FDA's Psychotropic Drug-Risk Guides Should be Mobile-Accessible to Avoid Harm

CCHR says consumers need to inform themselves of psychotropic drug risks through FDA Medication Guides but urges the FDA to make them mobile-friendly

CCHR, the mental health industry watchdog, says consumers need to inform themselves of psychotropic drug risks through FDA Medication Guides, but urges the FDA to make them mobile-friendly for fast access

LOS ANGELES, CALIFORNIA, UNITED STATES, November 14, 2022 /EINPresswire.com/ -- Citizens Commission on Human Rights (CCHR) advises consumers and parents to become better informed about psychotropic drug risks by accessing the Food and Drug Administration's online Medication Guides (Med Guides), designed to give consumers easy-to-understand information on drug side effects. This is because psychiatrists and doctors may not fully inform them of the documented risks. However, CCHR says the FDA should better service consumers by making the Med Guides mobile-friendly, as currently, they do not function correctly on mobile phones.

In the United States, 96% of the population has a cellphone, while individuals with smartphones have risen to 81%. At least 70% of internet access is through mobile phones.[1] The Guidelines need to be accessible on these.

Med Guides are usually paper handouts that come with many—but not all—prescription medicines. They contain risk information right up front and in language geared toward a patient or consumer, rather than a healthcare professional.

CCHR's co-founder, the late Professor Thomas Szasz advised that the best protection a mental health consumer can have is to better inform themselves. The Med Guides provide one means of doing this.

The importance is because, as attorney James Gottstein in the journal Ethical Human Psychology and Psychiatry, reported: “Psychiatrists regularly fail to obtain informed consent by not fully informing their patients of the risks of psychotropic drugs as well as overstating their benefits.”[2]

Attempting to read the drug packaging information that comes with any medication can be confusing, as evidenced by the more than 500,000 Americans who misinterpret them every year. Annually, there are about 1.5 million preventable medication errors. Roughly one-third of these occur outside of hospitals, where patients must rely upon their own ability to follow the instructions on their medication containers.[3]

In 2022, the FDA reported receiving more than 100,000 reports every year related to medication errors that can occur in pharmacies, hospitals, and patient homes.[4] This is further argument as to why the FDA needs to make the Med Guides mobile user-friendly.

Under the Food, Drug, and Cosmetic (FD&C) Act, the FDA requires that Med Guides be dispensed with products the agency deems a serious and significant public health concern. The manufacturer is responsible for ensuring that pharmacists have the Guides in sufficient numbers to provide one to each patient who receives the drug.[5]

These are also available on the FDA website, which should be more easily accessible. Med Guides were designed to be easier for the average consumer to read and understand. They must:

- Use larger font
- Use “nontechnical, understandable language,” and not be “promotional in tone or content”
- Describe “the particular serious and significant public health concern that has created the need for the Medication Guide” and note any known “pediatric risks”
- Include “the risk, if there is one, of the patients developing dependence on the drug product.”[6]

This does not supplant the responsibility of a psychiatrist, psychologist or doctor to fully inform their patients. According to the legal firm McKeen & Associates, PC, “psychiatrists have an obligation to follow certain procedures associated with patient treatment. For example, they must:

- Obtain informed consent of the patient or their guardian,
- Properly test and monitor a patient’s response to medication,
- Carry out a thorough neurological evaluation of a patient who demonstrates certain symptoms of high concern–such as impaired consciousness or altered mental state.[7]

However, as a British Medical Journal article notes, “Psychiatry is a disaster area in healthcare that we need to focus on. With its liberal use of psychiatric drugs, psychiatry—which includes the

work of GPs with psychiatric patients—does far more harm than good."[8]

That includes patients being given misleading information. The BMJ further reported that "many psychiatrists still tell their patients that they suffer from a chemical imbalance, and that taking a psychiatric drug is similar to taking insulin for diabetes." This is patently false and more recently was proven to be the case in a study published in Molecular Psychiatry debunking the chemical imbalance theory. Such misinformation constitutes consumer fraud and adds weight to the need for consumers to better inform themselves, minimally through the use of the Med Guides.

In March 2022, an article published by the Journal of Mental Health, revealed that patients are often not given full informed consent before being prescribed antipsychotics. John Read, professor of clinical psychology at the University of East London, based his conclusions on an online questionnaire. Of 757 individuals included in Read's analysis, 71% hailed from the U.S.[9]

More than 11 million Americans take antipsychotics, of which 829,372 are ages 0-17. Of the latter, 30,632 are aged 0-5, reinforcing the need for parents to be better informed.[10]

Prof. Read found that "hardly any of the 757 people were told about diabetes, sexual dysfunction, suicidality, potentially shortened life span, neuroleptic malignant syndrome (which is a life-threatening reaction to APs involving rapid onset fever and muscle rigidity), and none were told about withdrawal effects or reduced brain volume…."

CCHR International provides a free psychiatric drugs side effects searchable database at: https://www.cchrint.org/psychdrugdangers/ for consumers where they can obtain additional information, including studies and drug regulatory agency warnings about psychotropic drugs.

Consumers should contact the FDA to demand that the Med Guides be fully functional on mobile devices at 1-888-INFO-FDA or 1-888-463-6332.

Anyone suffering an adverse effect of a psychotropic or other prescribed drug can also report this direct to the FDA's MedWatch adverse drug reaction service.[11] If a psychiatrist or other mental healthcare professional failed to fully inform you of the treatment they recommended to you and you were harmed, you can report this to CCHR at: https://www.cchrint-programs.org/acms/case/create

Read full article here.

[1] https://tynmagazine.com/what-percentage-of-internet-traffic-is-mobile/; https://www.ciodive.com/news/70-of-internet-traffic-comes-from-mobile-phones/510120/

[2] https://www.proquest.com/docview/205070933

[3] https://www.consumerreports.org/cro/2011/06/can-you-read-this-drug-label/index.htm

[4] https://www.singlecare.com/blog/news/medication-errors-statistics/

[5] http://www.ncbop.org/faqs/pharmacist/faq_medicationguidelines.htm

[6] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=208.20

[7] https://www.mckeenassociates.com/blog/2019/01/5-types-of-psychiatrist-negligence-that-can-lead-to-a-lawsuit/

[8] https://www.bmj.com/content/360/bmj.k9/rr-15

[9] https://repository.uel.ac.uk/item/8q5xx; https://www.madinamerica.com/2022/03/antipsychotics-often-prescribed-without-informed-consent/

[10] https://www.cchrint.org/psychiatric-drugs/people-taking-psychiatric-drugs/

[11] https://www.accessdata.fda.gov/scripts/medwatch/index.cfm

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