PART 1

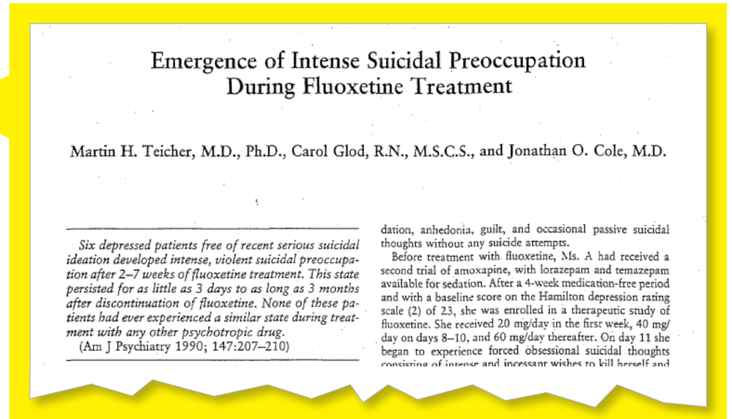
GSK's Negligence CAUSED Stewart Dolin's DEATH

1989

GSK submitted a "New Drug Application" to the FDA for Paxil which obscured an approximately 8-fold increased risk of suicidal attempts and suicide, through improper use of 2 "run in" suicides and 5 "run in" suicide attempts. This changed a danger signal into a reassuring one. As a result, doctors and the FDA were not warned about the increased risk GSK knew or should have known about.

1990

OCT 3
FDA requested a report from GSK on *"the same suicide issues"* as raised in the Teicher article about Prozac.



Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment

Martin H. Teicher, M.D., Ph.D., Carol Glod, R.N., M.S.C.S., and Jonathan O. Cole, M.D.

Six depressed patients free of recent serious suicidal ideation developed intense, violent suicidal preoccupation after 2–7 weeks of fluoxetine treatment. This state persisted for as little as 3 days to as long as 3 months after discontinuation of fluoxetine. None of these patients had ever experienced a similar state during treatment with any other psychotropic drug.
(Am J Psychiatry 1990; 147:207–210)

dation, anhedonia, guilt, and occasional passive suicidal thoughts without any suicide attempts.

Before treatment with fluoxetine, Ms. A had received a second trial of amoxapine, with lorazepam and temazepam available for sedation. After a 4-week medication-free period and with a baseline score on the Hamilton depression rating scale (2) of 23, she was enrolled in a therapeutic study of fluoxetine. She received 20 mg/day in the first week, 40 mg/day on days 8–10, and 60 mg/day thereafter. On day 11 she began to experience forced obsessional suicidal thoughts consisting of intense and incessant wishes to kill herself and

1991

MAY 10
Under increased scrutiny on the suicidality issue from the FDA, GSK's Director of Regulatory Affairs inaccurately informed the FDA: *"Analysis of data from prospective clinical trials in depressed patients clearly demonstrates that patients randomized to paroxetine therapy were at no greater risk for suicidal ideation or behavior than patients who were randomized to placebo..."* However, the hidden data revealed the opposite was true, there was an approximately 8-fold increased risk of suicidal attempts and suicides.

DEC
On behalf of GSK, Drs. Dunner & Dunbar gave a presentation at the American College of Neuropsychopharmacology Convention in San Juan, Puerto Rico, inaccurately stating the clinical trial data for paroxetine shows *"suicides and suicide attempts occurred less frequently with paroxetine than with either placebo or active controls."*

1992

JAN - DEC
Relying on these inaccurate representations as true, the FDA approved Paxil for marketing in the United States, adopting as part of its *"Summary Basis for Approval"* the inaccurate table GSK supplied to the FDA indicating there was no increased risk of suicides or suicide attempts.

DEC
GSK launched Paxil in the United States without warning prescribing physicians of the drug's association with suicide attempts and completed suicides.

1995 - 2002

JUL 1995
GSK instructs sales force to distribute false Montgomery & Dunbar article "to alleviate any concerns" doctors may have about Paxil & suicide.

JUN 1999
FDA requests death data. GSK lawyers raise concerns: "I want to ensure our positions are not inadvertently compromised as a result of anything we share with FDA."

NOV 1999
GSK realizes "This response to FDA seems to be setting us up for potential problems, suggesting that **Paxil is associated with a higher rate of suicide vs. placebo** ... Can we use the Montgomery meta-analysis ... in our response back to the FDA?"

DEC 1999
GSK raises "hypothetical example" about a suicide during run-in phase. FDA explains "such a patient should not be counted in our analyses."

DEC 1999
GSK submits Death Report, but claims its too burdensome to collect data from locally-funded studies.

JUN 2001
"These suicide reports seem to be appearing too often for comfort . . . This is potentially an area in which competitors are likely to capitalize on once the lawyers have finished their work in the courts."

APR 2002
GSK discloses run-in error for suicide attempts to FDA but makes "accidental" misrepresentation about the two run-in suicides.