



Statement of Consumers Union
The Independent, Non-Profit Publisher of Consumer Reports
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To the FDA Risk Management Advisory Committee
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Consumer Union¹ urges **faster action** on the development of simple, non-duplicative, objective, useful prescription drug safety information for consumers.

The health community, with little help from Congress, has spent about 360 months trying to figure out how to get honest, objective safety information to patients. By comparison, between Pearl Harbor and VJ Day, our parents won the war in the Pacific in 45 months. We should all be embarrassed. This continual delay is unacceptable.

We are in the process of conducting a national poll on what consumers want and expect from drug labeling information, and hope to have results soon to make public. But from our preliminary work on this issue, we are convinced that there is overwhelming interest by American consumers in clear, simple information on safety (which includes knowing how long a drug has been on the market), interactions, side effects, and comparative effectiveness.

The key to an effective label is KISS: Keep It Simple.

Health literacy is defined in HHS's *Healthy People 2010* as

¹ Consumers Union, the nonprofit publisher of *Consumer Reports*, is an expert, independent organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. To achieve this mission, we test, inform, and protect. To maintain our independence and impartiality, Consumers Union accepts no outside advertising, no free test samples, and has no agenda other than the interests of consumers. Consumers Union supports itself through the sale of our information products and services, individual contributions, and a few noncommercial grants.

The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.

Unfortunately, by that definition about 3 in 10 Americans are illiterate. As the Institute of Medicine's recent study on the issue concluded:

“About 90 million adults, an estimate based on the 1992 National Adult Literacy Survey (NALS), have literacy skills that test below high school level (NALS Levels 1 and 2). Of these, about 40–44 million (NALS Level 1) have difficulty finding information in unfamiliar or complex texts such as newspaper articles, editorials, medicine labels, forms, or charts. Because the medical and public health literature indicates that health materials are complex and often far above high school level, the committee notes that approximately 90 million adults may lack the needed literacy skills to effectively use the U.S. health system. The majority of these adults are native-born English speakers. Literacy levels are lower among the elderly, those who have lower educational levels, those who are poor, minority populations, and groups with limited English proficiency such as recent immigrants.”

The problem of health illiteracy (coupled with too many confusing choices) can be seen in the recent GAO report describing how Medicare Part D Annual Notice of Change (ANOC) information is too complex for many to understand.² That may explain why, despite major changes in premiums and drug coverage, only one million out of seventeen million Part D plan enrollees switched in 2008. For many, it is all just too much to handle. A new report out of the National Bureau of Economic Research³ shows the same problem in Medigap Supplemental Insurance policies, despite the fact that those policies have been drastically simplified. Even though two insurance policies are identical, the complexity of terms and the influence of advertising and salespersons have caused many seniors to waste a thousand dollars or more on the more expensive one. The report is another testament to the need for radical simplification in all health information.

Therefore, whatever information you decide upon, the key is making sure it is at roughly at the 6th grade reading level.

What is exciting news, and what we hope you will immediately consider are the result of the work on “Drug Facts Boxes” by Doctors Lisa Schwartz, Steven Woloshin, and H. Gilbert Welsh, announced by the *Annals of Internal Medicine*. Their work shows that a simple comparative box, with hard numbers, is more understandable by all segments of our society than are prose written descriptions. **The “Drug Facts Box” findings are so dramatic that (unless someone has evidence to the contrary today) we urge you and the FDA to call for their immediate use in direct to consumer print advertising, on**

² GAO-09-4, “Medicare Part D: Opportunities Exist for Improving Information Sent to Enrollees and Scheduling the Annual Election Period,” December, 2008.

³ “Price Variation in Markets with Homogeneous Goods: The Case of Medigap,” Nicole Maestas et al., NBER Working Paper Series 14679, January, 2009.

drug containers, and in inserts. Attached is a sample Drug Facts Box from an earlier paper⁴ by the same researchers.

The type of simple, easy-to-read information that is displayed in a Drug Facts Box is the same type of simple chart we at Consumers Union use in our Best Buy Drugs program that makes it easy for consumers to see objective scientific results about medicines and then compare it with recent average national retail prices (example attached). Our program is very popular, and has tens of thousands of website hits per month. Obviously, many are finding it easy to use. We hope this type of objective, simple information could be rapidly applied to printed DTC, to labeling, and to inserts. On labels and in printed materials, ideally there would be a simple Drug Facts Box, followed by a somewhat more detailed but still simple language description, and then the full description that would be of use to physicians and to those patients who really want the to know all the details.

While we believe a chart with numbers can help cut through the clutter and confusion, for many of our residents, it is still far too complex. We hope you will look at the recent Emory School of Public Health, AHRQ and RWJ Foundation-assisted paper and ‘slide show’ entitled “**PILL: Pharmacy Intervention for Limited Literacy.**”⁵ The work documents how terribly difficult it is for many of our fellow citizens to understand the simplest of instructions; it offers the idea of ‘picture’ or ‘pill card’ instructions. Attached is a sample. Since many of those who are illiterate are masters at hiding the fact, in some areas, we may want pharmacists to always offer such a ‘diagram’ in addition to the more detailed information. Pharmacy reimbursement rates may need to be adjusted, but certainly in some areas where we know there is higher illiteracy, it could pay off in much better health outcomes.

Finally, as for the question of the use of PPIs, MGs, and CMI, we hope that there will be **one really good piece** of information per prescription. Multiple papers that don’t say the same thing confuse. Multiple papers that say the same thing are wasteful.

⁴ Med Decis Making OnlineFirst, September 14, 2007 as doi:10.1177/0272989X07306786, “The Drug Facts Box: Providing Consumers with Simple Data on Drug Benefit and Harm,” Lisa Schwartz, et al.

⁵ “PILL: Pharmacy Intervention for Limited Literacy,” Sunil Kripalani, Kara Jacobson, et al., AHRQ Publication No. 07(08)-0051-1-EF, October 2007, jContract No. 290-00-0011.