Executive Summary

Background: This study serves as a follow-up to a 2001 evaluation of the quality of Consumer Medication Information dispensed in community pharmacies. The primary research questions were:

- What percentage of shoppers getting prescriptions filled in community pharmacy settings was given *any* written Consumer Medication Information (CMI) beyond label directions?
- What percentage was given CMI that adhered to quality criteria as judged by experts and consumers?
- How did expert and consumer evaluations of the quality of CMI differ in the 2001 and 2008 studies?

The 2008 study was conducted by the National Association of Boards of Pharmacy (NABP) through a subcontract with the University of Florida, College of Pharmacy. Study procedures followed closely the previous 2001 research conducted by Drs. Svarstad and Mount at the University of Wisconsin.

Methods: For the 2008 study, a list of pharmacies from the continental United States was selected by a randomized procedure from a national electronic list of retail pharmacies that was certified by the National Council for Prescription Drug Programs. To collect the CMI leaflets from the selected pharmacies, the NABP subcontractor Second to None hired professional shoppers to simulate patients and visit each pharmacy location to fill prescriptions written by FDA-recruited physicians for the two study drugs, lisinopril and metformin. Before the simulated patient shoppers were assigned to pharmacies, each individual underwent training to be able to play the role of a person recently diagnosed with diabetes and high blood pressure and to answer questions from pharmacy staff according to a standard patient role.   The quality of written information provided with the dispensed prescriptions was analyzed by expert and consumer evaluators.

Expert Evaluations: A panel of four clinical experts (an internist, endocrinologist, drug information specialist and community pharmacist) reviewed all drug monographs in standard compendia and common patient information references and defined explicit criteria for content and format of CMI leaflets following the eight general criteria defined for the 2001 evaluation. This panel developed the Expert Evaluation Forms for both lisinopril and metformin. Each item identified as critical for good-quality consumer information for each study drug was phrased as a single subcriterion under the eight general criteria. Criteria 1-6 describe content that should be present in CMI and specify that information must include: (a) drug names and indications for use, (b) contraindications and what to do if they apply, (c)

specific directions about how to use, monitor, and get most benefit, (d) specific precautions and how to avoid harm while using it, (e) symptoms of serious or frequent adverse reactions and what to do, and (f) general information and encouragement to ask questions. Subcriteria for Criterion 7 include requirements for scientifically accurate, unbiased, and up-to-date information. Finally, Criterion 8 includes criteria for formatting, legibility and comprehensibility.

A national panel of eight experts comprised of pharmacy practitioners, drug information specialists, and pharmacy educators with expertise in pharmacotherapy and patient education and communication reviewed the Expert Evaluation Forms and suggested changes. After completion of inter-rater reliability checks the final Expert Evaluation Forms included 77 subcriteria for lisinopril and 78 for metformin, with each item being scored as either met or not met. The national panel of experts then evaluated based on the subcriteria each of the CMI obtained by the simulated patient shoppers. The percent adherence of CMI to evaluation criteria was reported as an overall aggregate score across all subcriteria as well aggregate scores across the subcriteria for each individual general criterion (1-8). Frequency distributions were reported, reflecting six levels of adherence that that had been used to summarize findings in the 2001 study. Those leaflets not meeting a threshold of 60% of possible points were identified as not meeting standards for useful CMI.

Consumer Evaluation: The Consumer Evaluation Form (CEF) developed and validated by Svarstad and Mount and used in the 2001 study was used to obtain consumers' perceptions of the quality of the CMI leaflets. For each item, consumers were asked to circle the one number on a semantic differential scale with opposite adjectives that might describe the written leaflets (e.g., scores could range from 1 [adjective describing poor quality] to 5 [adjective describing good quality]). Forms were summarized in a similar fashion to the Expert Evaluation Forms as the percent of possible points that were met.

