

Institute for Safe Medication Practices
200 Lakeside Drive, Suite 200, Horsham, PA 19044
www.ismp.org

FOR IMMEDIATE RELEASE
October 8, 2014

CONTACT: Renee Brehio, Media Relations, ISMP
614-376-0212, rbrehio@ismp.org

Safety Leaders Seek Stronger Chantix Warnings

Horsham, Pa—Five leading nonprofit consumer, research, and medical organizations today filed a Citizen Petition asking the Food and Drug Administration (FDA) to clarify and strengthen the Boxed Warnings about psychiatric side effects of the smoking cessation aid Chantix (varenicline). They are also seeking restrictions against Chantix use in sensitive and hazardous occupations. Joining in the petition are the following organizations: Consumer Reports, Institute for Safe Medication Practices, National Center for Health Research, National Physicians Alliance, and Public Citizen.

The petition asks the FDA to require that Chantix product label Boxed Warnings clearly describe the four related psychiatric adverse effects: suicidal behaviors, aggression/violence, psychosis, and depression.

In addition to these risks, Chantix is associated with sudden blackouts, seizures, and impaired vision. The petition asks the FDA to add restrictions to the Indications section of the product label warning against the use by individuals in sensitive or hazardous occupations, such as pilots, air traffic controllers, military missile crews, police, fire fighters, and emergency medical workers. The Federal Aviation Administration, Department of Transportation, and Department of Defense currently restrict the use of Chantix; the petitioners are asking for an expanded and uniform label warning that would include these and non-federal workers.

The manufacturer of Chantix, Pfizer Inc., has publicly stated that it wants the FDA to remove the Boxed Warning, and the FDA has scheduled an advisory committee meeting for October 16, 2014 to consider changes. ISMP and the National Center for Health Research will testify at the meeting about the need for the opposite--to strengthen the Boxed Warnings and add restrictions for sensitive and hazardous occupations.

The Citizen Petition documents the extensive scientific evidence that has expanded our understanding of the substantial risks of this smoking cessation drug. Appropriate warnings and careful monitoring can prevent many of these potentially catastrophic adverse drug events.

-more-

Institute for Safe Medication Practices
200 Lakeside Drive, Suite 200, Horsham, PA 19044
www.ismp.org

The signing organizations of the Citizens Petition asking for improved safety information in the labeling for Chantix are:

- **Consumer Reports**, which serves consumers through unbiased product testing and ratings, research, public education and advocacy. (<http://www.consumerreports.org/cro/index.htm>)

- **Institute for Safe Medication Practices**, a nonprofit organization devoted entirely to medication error prevention and safe medication use. (<http://www.ismp.org/>)

- **National Center for Health Research**, a nonprofit think tank that scrutinizes scientific and medical research with public health implications. (<http://center4research.org>)

- **National Physicians Alliance**, a non-profit organization that promotes health and fosters physicians' active engagement with their communities to achieve high quality, affordable health care for all. (<http://npalliance.org/>)

- **Public Citizen**, a consumer advocacy organization with more than 350,000 members and supporters. (<http://www.citizen.org/>)

For more information and a copy of the petition, visit <http://www.ismp.org/docs/Chantix-Citizen-Petition.pdf>

About ISMP: The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents nearly 40 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit www.ismp.org

-end-