

TABLE 2
TREATMENT-EMERGENT ADVERSE EVENTS: INCIDENCE IN
PLACEBO-CONTROLLED CLINICAL TRIALS
Percentage of Patients Reporting Event
Major Depressive Disorder/Other*, OCD, Panic Disorder, PTSD, PMDD and Social
Anxiety Disorder combined

Body System/Adverse Event**	ZOLOFT (N=2799)☐	Placebo (N=2394)☐
☐	☐	☐
Autonomic Nervous System Disorders ☐	☐	☐
Ejaculation Failure ⁽¹⁾ ☐	14☐	1☐
Mouth Dry☐	14☐	8☐
Sweating Increased☐	7☐	2☐
Centr. & Periph. Nerv. System Disorders ☐	☐	☐
Somnolence☐	13☐	7☐
Dizziness☐	12☐	7☐
Headache☐	25☐	23☐
Paresthesia☐	2☐	1☐
Tremor☐	8☐	2☐
Disorders of Skin and Appendages ☐	☐	☐
Rash☐	3☐	2☐
Gastrointestinal Disorders ☐	☐	☐
Anorexia☐	6☐	2☐
Constipation☐	6☐	4☐
Diarrhea/Loose Stools☐	20☐	10☐
Dyspepsia☐	8☐	4☐
Nausea☐	25☐	11☐
Vomiting☐	4☐	2☐
General ☐	☐	☐
Fatigue☐	12☐	7☐
Psychiatric Disorders ☐	☐	☐
Agitation☐	5☐	3☐
Anxiety☐	4☐	3☐
Insomnia☐	21☐	11☐
Libido Decreased☐	6☐	2☐
Nervousness☐	5☐	4☐
Special Senses ☐		
Vision Abnormal☐	3☐	2

⁽¹⁾Primarily ejaculatory delay. Denominator used was for male patients only (N=1118 ZOLOFT; N=926 placebo).

*Major depressive disorder and other premarketing controlled trials.

**Included are events reported by at least 2% of patients taking ZOLOFT except the following events, which had an incidence on placebo greater than or equal to ZOLOFT: abdominal pain, back pain, flatulence, malaise, pain, pharyngitis, respiratory disorder, upper respiratory tract infection.