



MARCH 2021 REPORT

SAFETY-RELATED LABELING CHANGES TO PRESCRIPTION DRUGS IN THE U.S.

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WHY ARE WE REPORTING & HOW SHOULD YOU USE THIS INFORMATION?

Every day, the U.S. Food and Drug Administration (FDA) manages an enormous responsibility that most Americans may not know about. What is it? Well, we're referring to the constant changes to pharmaceutical drug labeling, often times due to new safety concerns or updates.

In fact, within a single year, hundreds of changes occur. All are changes that healthcare providers should be alerted to, but sometimes this may not be well communicated. Meanwhile, patients and consumers should know about these changes too, but may never know for many different reasons.

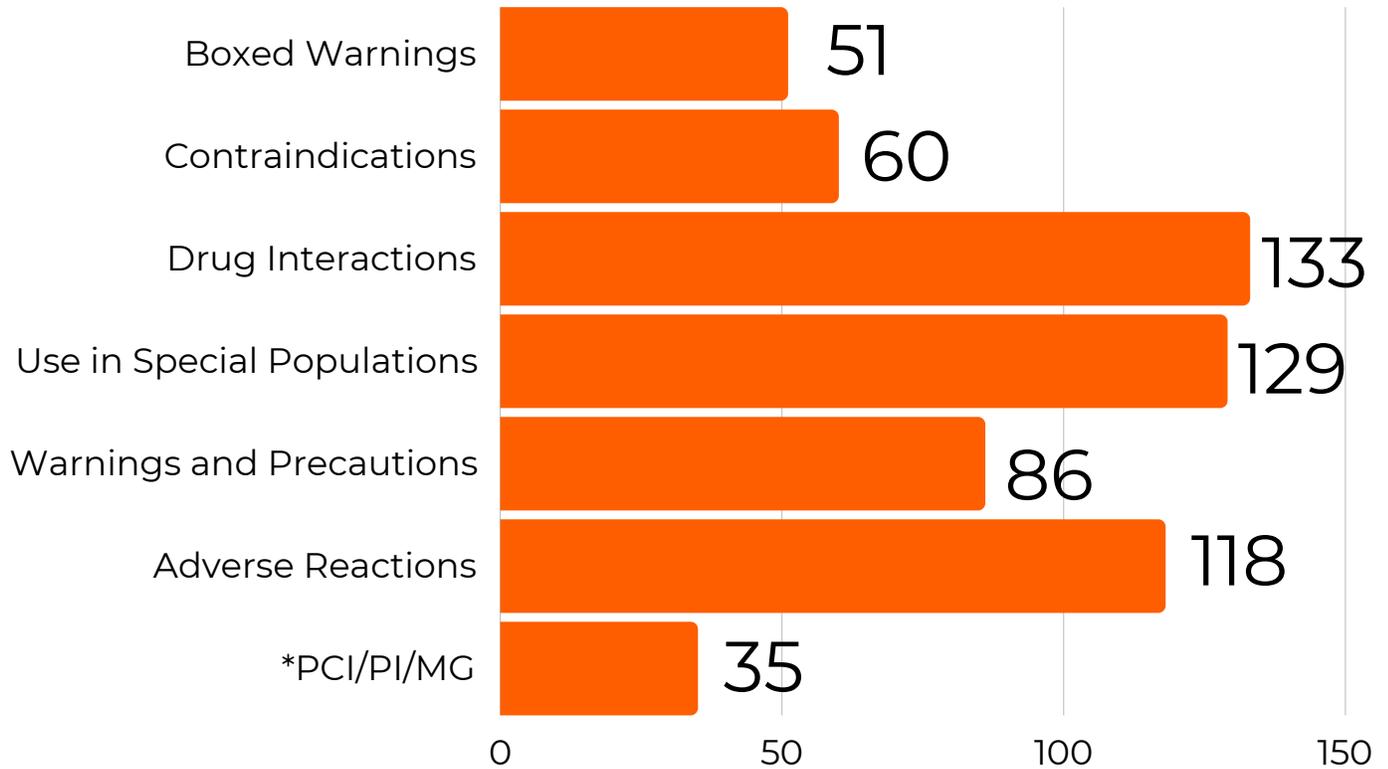
Those are the key reasons why our organization decided to develop these reports.

We want all safety-related labeling changes to be easily and transparently communicated to the general public, both healthcare providers and patients alike. Ultimately, we hope our reporting is informative and life-saving, given the vast majority of medications sold and marketed in the U.S. are associated with safety risks, some serious and life-threatening in nature.



TOTAL NUMBER OF CHANGES BY TYPE

There were 146 entries of safety-related drug labeling changes published by the FDA in March, impacting over 100 drugs.



