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*Non-voting liaison

July 22, 2005

Reference: Docket No. 2005D-0169

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir/Madam:

The National Council on Patient Information and Education (NCPIE) submits the following comments on the Food and Drug Administration's (FDA) *Draft Guidance on Useful Written Consumer Medication Information* (Federal Register: May 26, 2005, Volume 70, Number 101; Page 30467-30469). These comments do not necessarily reflect those of individual members of the National Council on Patient Information and Education (NCPIE).

While NCPIE commends FDA for attempting to define for publishers, pharmacies and other stakeholders what, in the agency's view, is "useful" CMI, NCPIE has significant concerns with regard to the Draft Guidance and the potential impact of FDA's recommendations on the subsequent operationalization / implementation of current efforts to achieve the goals of the Action Plan for the Provision of Useful Consumer Medicine Information (Action Plan) based on such Agency recommendations.

Since January 2003, in response to a request from the FDA, NCPIE has brought together a broad base of nearly two dozen key private sector stakeholder organizations to work collaboratively to better ensure that the final goals of the Action Plan (per P.L. 104-180) are achieved.

NCPIE, as one of the original members of the committee appointed by HHS Secretary Shalala in 1996 to develop the Action Plan, is pleased that the FDA has provided its draft guidance on *Useful Written Consumer Medicine Information*. Nevertheless, it must be pointed out that the guidance is provided so late in the 10-year timeframe delineated in the Action Plan, and that the Agency's views on what constitutes "useful" CMI are so broad as to be problematic for both stakeholders working to operationalize the Action Plan goals and consumers who would receive such CMI.

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Additionally, some proposed requirements in FDA's draft guidance – such as the need for “useful” CMI to include all indications, all contraindications, all precautions, and all warnings listed in the Package Insert (PI) – goes beyond what was called for in the Action Plan, will add complexity to production of CMI, create even longer documents that consumers are unlikely to read, and will likely increase the pharmacy's cost of doing business – which will undoubtedly be passed on to consumers.

The NCPIE CMI Initiative and individual stakeholders have requested specific advice from FDA regarding operationalization and implementation of the Action Plan since 2002. More recent requests by NCPIE for such advice were made:

- 1) At an “all-hands” stakeholder meeting with FDA in March 2004 (Carnegie Endowment for International Peace, Washington, DC).
- 2) At a meeting with FDA between drug information publishers and other members of the CMI Criteria Committee on June 17, 2004 (Parklawn Building, Rockville, MD).
- 3) Upon submission by NCPIE of a draft document to FDA entitled, *A Guide for Determining the Usefulness of Consumer Medicine Information* (September 17, 2004).

NCPIE Guide for Determining the Usefulness of Consumer Medicine Information

This document was prepared by the Criteria Committee of the NCPIE CMI Initiative. Its intended use, subsequent to review by FDA, was to provide detailed guidance to stakeholders on how to interpret and operationalize the Action Plan's *Guidelines for Useful [Written] Prescription Medicine Information*, i.e., Chapter 3 and Appendix G of the Action Plan, for the purposes of developing and evaluating written CMIs for “usefulness.” However, to date, we have not received the agency's feedback on our document, and have thus not distributed the Guide. A copy of NCPIE's *A Guide for Determining the Usefulness of Consumer Medicine Information* is included here as Attachment A.

FDA is urged to work in partnership with NCPIE to immediately finalize and adopt NCPIE's *Guide* as the basis for operationalizing the Action Plan in lieu of a final guidance document. Otherwise, more time will elapse until the Agency finalizes the guidance, and stakeholders will still be without a concise operationalization guide.

Draft Guidance Overly Broad

NCPIE is concerned about FDA's interpretation of the Action Plan wherein it recommends that for CMI to be useful, it must include all indications, all contraindications, all warnings, and all precautions from the prescribed drug's FDA-approved package insert (PI). FDA is calling for essentially the same information currently required in the brief summary that must accompany most prescription drug print advertising. The draft guidance goes even further than FDA's brief summary regulations, requiring for instance, information on route of administration, monitoring of therapy, and other details.

The brief summary required in print advertisements has been shown repeatedly to be an ineffective tool for communicating useful drug information to consumers. Including additional information (all indications, contraindications, warnings, and precautions) means also that CMI, when formatted to conform to design and layout recommendations (Appendix G of the Action Plan), will require significant additional space to print. Additionally, requiring all such information in CMI goes beyond requirements for Medication Guides. Thus a higher standard is proposed for CMI than FDA requires for itself.

