confusion with Lanoxin® (heart medicine) and Levoxine® (thyroid medicine) (327,328). Patients were receiving Lanoxin, when they should have been receiving Levoxine. The confusion was accentuated by the fact that the dosages were the same (0.125 mg). The medication errors and injuries were reported to the FDA using MedWatch forms and, as a result, the name of Levoxine was changed to Levoxyl® (329).

b. The MedWatch Form and the CIOMS I Form

A reproduction of the MedWatch form is shown below. The form can be mailed to the FDA or transmitted by way of the internet. The reproduced form is a slightly simplified version of the real form. The following discloses the time-line of how MedWatch forms influence the regulatory process. The FDA receives reports of adverse drug events primarily from physicians and pharmacists who submit them on MedWatch forms, as well as from information supplied by pharmaceutical companies.

After a sufficient number of reports, including reports published in medical journals, have accumulated implicating the drug, the division of the FDA that had initially reviewed and approved the drug examines the newly acquired data on AEs (330). If the FDA reviewers agree that the data are compelling enough to require regulatory action, the FDA notifies the manufacturer and requests the action. This action may take the form of a change in the package insert, a *Dear Healthcare Professional* letter, or withdrawal of the drug from the market. In Great Britain, the equivalent of the MedWatch form is the Yellow Card (331). The Yellow Card is administered by the Medicines and Healthcare products Regulatory Agency (MHRA) (332), located in London, UK. The MHRA is the British equivalent of the US FDA (333). The Yellow Card is not used in clinical trials, but by the public and healthcare professionals in the postmarketing context (334,335). In Great Britain, the CIOMS I form is used for reporting by manufacturers of suspected ADRs to regulatory authorities, but it is not used by healthcare professionals or patients. The FDA allows receipt of CIOMS forms in lieu of MedWatch forms (336).

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