

Varenicline: Where are we Today?

Phillip S. Gardiner, Dr. P. H.

Policy and Regulatory Sciences / Nicotine Dependence and
Neurosciences Program Officer, Tobacco Related Disease
Research Program (TRDRP) University of California Office of
the President

Live Webcast Panel Discussion UCSF Cole Hall

Thursday, September 20, 2012

San Francisco, California

Competing Interests

- TRDRP has had 2 discussions with Pfizer Representatives about jointly funding research on Varenicline and smoking cessation in general

Varenicline: A Chronology

- 2006 FDA Approval of Chantix
- 2006 -2008 5 Clinical Trials
- November 2007 ABC News Report
- November of 2007 FDA strengthened its language

Varenicline: A Chronology

- May 2008 Pfizer Strengthens its language on its website
- May 2008 Institute for Safe Medication Practices
- July 2009 FDA Black Box warning
- January 2010 Rigotti et al., Clinical Trial among patients with cardiovascular disease

Varenicline: A Chronology

- July/September 2011 Sonal Singh Meta-Analysis
- November 2011 Moore et al article on Suicide and Depression
- November 2011 Pfizer response
- May 2012 Prochaska and Hilton Meta-analysis

Varenicline: A Chronology; The Lawsuits

- 2007 Initial lawsuits
- 2009 United States Judicial Panel on Multidistrict Litigation
- March 2012 nearly 2500 (2498) lawsuits filed; 8 test cases identified
- October 22, 2012 first case to be heard

Varenicline: Where are we today?

- Prescribed in over a hundred countries to 15 million smokers
- 30 randomized trials w/ 8,000 smokers *all* showing Chantix to be safe and efficacious, including recent trials amongst psychiatric patients; still adverse events reports published
- Persistent complaints of adverse events, including suicidal ideation, depression and cardiovascular dysfunction
- Lawsuits mount

Goals of Webcast:

- To better understand the pharmacology of varenicline
- To better understand the literature on adverse psychiatric and cardiovascular events associated with people taking varenicline
- To better understand the issues and the differences between the Singh and the Prochaska meta-analyses.

Webcast Format

- 25 minute Presentations
- Panel Discussion Q and A after Presentations
- Questions will alternate between Cole Hall and webcast attendees; questions can be submitted at: varenicline@ucop.edu

Expert Panel

Neal Benowitz, MD, University of California San Francisco

Eden Evins, MD, MPH, Harvard University

Sonal Singh, MD, MPH, Johns Hopkins University

Judith Prochaska, PhD, MPH, Stanford University

•

Phillip Gardiner, Dr. P.H. Moderator, Tobacco Related Disease Research Program (TRDRP), University of California Office of the President

Panelist: Neal Benowitz

- Neal Benowitz, MD, University of California San Francisco
 - Research focuses primarily on the human pharmacology and metabolism of nicotine; the role of nicotine in maintaining addiction that causes tobacco-related diseases, including cardiovascular disease and cancer
 - Rigotti NA, Pipe AL, Benowitz NL, Arteaga C, Garza D, Tonstad S. **Efficacy and safety of varenicline for smoking cessation in patients with cardiovascular disease: a randomized trial.** *Circulation*. 2010 Jan 19; 121(2):221-9. Epub 2010 Jan 4.
<http://circ.ahajournals.org/content/121/2/221.long>

Panelist: A. Eden Evins

- A. Eden Evins, MD, MPH, Harvard University
 - Research focuses on the pharmacotherapy for nicotine dependence; co-occurring psychiatric and substance use disorders; and cognitive dysfunction in schizophrenia, including the effects of smoking cessation medications in these populations.
 - Pachas GN, Cather C, Pratt SA, Hoepfner B, Nino J, Carlini SV, Achtyes ED, Lando H, Mueser KT, Rigotti NA, Goff DC, Evins AE. **Varenicline for Smoking Cessation in Schizophrenia: Safety and Effectiveness in a 12-Week, Open-Label Trial.** J Dual Diagnosis. 2012; 8(2):117-125. Epub 2012 May 11.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3414422/>

Panelist: Sonal Singh

- Sonal Singh, MD, MPH, Johns Hopkins University
 - Research has focused on drug safety, regulatory policy, public health and human rights. He has conducted systematic reviews and developed reliable taxonomies, instruments and scales to measure human rights violations in relationship to health outcomes
 - Singh S, Loke YK, Spangler JG, Furberg CD. **Risk of serious adverse cardiovascular events associated with varenicline: a systematic review and meta-analysis.** CMAJ. 2011 September 6; 183(12): 1359–1366.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3168618/>

Panelist: Judith Prochaska

- Judith Prochaska, PhD, MPH, Stanford University
 - Research focuses on developing effective treatments for tobacco dependence with a specific focus on populations with co-occurring disorders
 - Prochaska JJ, Hilton JF. **Risk of cardiovascular serious adverse events associated with varenicline use for tobacco cessation: systematic review and meta-analysis.** BMJ, 2012; 344; 1-11.
http://www.bmj.com/highwire/filestream/582907/field_highwire_article_pdf/0.pdf