As FDA personnel know from participating in numerous NCPIE CMI Initiative committee conference calls and stakeholders' meetings, expanding further the amount of text in the CMI monographs directly affects the complexity of programming and capacity of existing pharmacy system hardware to produce Action-Plan-compliant CMI and the resulting length of the CMI itself. Requiring yet more information will result in CMI that is potentially very lengthy and therefore likely not to be either consumer friendly or useful.

A True Partnership

NCPIE still believes it can successfully lead the effort to meet these goals, as originally requested by the FDA, but only if the FDA is committed to working with NCPIE's CMI coalition and other stakeholders in a true partnership. Particularly during the next 18 months, and beyond, FDA is asked to provide technical advice as needed and flexibility to support stakeholders' efforts to achieve the goals of the Action Plan by, for example:

- 1) Providing comments on NCPIE's *Guide for Assessing the Usefulness of Consumer Medicine Information* and adopting it as the Agency's recommendations for operationalizing the Action Plan.

- 2) Providing specific examples of Action Plan-compliant CMI incorporating design and readability recommendations. As previously requested by NCPIE (March 2004), multiple examples are requested, to represent a range of medications, including, for example, a medication with a significant risk profile; a medicine used to treat a chronic condition, and a medicine used for an acute illness.
- 3) Providing more guidance with relevant examples of "patient-friendly" language describing various topics/conditions, e.g., warnings and precautions. For example, orthostatic hypotension could be described by the following terms, even though the etiologies of these symptoms may or may not be related to hypotension: orthostasis, lightheadedness, dizziness, or lightheadedness (dizziness) upon standing. Providing this type of guidance will help to ensure that information is communicated in a consistent manner by CMI publishers for the same product(s).
- 4) Providing feedback of publishers' CMI monographs through 2010 [see 6) below].
- 5) Publishing well in advance the specific research design that FDA will use to conduct its 2007 assessment and seeking comment on that design from stakeholders.
- 6) Using the Agency's 2007 CMI assessment to establish mid-course progress toward meeting Healthy People 2010 Objective 17-4 (see below), and continuing to partner with stakeholders to ensure this Healthy People 2010 goal is met. Assuming significant progress is demonstrated by the private sector pursuant to FDA's 2007 assessment, the final assessment of CMI would be conducted in 2010 to coincide with a final assessment of progress toward meeting the goals of HP 2010 Objective 17-4, for which FDA has lead federal agency status. Objective 17-4 states:

17-4. Increase the proportion of patients receiving information that meets guidelines for usefulness when their new prescriptions are dispensed (guidelines here refers to the Action Plan).

Beyond its 2001 assessment of CMI, FDA has not conducted a mid-course assessment of progress toward meeting Objective 17-4. Its ongoing assessment of consumers' reported receipt of prescription drug information (consumer telephone surveys) does not evaluate the quality of written drug information received.

Inclusion of Mail Order Pharmacies

NCPIE believes that any final guidance on useful CMI should specify that mail order pharmacies will be included in subsequent assessments of CMI conducted by FDA.

General Area(s) for FDA Clarification or Consideration

The proposed CMI does not offer guidance on providing useful information to a significant percent of the population that have challenges with literacy or disabilities (e.g., elderly dementia, blindness, etc.). Guidance on supplying CMI to special populations (e.g., illiterate or disabled) may be warranted, as well as feedback on how FDA would assess such information.

Specific Areas Requiring FDA Clarification or Consideration (line references refer to draft CMI guidance document)

Line 114: "However, the average usefulness of the information was only about 50 percent." At a June 2004 meeting of NCPIE's CMI criteria committee with FDA, this conclusion was refuted by an American Society of Health-Systems Pharmacists (ASHP) analysis of the study's methodology and findings.

Line 127-129: FDA considers meeting the criteria of the Action Plan as the "minimum" appropriate characteristics of useful CMI. Since the agency does not share what would be an improvement over the Action Plan.

Lines 166-169: The draft guidance includes the eight criteria that were used in the FDA-sponsored University of Wisconsin-Madison's 2001 evaluation of CMI. The document states that FDA believes the list provides the factors for determining if CMI is useful. The document continues to state that information that "substantially" satisfies each of the criterion will be deemed useful; however, FDA fails to define the term substantially.

