

The FDA recommended a registry, because even though the drug was for treating short bowel syndrome (which is not particularly relevant to cancer), it was the case that the drug (teduglutide) is a *growth factor*, and that some evidence suggests that administering growth factors may increase the risk for cancer (355,356). The FDA reviewer provided the following decision tree, which was recommended for including in the package label. In short, the package label should state that the drug should not be used in patients with gastrointestinal cancer, and that for patients with other types of cancer, the drug should be used only after a risk–benefit analysis.

c. *Dear Healthcare Professional Letters*

Dear Healthcare Professional letters are one form of risk minimization tool. These letters are issued in the postmarketing context.

The *Dear Healthcare Professional* letter fits into a broader context, namely that of risk

minimization tools. These tools include: (1) Patient package insert; (2) Medication guide; (3) Dear Healthcare Professional letter; (4) Prescription sticker attached to the prescription; (5) Patient information leaflet; (6) Consent forms; and (7) Limiting number of pills in each bottle (357,358).

The medication guide must conform to the CFR (21 CFR §208), must be provided by the pharmacist to the patient with every new prescription and with every refill (359), and must be written in nontechnical language (360). Patient package inserts are also mandated by the FDA, at least for oral contraceptives (21 CFR §310.501) and for estrogens (21 CFR §310.515). The patient information leaflet is generally written by a party other than the drug manufacturer. Consent forms are described in Chapter 30. Prescription stickers, which are written by the manufacturer in collaboration with the FDA (361), have been issued for isotretinoin, fentanyl, clozapine, thalidomide, alosetron, mifepristone, dofetilide, bosentan, and oxybate (362).

³⁵⁵DiVall SA, Radovick S. Growth hormone and treatment controversy; long term safety of rGH. *Curr. Pediatr. Rep.* 2013;1:128–32.

³⁵⁶Ibrahim YH, Yee D. Insulin-like growth factor-I and cancer risk. *Growth Horm. IGF Res.* 2004;14:261–9.

³⁵⁷U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for industry. Development and use of risk management action plans; March 2005 (27 pp.).

³⁵⁸Lee LY, Kortepeter CM, Willy ME, Nourjah P. Drug-risk communication to pharmacists: assessing the impact of risk-minimization strategies on the practice of pharmacy. *J. Am. Pharm. Assoc.* 2008;48:494–500.

³⁵⁹Lee LY, Kortepeter CM, Willy ME, Nourjah P. Drug-risk communication to pharmacists: assessing the impact of risk-minimization strategies on the practice of pharmacy. *J. Am. Pharm. Assoc.* 2008;48:494–500.

³⁶⁰U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for industry. Drug safety information—FDA’s communication to the public; March 2007 (17 pp.).

³⁶¹Food and Drug Administration. CDER 2002 report to the nation: improving public health through human drugs. Rockville, MD: Food and Drug Administration.

³⁶²Lee LY, Kortepeter CM, Willy ME, Nourjah P. Drug-risk communication to pharmacists: assessing the impact of risk-minimization strategies on the practice of pharmacy. *J. Am. Pharm. Assoc.* 2008;48:494–500.