Source: Drug Safety-related Labeling Changes (SrLC). US Food and Drug Administration Website.
Accessible at: <https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm>

*PCI/PI/MG = Patient Counseling Information/Patient Information/Medication Guide

QUICK COMMENTARY

From our observations, although Boxed Warning changes were not the most frequent changes, these labeling changes cannot be taken lightly because they are the most serious warnings that can be issued by the FDA. For the month of March, we noted that more than one drug had a Boxed Warning highlighting the risks for a number of concerning health outcomes. Examples included serious risks for addiction, abuse, misuse, life-threatening respiratory issues and even embryo-fetal toxicity, including fetal death. One drug with a change in March (Plavix), listed a warning that can only be managed if a person were to have a pharmacogenetics test ordered by their healthcare provider to determine if they would be a CYP2C19 gene poor metabolizer. Another drug (Onsolis) listed a potential risk of fatal overdoses in individuals but that would be dependent on how expressed the CYP3A4 gene was represented in their DNA. Currently, pharmacogenetics testing is not considered standard of care in every state.

DRUGS IMPACTED

- Actemra
- Actiq
- Acular LS
- Apadaz
- Arcalyst
- Auryxia
- Belbuca
- Belsomra
- Bunavil
- Bupivacaine Hydrochloride
- Butrans
- Cassipa
- Ceftin
- Ceftriaxone and Dextrose in Duplex Container
- Codeine Sulfate
- Conzip
- Cutivate
- Darzalex
- Darzalex Faspro
- Demerol
- Descovy
- Dilaudid
- Ditropan XL
- Dovato
- Duragesic-100
- Duragesic-12
- Duragesic-25
- Duragesic-50
- Duragesic-75
- Elmiron
- Exparel
- Fabrazyme
- Fentora
- Fioricet w/Codeine
- Firdapse
- Flagyl
- Flagyl ER
- Flagyl I.V. RTU in Plastic Container
- Fulphila
- Genvoya
- Glucagen
- H.P. Acthar Gel
- Helidac
- Hysingla ER
- Indocin
- Juluca
- Kadian
- Karbinal ER
- Keytruda
- Kyprolis
- Lamictal
- Lamictal CD
- Lamictal ODT
- Lamictal XR
- Lazanda
- Lobrena
- Lozol
- Lupron Depot- PED Kit
- Lynparza
- Methotrexate LPF
- Methotrexate Preservative Free
- Methotrexate Sodium Preservative Free
- Metro I.V. in Plastic Container
- Metronidazole
- Metronidazole in Plastic Container
- Morphine Sulfate
- Moxidectin
- MS Contin
- Mycobutin
- Myobloc
- Myrbetriq
- Neoprofen
- Ninlaro
- Novolog
- Novolog Flexpen

DRUGS IMPACTED

(continued)

- Novolog Flextouch
- Novolog Innolet
- Novolog Penfill
- Nucynta
- Nucynta ER
- Nutrestore
- Odefsey
- Olinvyk
- Onsolis
- Open ER
- Oxaydo
- Oxycodone Hydrochloride
- Oxycontin
- Padcev
- Patanase
- Picato
- Plavix
- Probuphine
- Pylera
- Roxicodone
- Roxybond
- Sandostatin LAR
- Sarclisa
- Sublocade
- Suboxone
- Subsys
- Subutex
- Symbyx
- Sympazan
- Thiola EC
- Tivicay
- Tivicay PD
- Triumeq
- Tyvaso
- Ultracet
- Uvadex
- Vasostrict
- Vemlidy
- Viltepso
- Viracept
- Vitrakvi
- Vivitrol
- Vyxeos
- Xanax
- Xanax XR
- Xtampza ER
- Zejula
- Ziac
- Ziextenzo
- Zohydro ER
- Zubsolv



NOTES

Read below for more information on the different types of drug labeling changes.

- **Boxed Warning:** These labeling changes may have occurred due to newly added boxed warnings, modifications to existing boxed warnings or boxed warnings now being removed from the labels of certain drugs.
- **Contraindications:** Per the U.S. National Library of Medicine, a contraindication is "a specific situation in which a drug, procedure, or surgery should not be used because it may be harmful to the person". Contraindications should be carefully followed.
- **Drug Interactions:** These labeling changes relate to circumstances where other pharmaceutical drug products may increase the frequency or severity of an adverse reaction, or a decrease in the effectiveness of the drug product.
- **Use in Special Populations:** These labeling changes will identify information and effects particularly of note for vulnerable or other specific populations (for example: pregnant women, lactating women, children, elderly, those with chronic conditions like kidney or liver impairment, or certain populations based on sex or race).
- **Warnings and Precautions:** This part of a drug's labeling will provide specific information about the frequency and severity of known adverse effects, including reactions that may require a medication is stopped from use in a given patient.
- **Adverse Reactions:** These labeling changes will reflect the most known and verified adverse effects found during clinical trials or reported by the public.
- **PCI/PI/MG (Patient Counseling Information/Patient Information/Medication Guide):** This is a collection of changes that relate to the labeling information healthcare providers should tell their patients (Patient Counseling Information) or updates to patient labeling information (Patient Information). May also address updates to a Medication Guide - a paper handout that is not written for every medication but, when available, should be provided to patients for their awareness on key medication use or safety information.