Results:

Simulated patient shoppers obtained new prescriptions for lisinopril at 365 and for metformin at 364 community pharmacies in 41 states. Twenty-two pharmacies representing 6% of the total (95% CI 3.6., 8.5) did not provide any written information beyond the directions on the prescription vials. A total of 274 or75% (95% CI 70.6, 79.5) of prescriptions for lisinopril and 233 or 64% (95% CI 59.1, 68.9) for metformin met at least 60% of all subcriteria. The mean overall quality score in 2008 was 62% (sd=21) for lisinopril and 59% (sd=21) for metformin while in 2001 the means ranged from 51% to 55% for four different study medications. Data on individual criteria comparing 2001 and 2008 and including only pharmacies that did dispense leaflets indicate that there were improvements in 2008 in providing specific information about drug name and indications, contraindications, precautions, adverse reactions, and general

information. However, CMI evaluated in 2008 had lower adherence to "directions about how to use, monitor and get the most benefit" than in 2001, due to increased emphasis in 2008 on information about how to monitor medications for safety and effectiveness. Importantly, there were lower levels of adherence in 2008 to the formatting criterion "information is readily comprehensible and legible", which is focused on how information is formatted and how difficult the CMI leaflets are to read and understand. Only 8% of CMI in 2008 had at least 60% of possible points for meeting criteria on comprehensibility and legibility.

The CMI leaflets that were provided to the simulated patient shoppers ranged from 33 words to 2,482 words. The total word count among leaflets that met more than 80% of the content quality criteria differed by more than 1000 words, indicating considerable variability in the efficiency and conciseness with which information is presented.

A total of 212 consumers evaluated six CMI leaflets each.   The same Consumer Evaluation Form as used in 2001 was used in this study. Comparison of the 2001 and 2008 consumer evaluations indicated overall improvements. In all, 56% of 2001 leaflets and 71% of 2008 leaflets had at least 60% of total possible points. Of concern, however, is that the items that were most negatively scored in the 2001 study (print size, line spacing, and ease of reading) continued to be scored lowest with mean scores that are nearly identical in the two studies.

Limitations:

Results of this study cannot be generalized to information provided by excluded pharmacy outlets such as mail order pharmacies. The consumer evaluators were not selected by a random sampling procedure and the results of their evaluations cannot be generalized to the broader population of consumers who receive Consumer Medication Information with their prescriptions. Furthermore, in the expert evaluation process, the weight assigned to each subcriterion was equal, implying equal importance in evaluating the quality of CMI.   The question of the relative importance of content provided to consumers is currently an unresolved issue, as is the importance of specific formatting and legibility features on patient comprehension. Finally, content was evaluated only in terms of presence, but not in terms of avoidance of unnecessary information. The amount of redundant information in CMI as well as the presentation of clinically irrelevant information, which result in information overload, should be examined. Given concerns with "information overload," the focus of future research should be on the relative importance of content criteria and its effect on patient comprehension and information recall.

Results of the 2008 study continue to point to great variability from pharmacy to pharmacy in the content and quality of CMI distributed. With an essentially voluntary effort, such variability might be expected. The lack of transparency of how information is selected by publishing

companies and how pharmacies determine alterations made complicates the identification of specific causes of variability.

Conclusions:

While the percent of content criteria met by leaflets has increased over that found in 2001, information about the use of medications and how effectiveness and safety should be monitored is lacking. In addition, even though the CMI examined identified only a few publishers, there was considerable variability in both the amount of information and the formatting of information presented.   Comparison of 2001 and 2008 on adherence to formatting criteria, which is crucial to making information comprehensible and readable, indicates that no improvement has taken place in 7 years in meeting these quality criteria. Beginning with the *Action Plan for the Provision of Useful Prescription Information* presented to the Secretary of the Department of Health and Human Services in 1996, continuing with the 2001 evaluation of the quality of written prescription information provided nationwide to consumers, to the 2006 FDA document *Guidance: Useful Written Consumer Medication Information (CMI)*, the provision of "useful" written information has emphasized the importance of legibility and comprehensibility to the usefulness of the information provided. Findings from this study indicate the ongoing need for more uniform, "user-friendly", concise and clinically relevant written consumer medication information.