



**PPD**

# Dapoxetine

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PENN EX. 2045  
CFAD V. UPENN  
IPR2015-01836

# Dapoxetine

*Program highlights*

**PPD**

- 1998-1999: PPD licenses dapoxetine from Lilly and investigates drug as treatment for premature ejaculation
- 2000: PPD licenses dapoxetine to Alza
- 2003: PPD acquires from Lilly the patents for dapoxetine for development in the field of genitourinary disorders



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*DSM IV diagnostic criteria for Premature Ejaculation (302.75):*

- Persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the person wishes it. The clinician must take into account factors that affect duration of the excitement phase, such as age, novelty of the sexual Partner or situation, and recent frequency of sexual activity
- The disturbance causes marked distress or interpersonal difficulty
- The premature ejaculation is not due exclusively to the direct effects of a substance (e.g., withdrawal from opioids)

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*Prevalence*



Prevalence of Premature Ejaculation (PE) v  
Erectile Dysfunction (ED)  
[% within each age group]<sup>1</sup>

Age (# Affected in US)	PE (20 million)	ED (5 million)
18-29	30	7
30-39	32	9
40-49	28	11
50-59	31	18

<sup>1</sup>Laumann et al., JAMA 281: 537 (1999)



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## *Consequences of PE*

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- **Sexual avoidance, anxiety, inadequacy**
  - Kockott et al., "Symptomatology and Psychological Aspects of Male Sexual Inadequacy...." Archives Sex. Behav. 9:457 ('80)
- **PE correlates significantly with male perception of poor marriage**
  - Rust et al., "Marital Problems and Sexual Dysfunction..." Br.J. Psychiatry 152:629 ('88)
- **PE correlates with decreased levels of intellectual, emotional, and sexual intimacy and various aspects of "Quality of Life"**
  - McCabe, "Intimacy and Quality of Life Among Sexually Dysfunctional Men..." J. Sex Marital Ther. 23: 276 ('97)

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