Is the FDA Bipolar or Complicit in Legitimizing Illegal Marketing?

Friday, 17 April 2009

The FDA expanded approval process for toxic drugs is unaffected by evidence uncovered by the US Justice Department showing the studies to be flawed, if not fraudulent.

NEWS BLAZE

April 16,2009

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Is the FDA Bipolar?

In February the Justice Department charged Forest Laboratories with illegally marketing antidepressants Celexa and Lexapro to younger patients and burying a study that showed suicidal side effects in children. But the next month the FDA approved Lexapro for depression in adolescents 12 to 17.

In March the Justice Department charged AstraZeneca with knowing and hiding the diabetes side effects of Seroquel. But this month the FDA considers expanding the antipsychotic's approvals to depression and anxiety.

And in January, Eli Lilly pled guilty to promoting its antipsychotic Zyprexa for unapproved and dangerous uses in a $1.4 billion settlement. But in March the FDA approved Lilly's Zyprexa/Prozac combo, Symbyax for treatment resistant depression (TRD). What do you get when you cross Zyprexa with Prozac? Someone who gains 100 pounds and feels great about it!

"TRD" is such a new pharma invention it googles as Toyota Racing Development and Teacher Recruitment Days. But it will soon move 'script like GAD (general anxiety disorder), MDD (major depressive disorder) ADD (attention deficit disorder) RLS (restless legs syndrome) GERD (gastroesophageal reflux disease) and PMDD (Premenstrual dysphoric disorder)-and for the same reasons.

Of course FDA drug approvals are only as good as the studies. Which is the problem.

Forest paid Massachusetts General Hospital's Jeffrey Bostic, MD $750,000 to chat up Celexa and Lexapro according to US District Court in Boston filings. AstraZeneca paid University of Minnesota Charles Schulz, MD $112,000 to push Seroquel according to US District Court in Orlando filings. And a decade of pain "studies" conducted by Baystate Medical Center's Scott S. Reuben, MD on Vioxx, Lyrica, Celebrex and Effexor were completely fabricated-including the patients say published reports.

And speaking of "made up, Coast IRB, an institutional review board which oversees some 300 clinical trials and 3,000 researchers agreed last year to approve a human trial for "Adhesiabloc," a surgical gel which Congress and the Government Accountability Office completely made up in a sting operation. Oops.

And let's not forget Joseph your-child-is-bipolar Biederman, MD at Harvard who assured benefactor Johnson & Johnson his studies would have pro Risperdal results according to the New York Times-in advance of doing them. (Why leave things up to science?)

And Charles "Paxil" Nemeroff, MD who was forced to step down in December as psychiatry chairman at Emory University thanks to unreported GlaxoSmithKline income of up to $800,000.

And the pharma funded studies continue!

Last May a pro Lexapro article, "Escitalopram and Problem-Solving Therapy for Prevention of Poststroke Depression," ran in JAMA, the Journal of the American Medical Association, with no mention of financial ties author Robert G. Robinson, MD has to Forest.

Why was, "a researcher with a history of being funded by SSRI makers...given a forum in the national media to tell the general public that anyone who has had a stroke, whether or not they have been diagnosed with depression, should start a prophylactic regimen of Lexapro...even though non-medical approaches perform just as well," wrote Jonathan Leo, PhD, Associate Professor of Neuroanatomy at Lincoln Memorial University in the British Medical Journal in March.

And then there's AstraZeneca's "studies."

Seroquel is linked to high blood sugar, weight gain, diabetes, cholesterol and triglycerides abnormalities, sudden cardiac death, suicide, Iraq war veteran deaths and the tardive dyskinesia it is supposed to prevent.

But its "safety" was established by a different kind of chemistry.

Research director for Seroquel, Wayne MacFadden, was having affairs with two women responsible for Seroquel studies say court documents: a researcher at the Institute of Psychiatry in London and a ghostwriter at Waltham, MA-based medical communications firm Parexel.

The studies upon which the FDA approved Seroquel for bipolar disorder-called "Bolder" I and II-were written by a ghostwriter, possibly accelerated by a motel room. And seated on the FDA's Psychopharmacologic Drugs Advisory Committee at the time was Jorge Armenteros, MD, who has been a paid AstraZeneca speaker for five years according to the Philadelphia Inquirer.

He now heads the committee as the FDA considers expanding Seroquel approvals to include depression and anxiety this month-and to children in June.

Hopefully FDA will keep some Seroquel for itself.

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