MEDIA ADVISORY
December 11, 2006

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TWO PRESS BRIEFINGS SCHEDULED December 12, 2006

Drug Victim Advocates will testify about the human cost of FDA's failure to warn about severe concealed drug-induced hazards.

Expert Scientists, Psychiatrists, a Primary Care Physician, a Leading Attorney, will shed light on FDA's Review of selected data Re: Antidepressants and Adult Suicidality One day prior to FDA's Advisory Committee Hearing, December 13.

Press Briefing #1:

Tuesday, December 12, 2006
9:00 a.m. - 11:00 a.m.
National Press Club, Washington D.C.
First Amendment Lounge
529 14th Street NW
Washington DC 20045
(202) 662-7500
and

Press Briefing #2:

Tuesday, December 12, 2006
4:00 p.m. - 6:00 p.m.
Hilton Silver Spring
Assembly Room
727 Colesville Road
Silver Spring, MD 20910
(301)589-5200

Both Press Briefings are taking place the day before the FDA plans to share the results of its ongoing meta-analysis of suicidality data from a selection of the original adult antidepressant clinical trials at the FDA's Psychopharmacologic Drugs Advisory Committee (PDAC) public hearing on Wednesday, December 13, 2006.

*** PRESS BRIEFINGS***

Families, advocates, critics and stakeholders in psychotropic drugs are heading to Washington for an FDA advisory committee hearing. The subject of the hearing is evidence confirming that the new antidepressants—i.e., SSRIs and SNRIs—increase the risk of suicide and suicidal behavior in adults.

FDA has released its first ever data analysis of adult antidepressant clinical trials conducted between 1985 – 2004. The findings confirm critics' warnings for the last 15 years that the drugs, not the condition, pose an increased risk of suicidality. FDA is now conceding that the risk exists, at least for adults under age 25--but the evidence of a risk crosses age groups.

FDA's partial admission comes 8 months after GlaxoSmithKline reversed it 15 year denial, and acknowledged a six-fold increased risk of suicidal behavior in young adults who take Paxil (May, 2006).
http://www.gsk.com/media/paroxetine/adult_hcp_letter.pdf
See also:
http://www.ahrp.org/cms/content/view/166/28/ [See critique of FDA's analysis below]

The Alliance for Human Research Protection and a victim advocacy group, Woodymatters, will convene a press briefing at which Kim Witczak, whose husband committed suicide on Zoloft, an SSRI antidepressant, in August 2003, and her brother-in-law, Eric Swan, will speak on behalf of victim advocates for drug safety. Their personal testimonies will be followed by independent experts who will review scientific and clinical evidence, shedding light on what was known 20 years ago, and what is known and not known today about the safety

and efficacy of antidepressant drugs.

The press briefing will focus on the important clinical issues and a body of evidence withheld from the FDA advisory committee. The FDA withheld all critical analyses, internal company documents that are now in the public domain, and all reports by outside independent experts—just as these same officials had done in 1991 when FDA last discussed the adult SSRI suicidality data at a public hearing. FDA's concerted effort to limit and contain the discussion to a selective dataset that it alone has access to, is contrary to the scientific method. Thus, serious doubts are raised about the integrity of the claimed limited findings.

A demonstration of how this politicized agency operates: Suppression of FDA safety officers' reviews in 1990 (David Graham memo); in 2004 (report and recommendations by Dr. Andrew Mosholder); and by FDA's effort to block one third of members of the public who had signed up for a 3 minute speaking slot for this upcoming hearing.

Woodymatters and AHRP have assembled an independent expert panel who will brief the press:

* David Healy, MD, is a professor of psychiatry at the University of Wales College of Medicine. He is one of the foremost experts in the world on antidepressants, particularly the class known as selective serotonin reuptake inhibitors (SSRIs). In large measure Dr. Healy has brought pressure to bear both on the FDA and the MHRA in the UK to examine the data. The author or co-author of seventeen books in the field of mental health and psychiatric drugs. Dr. Healy will discuss how fraudulent data has corrupted the drug safety and efficacy evaluation process and how the FDA is deaf, blind, and mute.

* Joseph Glenmullen, MD, psychiatrist who is on the staff of the Harvard Law School Health Services, author of Prozac Backlash and the Antidepressant Solution. Dr. Glenmullen will critique the FDA analysis and discuss the drug-induced severe withdrawal symptoms that trigger suicidal behavior.

* John Abramson, MD, is an award-winning doctor, on the clinical faculty at Harvard Medical School, and author of the book Overdosed America. Dr. Abramson, a primary care physician will discuss the relationship between the FDA and information that practicing doctors rely upon to make their clinical decisions, using antidepressants as well as several other classes of drugs as cases in point.

* **David Cohen, Ph.D Cohen is recognized as an expert on the adverse effects of psychotropic drugs and on psychiatric drug withdrawal. He has authored over 100 articles in journals, and is Associate Editor of both The Journal of Mind and Behavior and Ethical Human Sciences and Services. Dr. Cohen will discuss the flip side of SSRIs—the lack of evidence for their efficacy.

