



June 7, 2010

Dear CEO,

All too often, US patients assume that if a licensed US pharmacy dispenses a prescription drug, then the drug must be FDA-approved. While this is true in most cases, many US patients continue to be put at risk when pharmacies fill prescriptions with unapproved drugs that have not been proven safe and effective by the Food and Drug Administration.

The health care and pharmaceutical industry share the common goal of providing people with life saving care and drugs. Unapproved drugs pose a grave danger to their users because they lack the dosage, regimen, and drug to drug interaction analysis necessary to be deemed safe by the FDA for public use. We encourage you and your healthcare staff to visit the FDA's website and view their warning video on unapproved drugs.

LegitScript is the leading source of information for patients, Internet users, physicians, businesses and other third parties who need to know if an Internet pharmacy is acting in accordance with the law and accepted standards of ethics and safety. We believe that any pharmacy, whether online or offline, should be aware of the safety risks, and ethical implications, involved with filling prescriptions with unapproved drugs, especially when an FDA-approved version is available.

LegitScript supports the FDA's Unapproved Drug Initiative which calls for the removal of unapproved drugs from the market place. The FDA utilizes a risk based enforcement process to determine which drugs pose the greatest threat to the public without imposing an undue burden on consumers or the market. The compliance policy enforcement process described by the FDA is as follows: 1) A statement that the FDA intends to use a risk-based approach to enforcement; 2) A request for voluntary compliance; 3) Notice of action in the Federal register; 4) The issuance of an untitled letter; 5) The issuance of a warning letter; and 6) Initiation of a seizure, injunction, or other proceeding. These steps can be avoided by the voluntary submission of medications to the FDA for approval.

As the purveyors of drugs, pharmacies and pharmaceutical distributors play an important role in providing life improving products to the public. As such it is vital to supply only the drugs that have been subjected to the rigorous FDA approval process. It is a fundamental responsibility of those who manufacture unapproved drugs to be aware of the potential harm that could result to patients who take them. As a result, LegitScript is reaching out to all those in the drug chain to inform them of their ethical legal responsibility toward patients, and to invite them to join our effort to educate the public about the dangers of unapproved drugs. This campaign praises the important work that drug companies are doing in the area of research and development. However, the ultimate goal of the campaign is to raise awareness of the dangers posed by unapproved drugs, and to get patients to understand that there is no need to subject themselves to unnecessary risks when an approved drug is available.

Additionally, LegitScript recognizes that in some cases, there may be concerns about the cost of FDA-approved drugs, as compared to unapproved drug versions. It is important to note that several manufacturers of FDA-approved drugs have implemented patient assistance programs to ensure access to these life-saving medications, regardless of economic status.

For the health and safety of the public, LegitScript encourages all manufacturers of unapproved drugs to take the necessary steps to drug approval and submit their products to the FDA. Pharmacies and distributors have the ability to change the unapproved drug market by encouraging drug manufacturers to seek FDA approval, and to refuse to fill prescriptions with unapproved drugs. Consumer protection is the public's right and your responsibility.

Sincerely,



John Horton  
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cc: Janet Woodcock, MD  
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