Experience Is a Gloomy Lantern That Does Not Even Illuminate Its Bearer

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In reply

It is unlikely that direct-to-consumer ads will be allowed any time soon. This underscores the need to provide physicians and patients with independent, balanced information about the benefits, harms, and uncertainties of Food and Drug Administration (FDA)-approved prescription drugs. A number of groups have undertaken such efforts, including academicians, policy groups, and consumer organizations. We have proposed that the FDA itself produce a standardized 1-page summary, called drug facts boxes, to provide the necessary information. On the basis of a body of evidence, including national randomized trials demonstrating that drug facts boxes improve patient decision making,1 the FDA’s Risk Communication Advisory Committee unanimously recommended that the FDA adopt the Drug Facts Boxes as the standard format for all communications. Unfortunately, the FDA has made no steps toward implementing this recommendation. The rapid uptake of many newly approved drugs—often with minimal benefits over placebo and uncertain safety records—suggests physicians may also overinterpret the meaning of FDA approval in terms of drug efficacy and safety. Physicians clearly need better drug information now.

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