



For immediate release:
May 27, 2011

Statement Regarding Chantix Adverse Event Reporting

“Pfizer takes patient safety and regulatory reporting obligations very seriously. All post-marketing reports of adverse events are reviewed by Pfizer and reported to regulatory agencies, including FDA. As FDA stated on May 19, 2011, the Agency clarified its instructions for reporting to some drug manufacturers, including Pfizer last year. As a result, CHANTIX adverse event reports previously submitted in 2006-2009 were resubmitted again in third quarter of 2010. This explains the apparent increase in the number of reports in the AERS for that quarter.

“In their statement on May 19th, the FDA noted that the re-submitted reports ‘confirm what we already knew about CHANTIX and would not have changed the Agency’s position on the drug’s risks and benefits, given that the data in these reports were consistent with those that led to the 2009 labeling change,’ adding ‘At this point, based on the data, FDA does not have any new safety concerns with CHANTIX, though those that have been established remain under active review.’

“It is acknowledged that adverse event reports have significant limitations and do not establish a cause-and-effect relationship between a medicine and an adverse event. The overall benefit versus risk profile of varenicline remains favorable. Given the significant public health risks of smoking, varenicline is an important treatment option for adult smokers to help them succeed in stopping smoking. Pfizer continues to conduct studies of varenicline, including in smokers with and without mental health disorders.”

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