ConsumersUnion
POLICY & ACTION FROM CONSUMER REPORTS

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Docket No. FDA-2014-N-0168
Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements

To Whom It May Concern:

Consumers Union's Safe Patient Project opposes the Food and Drug Administration's (FDA) proposed rule to study limiting the major statement in television and radio ads about pharmaceuticals to contain some, but not all, of a drug's major side effects. The FDA seeks to determine the impact of limiting the risks presented in direct to consumer (DTC) ads to side effects that are "serious and actionable." In addition to looking at ads with a shorter list of side effects, the study will examine the impact of a version of ads that would contain a statement that more risks exist than are disclosed in the ad. This version is referred to as "limited risks plus disclosure."

Consumers Union has consistently opposed DTC advertising for both drugs and medical devices because they are often misleading, drive up health care costs, and lead to needless suffering by improperly characterizing a drug's benefits, risks and targeted population. When drug companies elect to advertise their products directly to consumers, companies have an obligation to accurately characterize the drug's risks and benefits. Any limitations on the information contained in DTC ads would be an inadequate portrayal of a drug's safety. Only New Zealand and the United States allow DTC pharmaceutical advertisements.

A drug's side effects are usually rattled off at warp speed during a television or radio ad. While consumers might be alarmed at the list of reactions that have been documented, the FDA's concern should not be whether an ad negatively affects consumers' perception of the drug. On the contrary, these ads should motivate consumers to ask their doctor about all possible side effects of a drug before taking it. Doctors can help patients determine if they are vulnerable to any of the side effects identified.

According to the FDA, the length of a "major statement" (statement of side effects) can be long and result in reduced understanding of the risks by the consumer and minimize the most important risks. The proposal seeks to study how to limit this list of risks but fails to define "serious and actionable" - this should be publicly clarified prior to doing such a study.

The FDA proposal acknowledges concerns that the current format for broadcast ads leave out important information. A 2006 presentation by FDA's Division of Drug Marketing, Advertising and Communications indicated that the most common violation was inadequate risk information (82%); this proposal might lead to normalizing this inadequacy. Broadcast ads are currently allowed to include only the most important risk information—as long as the ads tell viewers or listeners how to get the full FDA-approved prescription information, which describes all of the

drug's risks. Our concern is that the FDA proposed study could lead to replacing the current requirement to reference where to get full drug/device information with a mere mention that there are more side effects.

According to the FDA's proposal, one possible outcome of the study is that it will show that providing limited risk information along with the disclosure statement that additional risks exist will improve consumer perception and understanding of serious and actionable drug risks.

In addition to our concerns about limiting information in broadcast ads, we believe the study as currently designed is flawed. It does not represent the way an average consumer would see or hear an ad; that is, one airing at arbitrary times on the TV or radio when a consumer's focus is not necessarily on the drug ad. In these situations, the length of possible risks or side effects alone is likely to get the attention of someone casually watching/listening to an ad, which is very different from the pilot study design. The study should at least simulate the actual consumer experience.

In addition we urge the FDA to apply the current standards for drugs in DTC ads to medical devices. Currently medical device companies are not held to the same standards as drug companies with regard to ads. By contrast, FDA's device regulations do not contain specific requirements regarding the content of advertisements for restricted medical devices. At a hearing in 2008 Consumers Union testified that current rules requiring consumer drug advertisements to provide balance between a medication's benefits and risks should be extended to cover medical devices. Medical device advertising is becoming more prevalent and standards to protect consumers' interests need to be in place.

Consumers Union also advocates for all broadcast ads to include information about FDA's MedWatch program. We have previously petitioned FDA to require all television drug ads to list the MedWatch toll free number and website to report serious adverse events. In 2008, we raised this issue again to a Congressional Committee, citing results from a national poll by *Consumer Reports* National Research Center that found that "among consumers who have ever taken a prescription drug, one in six (16 percent) had experienced a serious drug side effect at some time in their life, but only 35 percent of consumers polled were aware that serious side effects can be reported to the FDA. Yet
Americans were very familiar with drug advertising. Eight in 10 (81 percent) said they had seen or heard an advertisement for prescription drugs within the past 30 days. Among them, virtually all – 98 percent – viewed an ad on television. When asked if they think prescription drug advertising should include information to report an adverse drug reaction to the FDA, 87 percent of consumers said TV ads should contain this information."

In conclusion, we think this study is unnecessary and could lead to consumers getting less information about a drug than is currently required.

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