Statement of Consumer Reports,
an independent, non-profit organization.
By Doris Peter, PhD, Associate Director, Consumer Reports Health Ratings Center

Before the Senate Aging Committee hearing entitled:
"Protecting Seniors from Medication Labeling Mistakes"
December 11, 2013

Thank you for this opportunity to speak on the consumer perspective in making Patient Medication Information more effective. Patient Medication Information (or PMI) is the new consumer drug information communication device that FDA has proposed, which aims to replace all other forms of drug information targeted at consumers (e.g. Medication Guides, Patient Package Inserts, Consumer Medication Information).[1]

According to the IOM report, "Preventing Medication Errors", approximately 1.5 million preventable adverse drug events (ADEs) occur each year. Of these, more than 500,000 occur in outpatient settings, costing $1 billion each year.[2] In consumers who are age 65 and older, it is estimated that ADEs cause approximately 100,000 emergency hospitalizations each year.[3]

Health literacy is an important factor in reducing the amount of harm consumers experience with regard to ADEs. For example, studies have shown that consumers with lower literacy are at greater risk for errors in dosing and administration.[4] Older adults can have a number of challenges related to health literacy: more than 70 percent of consumers over age 60 have trouble using print materials; 80 percent have trouble using forms and charts and about 70 percent have trouble interpreting numbers and performing calculations.[5] In addition, seventy-five percent of consumers age 65 and older regularly take a prescription drug, and those consumers take, on average, almost six prescription drugs at one time.[6] PMI must also be a comprehensive information source, since, according to Consumer Reports' research, about 30 percent of older consumers reported that they did not have a conversation with their physician or pharmacist about side effects when starting a new drug.[7] Therefore it is critical that PMI address these concerns and

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[1] http://www.fda.gov/drugs/newsevents/ucm219716.htm; Accessed December 9, 2013.
[2] Institute of Medicine. Preventing Medication Errors. Aspden P, Wolcott J, Bootman L, Cronenwett LR (eds). Washington D.C., National Academy Press, 2006.
[3] Budnitz et al., 2011. Emergency hospitalizations for adverse drug events in older Americans. NEJM. 365:2002. http://www.nejm.org/doi/full/10.1056/NEJMsa1103053
[4] Standardizing Medication Labels: Confusing Patients Less, Workshop Summary; http://www.iom.edu/~/media/files/activity%20files/publichealth/healthliteracy/commissioned%20papers/improving%20prescription%20drug%20container%20labeling%20in%20the%20united%20states.pdf
[5] National Library of Medicine - Health Literacy. http://nnlm.gov/outreach/consumer/hlthlit.html. Accessed December 6, 2013.
[6] Consumer Reports Prescription Drug Tracking Poll #5; July 2013. Available upon request.
[7] Ibid.

that it is tested to ensure that the content (in addition to format) adequately addresses the needs of consumers, including older consumers and their caregivers.

Consumers Reports[8] is a non-profit organization, and through our Best Buy Drugs Project,[9] we create and disseminate unbiased information about the comparative effectiveness, safety and cost of prescription and over-the-counter medications. We have conducted our own consumer research through national annual surveys of consumers on their perspectives on the use of prescription and over-the-counter medications.[10] This research, taken together with our experience and the research and experience of others, has informed Consumers Reports' recommendations regarding the development and dissemination of PMI.

As an overarching theme, **PMI content and format must be evidence-based, patient-centered, and transparent**. **This is an opportunity for FDA to make an enormous impact on the ability of consumers to participate in their healthcare and transfer some of the power of knowledge to the consumer**. Consumers are at a disadvantage (compared to the FDA, the drug industry and prescribers/pharmacists) in terms of their knowledge and access to information that can help them better manage their care. We urge FDA to provide consumers with the information (both in terms of content and format) that has been shown, in controlled clinical trials with consumers, to promote better decision making. **Currently, important information that can improve the outcomes of patients (in terms of both benefit of treatment, and safety) is being intentionally withheld from consumers.**

Consumer Reports urges FDA to adopt our recommendations below:

- **Consumers need (and can understand) quantitative information about the benefits and risks of a drug.** There is an evidence-based approach to presenting this information to consumers -- the Drug Facts Box -- developed by Drs. Lisa Schwartz and Steven Woloshin. The Drug Facts Box is a one-page table that summarizes the benefits and harms for each use of a drug (an example is provided on the last page of this document).[11] This approach has been carefully studied, including through national, randomized trials. These studies have shown that most consumers understand the information presented in the Drug Facts Box and

[8] Consumer Reports is a nonprofit membership organization chartered in 1936 to provide consumers with information, education, and counsel about goods, services, health and personal finance. Consumers Union's publications have a combined paid circulation of approximately 8.3 million. These publications regularly carry articles on Consumers Reports' own product testing; on health, product safety, and marketplace economics; and on legislative, judicial, and regulatory actions that affect consumer welfare. Consumers Reports' income is solely derived from the sale of Consumer Reports®, its other publications and services, fees, noncommercial contributions and grants. Consumers Union's publications and services carry no outside advertising and receive no commercial support.

