

2002 2005

Additional data collected by GSK revealed a continuing signal of substantial increased risk of suicide and suicide attempts associated with Paxil. GSK continued to market the drug without informing physicians of this risk.

GSK added a black box warning for suicidality in "children and adolescents" with Major Depressive Disorder, noting a two-fold increased risk for paroxetine versus placebo. No similar warning for adults was included.

# **AUG 2007 - JULY 15, 2010**

GSK again marketed Paxil without warning prescribing physicians about the increased risk of suicides and suicide attempts it knew or should have known about for patients of all ages on paroxetine.

2006 2007 2010

#### **APRIL 5**

GSK's new analysis of data revealed "evidence of an increase in suicide attempts in adults with Major Depressive Disorder treated with paroxetine compared to placebo," with an "odds ratio of 6.7" that was statistically significant.

## MAY 5

GSK temporarily amended the Paxil label to include reference to MDD clinical trial data suggesting the higher frequency of suicidal behavior "observed in the younger adult population across psychiatric disorders may extend beyond the age of 24," noting 8 of 11 suicide attempts in the clinical trials "involved younger adults aged 18-30." HOWEVER, THIS TEMPORARY AND **OVER 24 ADULT WARNING** WAS REMOVED FROM THE **LABEL IN AUGUST OF 2007.** 

#### **JUNE 28**

Relying on the 2010 version of the Paxil label, Dr.
Sachman prescribed 10 mg per day of paroxetine for Stewart Dolin, to be taken after a ten-day waiting period as Zoloft cleared Mr. Dolin's system. Dr. Sachman would not have prescribed paroxetine for Mr. Dolin if there had been a paroxetine induced suicide association warning for adults over 24.

## **JULY 8**

Dr. Sachman told Mr. Dolin he was free to start the paroxetine and on July 10, Mr. Dolin started taking it.



## **JULY 15**

Stewart Dolin's paroxetine-induced death by train, as a direct and proximate result of taking paroxetine and the inadequacies in GSK's label, which did not properly inform Dr. Sachman about the risks GSK knew or should have known about.

