Chantix® (varenicline) and Zyban® (bupropion) – Safety Update

- On December 16, 2016, the FDA announced that the *Boxed Warning* regarding serious mental health side effects from the Chantix (varenicline) and Zyban (bupropion) drug labels will be removed. Based on a review of a large clinical trial, the FDA has determined that the risk of serious side effects on mood, behavior, or thinking with these drugs is lower than previously suspected.

- Chantix and Zyban are indicated for use as an aid to smoking cessation treatment.

    - The Zyban boxed warning for suicidality and antidepressant drugs will remain in the drug label.

- The FDA's review of the clinical trial results also confirmed that Chantix, Zyban, and nicotine replacement therapy (NRT) were all more effective for helping people quit smoking vs. placebo, regardless of whether or not they had a history of mental illness.

- The FDA is also updating the existing warning section in both labels that describes the side effects on mood, behavior, or thinking to include the results from the clinical trial.

    - The risk of these mental health side effects is still present, especially in those currently being treated for mental illnesses such as depression, anxiety disorders, or schizophrenia, or who have been treated for mental illnesses in the past. Most people who had these side effects did not have serious consequences such as hospitalization.

- The patient Medication Guide that explains the risks associated with the use of these medicines will continue to be provided with every patient prescription; however, the risk evaluation and mitigation strategy (REMS) that formally required the Medication Guide will be removed.

- The FDA's decision is consistent with the recommendations of a recent FDA Advisory Committee meeting:

    - Ten panel members voted to remove the boxed warning.
    - Four panel members voted to modify the boxed warning language.
    - Five panel members voted to keep the current boxed warning.

- Healthcare providers should counsel patients about the benefits of stopping smoking and how they can get help to quit, and discuss the benefits and risks of using medicines to help them quit smoking.

- Patients should stop taking Chantix or Zyban and call their healthcare providers right away if they notice any side effects on mood, behavior, or thinking. Patients should also discuss any other questions or concerns they may have regarding their smoking cessation therapy.

- The clinical trial evaluated the neuropsychiatric safety of Chantix and Zyban for smoking cessation in patients without and with a history of psychiatric disorders.

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- A total of 8,144 patients were randomized to Chantix, Zyban, NRT, or placebo. The duration of active treatment was 12 weeks followed by a non-treatment follow up phase for an additional 12 weeks.
- Clinically significant neuropsychiatric adverse effects occurred at a similar frequency of 3.1%, 3.5%, 3.3%, and 4.1% in patients without psychiatric diagnoses in the Chantix, Zyban, NRT and placebo groups, respectively.
- Clinically significant neuropsychiatric adverse effects occurred at higher frequencies in patients with psychiatric diagnoses in the Chantix (12.2%), Zyban (11.8%), NRT (9.8%) and placebo groups (9.5%).
- There was no meaningful difference in risk between the Chantix and Zyban groups.

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