[9] www.ConsumerReportsHealth.org/BestBuyDrugs; information provided free to the public; funded in part by the Attorney General Consumer & Prescriber Education Grant Program.

[10] Consumer Reports Prescription Drug Tracking Poll #5; July 2013. Available upon request.

[11] Schwartz, LM and S Woloshin. 2013. PNAS. 110 (Suppl 3); http://www.pnas.org/content/110/Supplement_3/14069.full. Accessed December 8, 2013.

that it improves decision-making.[12,13] In fact, FDA's own Risk Communication Advisory Committee[14] and Congress (in the Affordable Care Act) [15] supported FDA's consideration of the Drug Facts Boxes. FDA, however, has not decided to implement the boxes as part of the PMI process. Importantly, FDA's own work in this area has identified that "fear of potential side effects is the single greatest deterrent from filling and taking prescription drugs."[16] The FDA report goes on to cite that, if consumers do fill the prescription, the long list of potential adverse effects keeps some from taking the drug. Then, on the other extreme, for some consumers the long lists result in ignoring the potential adverse effects, or missing important ones that are buried in the long lists. In addition, results from FDA focus groups underscore the point that consumers feel that they need to be involved in the process of weighing a drug's benefits and harms.[17] Providing consumers with quantitative information about the potential benefits and harms (rather than a long list of adverse events that are out of context) will aid consumers in their decision to take a prescription medication, or to not take it, but for reasons based on fact rather than on fear.

- **PMI needs to include dosing information; consumers want (and need) dosing information.** The current FDA proposal for PMI does not include the approved dosing information. However, patients characterize dosing information as "very important" and rank it second only to approved uses among the drug information items they need.[18] In another study, dosing errors were found to be the most common medication error associated with death[19] and in a study of adverse drug events in patients 65 years and older, almost two-thirds of hospitalizations were caused by unintentional overdoses.[20] In a database collected by Consumer Reports of consumer-reported harm related to drugs, 40 percent of reports were related to dosing errors and more than 12 percent were due to problems with packaging, labeling, or complicated or incomprehensible instructions. [21] In other

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[12] Schwartz SL and Woloshin, S., 2011. Communicating uncertainties about prescription drugs to the public: A national randomized trial. Arch Intern Med 171(16):1463–1468. http://www.ncbi.nlm.nih.gov/pubmed/21911629

[13] Schwartz et al., 2009.Using a drug facts box to communicate drug benefits and harms: Two randomized trials. Ann Intern Med 150 (8):516–527. http://www.ncbi.nlm.nih.gov/pubmed/19221371

[14] http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM152593.pdf. Accessed December 8, 2013.

[15] Patient Protection and Affordable Care Act. Pub. L, No. 111-148, Section 3507 (Mar. 23, 2010).

[16] Prescription Drug Risk and Benefits, Focus Group Reports (FDA); http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM312395.pdf. Accessed December 6, 2013.

[17] Consumer Perceptions of Prescription Drug Communications, Focus Group Reports (FDA); http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM312767.pdf. Accessed December 9, 2013.

[18] A survey of package insert use by patients, 2005. http://paint-consult.com/de/publikation/pdf/PAINT-Consult_package_inserts_use_patients.pdf. Accessed December 6, 2013.

[19] Phillips et al., 2001. Retrospective analysis of mortalities associated with medication errors. Am J Health System Pharm; 58(19):1835. http://www.ncbi.nlm.nih.gov/pubmed/11596700

[20] Budnitz et al., 2011. Emergency Hospitalizations in for Adverse Drug Events in Older Americans. NEJM. 365: 2002. http://www.nejm.org/doi/full/10.1056/NEJMsa1103053

[21] Internal Consumer Reports database; summary information available upon request.

countries, the usual dosages can be found as part of the patient leaflets,[22,23] but not the consumer medical information (CMI) published here in the United States.[24] In addition to providing key information that consumers need to stay safe, providing dosing information can help alert consumers to other prescribing errors and potential unsupported off-label use of drugs (by noting any inconsistencies in the dosing indicated in the PMI compared with the label on the prescription drug container).

