January 22, 2002, NCPIE’s “**Be MedWise**” campaign has experienced tremendous success at reaching the American public, with more than 1.2 billion consumer impressions and more than 140,000 visitors to the campaign web site recorded:

**Broadcast**

Total Radio Hits	581	Impressions	13,638,000
Total Broadcast Hits	476	Impressions	66,162,010
Total VNR Hits	73	Impressions	4,031,000
:30 TV Spot	>1 Billion Household Impressions		

**Print/Internet**

Total Print Hits	190	Impressions	69,557,135
Coverage - major web sites	94		
Visitors: <a href="http://www.bemedwise.org">www.bemedwise.org</a>	>140,000		

As Phase III activities continue, NCPIE looks forward to assessing the campaign’s impact vis-à-vis consumers’ response to key message points.

Over the years, the Food and Drug Administration – which serves as a non-voting liaison on NCPIE’s Board of Directors – has worked closely with NCPIE on many educational campaigns. Our partnership to promote the “**Be MedWise**” messages, and especially the new “Drug Facts” label, was particularly rewarding. Thus, we commend NDAC for highlighting these important safety issues as we continue working together to ensure the public’s wise use of medicines.

Sincerely,



Wm. Ray Bullman, M.A.M.

Executive Vice President

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Enclosures