* **Stefan Kruszewski, MD, a clinical psychiatrist, and Associate Medical Director of Physicians' Health Programs, Pennsylvania Medical Society. Dr. Kruszewski is an expert in addictive diseases and the scientific basis that underscores certain neuropsychiatric drugs who will discuss the impact of over-prescribing SSRIs.

* Karen Barth Menzies is a partner at the Los Angeles based law firm Baum Hedlund and heads the firm's Pharmaceutical Litigation Department. For more than a decade, she has been handling SSRI-induced suicide/ violence cases involving Prozac, Paxil and Zoloft. Having seen the internal company documents, she knows what dangers lurk under the shield of confidentiality. She has been an invited speaker in a number of public forums, at both medical and legal conferences, on the risks of antidepressants and the need for FDA reform For her exemplary achievements, Ms. Menzes has garnered more than once, “Lawyer of the Year” award.

**Disclosure: Dr Cohen and Dr. Kruszewski are members of the board of directors of AHRP

Following the briefings, questions from members of the press will be answered.

Families will be in attendance. They more than anyone can testify to the chilling reality of the life-threatening consequences of SSRI antidepressant drugs.

REFRESHMENTS WILL BE SERVED.

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PRESS BRIEFING
Bullet points: Critique of FDA Report Relationship Between Antidepressant Drugs and Suicidality in Adults (dated 11/17/06)

• Report is a slipshod exercise: an in-house examination of partial data supplied and coded by drug companies.

• No data has been posted to allow for other independent verifications, analyses and conclusions.

• Members of Advisory Committee, who are not necessarily experts on the issue, have had less than one month to examine report.

• Although FDA has denied importance of drug induced suicidality for 15 years, none of the scientists who have warned for 15 years that antidepressants regularly induce suicidality have been consulted.

• Scientifically vetted publications from these scientists were not shared with members of Advisory Committee.

• The design and reporting of clinical trials have a single purpose: to present sponsor's drug in the most favorable light in order to gain market approval from the FDA.

• After years of denials, FDA first reluctantly admits of a causal link between drugs and suicidality in children and adolescents. Now, it admits of a link in young adults, but not in adults. What's next?

* Table 18 actually shows a greater than two-fold risk of suicidality for drug-treated adults aged 45-54 compared to those on placebo.

Age <25: RR = 2.30 (Confidence Interval = 1.04 - 5.09)
Age 45 - 54: RR = 2.29 (Confidence Interval = 0.73 - 7.14)
Age 45 - 64: RR = 1.75 (Confidence Interval = 0.68 - 4.48)

* FDA continues to hide the drugs' hazards behind a statistical smokescreen.

How can one deny that a risk exists if the data shows a possible five-fold, even seven-fold increased relative risk?

*FDA puts statistical significance ahead of clinical importance and public health.

* This is what authoritative clinical trial experts have to say about statistical significance:
"The difference between statistical significance and clinical importance should always be borne in mind. Authors should particularly avoid the common error of interpreting a nonsignificant result as indicating equivalence of interventions. The confidence interval (see item 17) provides valuable insight into whether the trial result is compatible with a clinically important effect, regardless of the P value (94)." [Ref. 1]

• FDA provides no evidence that any age group or any indication is immune from the risk of drug-induced suicidality.

• Drug companies have previously not complied with earlier FDA requests to provide data from all trials. What reason is there to believe that all relevant trials are now in FDA's possession?

• Inexplicably, FDA asked drug companies to exclude suicide-related data occurring more than one day after drug discontinuation. That is one of the periods of greatest risk--as is acknowledged in the 2004 FDA-approved SSRI label. So, FDA's inexplicable cut-off ensures that any discontinuation-induced adverse effects are not counted.

• Subjects in placebo groups have often been "washed out" of psychotropic drugs whose withdrawal effects persist for weeks -- suicide-related events in placebo groups may be drug induced.

• The Gunnell (2005) study cited in FDA report counted 16 completed suicides among 40,000+ clinical trial participants; but the FDA reports 8 completed suicides from a database of almost 100,000 participants.

• Precisely because (1) suicide-related events are rare, (2) clinical trials exclude suicidal participants, and (3) clinical trials are not designed to detect suicidality, signals of suicidality in such trials must be taken extremely seriously, which the FDA fails and has continually failed to do.

• FDA's analysis is a highly selective document that obscures the full extent of the risk these drugs pose.

Reference 1. See: Section 20 on "Discussion: Interpretation of Results":
The Revised CONSORT Statement for Reporting Randomized Trials: Explanation
and Elaboration
Douglas G. Altman, DSc; Kenneth F. Schulz, PhD; David Moher, MSc;Matthias Egger, MD; Frank Davidoff, MD; Diana Elbourne, PhD; Peter C. Gøtzsche, MD; and Thomas Lang, MA, for the CONSORT Group. (Annals of Internal Medicine. 2001;134:663-694.) http://www.consort-statement.org/newene.htm