- **PMI should not be based on the professional package insert for each drug; package inserts are inconsistent and not timely.** The FDA position is to base PMI on the professional package insert. However, it is widely known that package inserts can contain errors, are often not up-to-date, and that they can be inconsistent across drugs in the same class, and lack consistency across brand and generic versions of the same drug.[25,26] Therefore, PMI that is based on inconsistent package inserts will generate PMI that is inconsistent across classes and between brand and generic drugs. There is also evidence that it can take years or even decades for important safety information to be published in the package insert.[27] Therefore consumers will not have the most accurate and up-to-date information if PMI is based on the package insert.

- **Manufacturers should not author PMI** -- Virtually every major pharmaceutical company has either been fined or is under investigation by the Department of Justice. Companies have either pled guilty or paid a fine to resolve allegations of: illegal promotion of drugs, failing to report safety problems, and financial fraud.[28] The pharmaceutical industry currently ranks 7th out of 11 industries in terms of consumer trust, according to a 2012 study.[29] Furthermore, FDA's own work in this area has shown that consumers mistrust the pharmaceutical industry based on consumers' feeling that the industry is more concerned with profit than with safety.[30] Therefore, to ensure the generation of objective, unbiased PMI, and to ensure consumer confidence and trust in the content, the creation of PMI should be delegated to an independent, unbiased third party other than that of the drug manufacturers.

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[22] Patient leaflet for Celebrex in Australia: http://www.mydr.com.au/medicines/cmis/celebrex-capsules; Accessed December 9, 2013

[23] Patient leaflet for Celebrex in the United Kingdom: http://www.medicines.org.uk/emc/pdfviewer.aspx?isAttachment=true&documentid=4079

[24] Consumer Medication Information for Celebrex (United States); http://www.nlm.nih.gov/medlineplus/druginfo/meds/a699022.html. Accessed December 9, 2013

[25] Panagiotou et al., 2011. Different black box warning labeling for same-class drugs. J Gen Intern Med. 26(6):603. http://www.ncbi.nlm.nih.gov/pubmed/21286838

[26] Duke et al, 2013. Consistency in the safety labeling of bioequivalent drugs. Pharmacoepidemiol Drug Saf. 22(3):294. http://www.ncbi.nlm.nih.gov/pubmed/23042584

[27] http://www.propublica.org/article/tylenol-mcneil-fda-use-only-as-directed

[28] http://projects.propublica.org/graphics/bigpharma. Accessed December 6, 2013.

[29] http://trust.edelman.com/trust-and-health/. Accessed December 6, 2013

[30] Prescription Drug Risk and Benefits, Focus Group Reports (FDA); http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM312395.pdf. Accessed December 6, 2013.

Lunesta

(compared to sugar pill) to reduce current symptoms for adults with insomnia

What this drug is for:

To make it easier to fall or to stay asleep

Who might consider taking it:

Adults age 18 and older with insomnia for at least 1 month

Recommended monitoring:

No blood tests, watch out for abnormal behavior

Other things to consider:

Reduce caffeine intake (especially at night), increase exercise, establish a regular bedtime, avoid daytime naps

How long has the drug been in use?

Lunesta was approved by FDA in 2005. As with all new drugs we simply don't know how its safety record will hold up over time. In general, if there are unforeseen, serious drug side effects, they emerge after the drug is on the market (when a large enough number of people have used the drug).

Lunesta Study Findings

788 healthy adults with insomnia for at least 1 month – sleeping less than 6.5 hours per night and/or taking more than 30 minutes to fall asleep – were given LUNESTA or a sugar pill nightly for 6 months. Here's what happened:

What difference did LUNESTA make?	People given a sugar pill	People given LUNESTA (3 mg each night)
Did Lunesta help?		
LUNESTA users fell asleep faster (15 minutes faster due to drug)	**45 minutes to fall asleep**	**30 minutes to fall asleep**
LUNESTA users slept longer (37 minutes longer due to drug)	**5 hours 45 minutes**	**6 hours 22 minutes**
Did Lunesta have side effects?		
Life threatening side effects:		
No difference between LUNESTA and a sugar pill	**None observed**	**None observed**
Symptom side effects:		
More had unpleasant taste in their mouth (additional 20% due to drug)	**6%**	**26%**
More had dizziness (additional 7% due to drug)	**3%**	**10%**
More had drowsiness (additional 6% due to drug)	**3%**	**9%**
More had dry mouth (additional 5% due to drug)	**2%**	**7%**
More had nausea (additional 5% due to drug)	**6%**	**11%**