

Drug Recall: Patient Safety Comes First



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Prescribing drugs for the treatment of various types of diseases is no longer considered to be 100 % safe. Patients being treated for a certain disease end up in some cases either with deteriorating health or with the appearance of symptoms for a newly developed disease. These health risks associated with once being as FDA approved drugs raises the public's alertness. The FDA has been releasing several alerts over the year about drugs that require change of doses, being contaminated or having fatal risk factors



(FDA). The list of drugs with related health risks increases year after year; and here's a short summary for some of the drugs with their risk factors dating from 2000 till now:

- **Depakote/Depakene/Depacon:** drugs used as valproate therapy in patients with urea cycle disorders (UCD). Health risks: reports of hyperammonemic encephalopathy upon initiating this therapy.
- **Alosetron Hydrochloride:** trade name: Lotronex: used only in women with irritable bowel syndrome (IBS). Health risks: reports of associated constipations resulting in serious sequelae in addition to reports of ischemic colitis.
- **Phenylpropanolamine Hydrochloride (PPA):** used in prescription and over-the-counter cough and cold drugs. Health risks: high risk of hemorrhagic stroke.
- **Troglitazone:** trade name: Rezulin: used as an antidiabetic and anti-inflammatory drug for patients with diabetes mellitus type 2. Health risks: serious toxicity to the liver.
- **Rosuvastatin:** trade name: Crestor and simvastatin; trade name: Zocor: used for controlling hypercholesterolemia. Health risks: myopathy when given with a higher dose and when administered with other drugs. Simvastatin is also associated with a genetic predisposition toward simvastatin-related myopathy.
- **Imatinib Mesylate:** trade name: Gleevec: used in the treatment of multiple cancers including Chronic Myelogenous Leukemia (CML). Health risks: reported cardiac events such as severe congestive heart failure and left ventricular dysfunction.
- **Tolvaptan:** trade name Samsca: treats hyponatremia which is associated with congestive heart failure, SIAD-syndrome of immoderate antidiuresis and cirrhosis. Health risks: can cause possible fatal liver injury to patients with autosomal dominant polycystic kidney disease (ADPKD).
- **Dalfampridine:** trade name: Ampyra: improve walking in patients with multiple sclerosis. Health risks: increased risks of seizures in MS patients and patients with renal kidney impairment.
- **Brentuximab Vedotin:** trade name: Adcetris: used to

treat Hodgkin lymphoma and anaplastic large cell lymphoma.

Health risks: can cause progressive multifocal leukoencephalopathy (PML) which is a rare fatal brain infection and lung toxicity if administered with the cancer drug bleomycin.

This is a short list but greatly calls attention to the serious health risks associated with certain powerful drugs. In the developed countries, mainly in the US, the FDA plays a substantial role in identifying the associated health risks with drugs released in the market and cooperates with the manufacturing pharmaceuticals to ensure that these drugs hold the minimal amount of risk unto patients. Once a drug is identified to have hazardous health risks or needs to have a reevaluation of its compositions, the FDA would demand a recall of this drug from the market and requests the given



Infos

Insolite: Les Pessimistes Plus Accros Aux Mails?

Les ingénieurs de la plateforme de marketing Contactually se sont amusés à décortiquer les contenus de 100 millions de conversations entretenues par mails. Ils en ont tiré une conclusion surprenante et plutôt utile pour les personnes à qui l'on reproche un excès de pessimisme. Il semblerait en effet que le pessimisme n'ait pas que des mauvais côtés. Cette propension à la négativité augmente la rapidité à écrire des mails, selon les conclusions de l'enquête. Les auteurs sont catégoriques: les pessimistes répondent 36% plus vite à leurs mails que leurs collègues plus optimistes. Les ingénieurs ont fait cette analyse en regardant le contenu des mails. Ils ont compté et trié les termes négatifs

modifications from the manufacturing pharmaceuticals.

At this point, the main question is: How will the consumers be informed of such drug recalls in order to ensure their safety and well-being?

Since 1993, Med Watch is the FDA safety information and adverse event reporting program where consumers would be alerted through newsfeeds, twitter or by email. Moreover, the FDA has its own direct means to inform the consumers about drug recalls; this is through podcasts, twitter, product recalls mobile phone application, newsfeeds and e-mail alerts. This is an example of what developed countries have achieved regarding patients' safety service.

On the other hand, Lebanon's contribution concerning this issue is very minimal and not very competent. All what is being done in Lebanon through the Ministry of Health is the release of drug recall lists attributed to each year on their website (MOPH). However, this is not enough, because consumers are being fully informed about these lists due to the lack of means similar to those used by the FDA mentioned earlier. Certain potential improvements can be easily implemented in Lebanon regarding this issue, and that is by starting a mobile phone application and by sending e-mail alerts to ensure the safety of the patients. Once these patients get informed about a certain drug recall, they will be able to avoid purchasing it and might as well return they already purchased drugs to avoid any further consequence on their health.