When CMI is evaluated against the criteria, what rating will indicate a "passing grade?" Must CMI be rated a four or five on a five-point scale to "substantially" meet the criteria?

- Lines 181 – 183: “Established name and brand name (e.g., the trademark or proprietary name) of the drug and the phonetic spelling (pronunciation) of the established name...” Guidance does not specifically address generic drug products that do not have a brand (or proprietary) name. FDA’s Guidance, unlike the Action Plan, would now require that the phonetic spelling be included for brand names. This creates a higher standard that would be difficult to meet for two reasons: 1) there is no standard pronunciation for brand names (there is for generic names (i.e., USAN), and 2) some drugs have so many brand names as to make this extremely burdensome.
- Lines 189 – 192: “...how to monitor for therapeutic effectiveness...” Effectiveness of medication should be determined by the healthcare professional as determined through patient-provider communication. Some drugs are palliative and not curative, others may be effective without subjective improvement or change in clinical symptoms. Bulleted statement (line 189) may benefit if expanded to address comment.
- Line 219: It is unclear what FDA means when they say the CMI must be a stand-alone document. This raises such questions as: Does all the information on prescription vial labels (e.g., Directions for use) have to also be in the CMI?
- Lines 224-227: If detailed instructions describing how to administer the medication (instructions for use) are included in the manufacturer’s patient labeling for the product...” How does this differ from “Specific directions about how to use the medication?” If CMI is to be considered a stand-alone document, as stated in previous bullet (line 219), this item becomes contradictory.
- Lines 229 – 230: “A statement should be included in the CMI to stress the importance of adhering to the dosing instructions prescribed by the healthcare provider.” What if the prescribed dose is outside the dosing range of the FDA-approved label? Does this become an off-label use? Will this warrant a customized CMI?
- Line 232-233: Guidance about “route of administration” here implies to always state the route, whereas the Action Plan specifies to describe “any special instructions on how to administer (e.g., route).” This is a very different interpretation by FDA. For example, “Take with food or milk” does not explicitly “state the route.”

- Lines 240-241: "Describe what patients can do if they miss a scheduled dose, if this information is in the P.I." If this information were not included in the P.I., would it not be important to include some general advice for the patient in the CMI?
- Lines 280 - 282: "If the P.I. states that the product can cause drowsiness... While patients must be informed of this risk, consider providing some perspective on this recommendation. A search of the on-line Physician's Desk Reference shows that over 550 PIs contain the words "somnolence" or "drowsiness." In some cases, these terms may be in a Table of adverse events with a rate that is similar to placebo. Is it the intent of the Agency that CMI for each of these products carry such precautionary language? If so, will this diminish the intended impact of such precautions because so many products will carry this language?
- Lines 285 - 286: The FDA also recommends that for all drugs with unknown risks, CMI should include a statement such as, "*Talk to your doctor if you are pregnant or breast-feeding...*" NCPIE recommends that the first sentence be amended to read, "Talk to your doctor or pharmacist...."
- Lines 298 - 299: "... the symptoms of at least the 5 to 9 most frequently occurring (common) adverse reactions." What if the 5 to 9 most frequently occurring reactions are not common? Without quantitative definitions (for such qualitative terms as "common") this will continue to be an extremely subjective criterion.
- Lines 320 - 327: FDA recommends that the CMI include a statement encouraging discussion with a health care professional about the prescription medicine. The example used by the FDA, "*If you would like more information, talk with your doctor,*" excludes the pharmacist supplying CMI. NCPIE recommends that the statement be revised to read: "If you would like more information, talk with your doctor or pharmacist."

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Lines 391-404: FDA gives its favored headings/order, but says this is not the only appropriate headings/order. The draft guidance does not even refer to example CMI's in Appendix G of the Action Plan. As requested in prior discussions with FDA, NCPIE requests that FDA provide examples that it deems to be Action Plan-compliant CMI.

NCPIE is pleased to have this opportunity to comment.

Sincerely,

A handwritten signature in black ink, appearing to read "Wm Ray Bullman", with a long horizontal flourish extending to the right.

Wm. Ray Bullman
Executive Vice President

Attachment: NCPIE *Guide to Assessing the Usefulness of Consumer Medicine Information* (2004)