

Clinical Trial	Trial Length	Number of Patients on Risperdal	Reports of Gynecomastia	Gynecomastia Rate
NED-9 (12/1996)	10 weeks	19	0	0%
BEL-22 (2/1995)	4 weeks	7	0	0%
BEL-24 (6/1994)	4 weeks	6	0	0%
INT-41 (7/2001)	1 year	504	24	4.8%
USA-93 (10/98)	7 weeks	55	0	0%
USA-97 (9/1999)	1 year	107	1	0.9%
CAN-19 (7/1999)	7 weeks	53	0	0%
CAN-20 (8/2000)	1 year	77	0	0%
USA-150 (4/2001)	8 weeks	49	1	2%
CAN-23 (12/2001)	8 weeks	41	0	0%
HUN-4 (1/2003)	2 years	(918) 35	0	(2.7%) 0%
INT-70 (8/2002)	1 year	48	3	6%
USA-231 (3/2006)	8 weeks	279	2	0.7%
USA-234 (3/2006)	6 months	297	4	1%
INT-79 (9/2003)	9 months	527	8	1.5%
INT-84 (7/2004)	1 year	232	2	0.8%
BIM-301 (12/2005)	3 weeks	111	0	0%
SCH-302 (12/2005)	6 weeks	106	0	0%

Source: D-19

EXHIBIT
Date: P-17
M.L. GRAY, CSR, RPR

PLAINTIFF'S
EXHIBIT
17

REAL JANSSEN
II

Clinical Trial	Trial Length	Number of Patients on Risperdal		Reports of Gynecomastia	Gynecomastia Rate
NED-9	10 weeks	19	19	0	0%
BEL-22	4 weeks	7	7	0	0%
BEL-24	4 weeks	6	6	0	0%
INT-41	1 year	494	504	24	4.8%
USA-93	7 weeks	55	55	0	0%
USA-97	1 year	59	107	1	0.9%
CAN-19	7 weeks	53	53	0	0%
CAN-20	1 year	39	77	0	0%
USA-150	8 weeks	49	49	1	2%
CAN-23	8 weeks	41	41	0	0%
HUN-4	2 years	0	35	0	0%
INT-70	1 year	0	48	3	6%
USA-231	8 weeks	279	279	2	0.7%
USA-234	6 months	41	297	4	1%
INT-79	9 months	527	527	8	1.5%
INT-84	1 year	0	232	2	0.8%
BIM-301	3 weeks	111	111	0	0%
SCH-302	6 weeks	106	106	0	0%

Sources: 2-43

1585 2553

PLAINTIFFS EXHIBIT
P. 1175

Clinical Trial	Trial Length	Number of Patients on Risperdal	Reports of Gynecomastia	Gynecomastia Rate
AGES NED-9 (11-18)	10 weeks	19	0	0%
BEL-22 (3-14)	4 weeks	7	0	0%
BEL-24 (6-14)	4 weeks	6	0	0%
INT-41 (4-14)	1 year	504	24	4.8%
USA-93 (5-12)	7 weeks	55	0	0%
USA-97 (5-12)	1 year	107	1	0.9%
CAN-19 (5-12)	7 weeks	53	0	0%
CAN-20 (5-12)	1 year	77	0	0%
USA-150 (5-17)	8 weeks	49	1	2%
CAN-23 (5-12)	8 weeks	41	0	0%
HUN-4 (6-16)	2 years	35	0	0%
INT-70 (6-14)	1 year	48	3	6%
USA-231 (13-17)	8 weeks	279	2	0.7%
USA-234 (13-17)	6 months	297	4	1%
INT-79 (5-17)	9 months	527	8	1.5%
INT-84 (6-18)	1 year	232	2	0.8%
BIM-301 (10-17)	3 weeks	111	0	0%
SCH-302 (13-17)	6 weeks	106	0	0%

Clinical Trial	Number of Patients on Risperdal		Reports of Gynecomastia Among Patients on Risperdal	Submitted to FDA	Published
# WEEKS	ST/LT				
BEL-24 (4)	ST	6	0	✓	✓
NED-9 (10)	ST	19	0	✓	✓
CAN-19 (7)	ST	53	0	✓	✓
USA-93 (7)	ST	55	0	✓	✓
INT-79 9 months	LT	527	8	✓	✓
USA-150 (8)	ST	49	1	✓	✓
CAN-23 (8)	ST	41	0	✓	✓
SCH-302 (6)	ST	106	0	✓	✓
BIM-301 (3)	ST	111	0	✓	✓

PLAINTIFF'S
EXHIBIT
P-117D

Clinical Trial	Trial Length	Number of Patients on Risperdal	Reports of Gynecomastia	Gynecomastia Rate
NED-9	10 weeks	19	0	0%
BEL-22	4 weeks	7	0	0%
BEL-24	4 weeks	6	0	0%
INT-41	1 year	504	24	4.8%
USA-93	7 weeks	55	0	0%
USA-97	1 year	107	1	0.9%
CAN-19	7 weeks	53	0	0%
CAN-20	1 year	77	0	0%
USA-150	8 weeks	49	1	2%
CAN-23	8 weeks	41	0	0%
HUN-4	2 years	35	0	0%
INT-70	1 year	48	3	6%
USA-231	8 weeks	279	2	0.7%
USA-234	6 months	297	4	1%
INT-79	9 months	527	8	1.5%
INT-84	1 year	232	2	0.8%
BIM-301	3 weeks	111	0	0%
SCH-302	6 weeks	106	0	0%

Source: DX-442; DX-449; DX-445; DX-436; DX-439; DX-440; DX-435; DX-437; DX-450; DX-451; DX-445; DX-446; DX-427; DX-429; DX-434; DX-453; DX-425; DX-428

DG6-3



Clinical Trial	Number of Patients on Risperdal	Reports of Gynecomastia	Gynecomastia Rate
USA-93	55	0	0%
USA-97	107	1	1%
CAN-19	53	0	0%
CAN-20	77	0	0%
INT-41	504	24	4.8%