

# David Healy

## Appendix 5:

### Reports to FDA on RxISK.org

The data here are drawn from FDA's adverse events database, along with HealthCanada's adverse events database and data reported directly to RxISK.org.

There are values for the absolute number of events that have been coded under the respective MedDRA codes below. There are also data for proportional reporting ratios (PRR). A PRR value greater than 1.0 gives an indication that this event is occurring disproportionately often on this drug compared to others.

The FDA data covers the period 2004 to 2012. There is earlier FDA data dating back to the launch of Zoloft in 1991. This can be assembled for the court if requested.

Comparable data for all other SSRIs – Prozac, Paxil, Celaxa and Lexapro can also be assembled on request.

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JULY 30<sup>TH</sup>

## Zoloft (Sertraline)

### Violence – Summary

The table below shows the side effects reported to the FDA and/or Health Canada and to RxISK to date for the drug you entered. **Simply check the boxes of the side effects you are experiencing then click on Report a Drug Side Effect above, or type your side effect at the bottom of the page if it is not listed here.** After a few more questions we provide a free RxISK Report to take to your doctor or pharmacist.

|   | FDA        |           | RxISK     |
|---|------------|-----------|-----------|
|   | # Reports  | PRR Value | # Reports |
| – <b>Aggression</b>                               | <b>534</b> |           | <b>13</b> |
| <input type="checkbox"/> Aggressive behaviour     | 534        | 4.7       | 13        |
| – <b>Violence</b>                                 | <b>915</b> |           | <b>21</b> |
| <input type="checkbox"/> Aggression               | 534        | 4.7       | 13        |
| <input type="checkbox"/> Anger                    | 309        | 5         | 5         |
| <input type="checkbox"/> Child abuse              | 3          | 5.9       | 1         |
| <input type="checkbox"/> Physical abuse           | 3          | 6.1       | 0         |
| <input type="checkbox"/> Physical assault         | 51         | 7.4       | 1         |
| <input type="checkbox"/> Violence-related symptom | 15         | 3.9       | 1         |
| – <b>Homicide</b>                                 | <b>292</b> |           | <b>9</b>  |
| <input type="checkbox"/> Homicidal ideation       | 110        | 7.3       | 6         |
| <input type="checkbox"/> Homicide                 | 67         | 15        | 1         |
| <input type="checkbox"/> Hostility                | 64         | 8.1       | 1         |
| <input type="checkbox"/> Physical assault         | 51         | 7.4       | 1         |

|                          |  |            |      |           |
|--------------------------|--|------------|------|-----------|
| –                        | <b>Agitation</b>                                 | <b>856</b> |      | <b>16</b> |
| <input type="checkbox"/> | <a href="#">Activation syndrome</a>              | 37         | 33   | 1         |
| <input type="checkbox"/> | <a href="#">Agitation / Excitability</a>         | 718        | 5    | 9         |
| <input type="checkbox"/> | <a href="#">Hyperactive behaviour</a>            | 101        | 3.5  | 6         |
| –                        | <b>Dangerous Acts</b>                            | <b>134</b> |      | <b>6</b>  |
| <input type="checkbox"/> | Asphyxiation / Suffocation                       | 29         | 3.2  | 0         |
| <input type="checkbox"/> | Bite   | 1          | n/a  | 1         |
| <input type="checkbox"/> | Delinquency                                      | 0          | n/a  | 0         |
| <input type="checkbox"/> | Pyromania  | 6          | 16.2 | 0         |
| <input type="checkbox"/> | Screaming  | 45         | 3.7  | 2         |
| <input type="checkbox"/> | Skin laceration                                  | 42         | 1.9  | 0         |
| <input type="checkbox"/> | Spousal abuse                                    | 1          | n/a  | 0         |
| <input type="checkbox"/> | Theft  | 5          | 3.8  | 0         |
| <input type="checkbox"/> | Verbal abuse                                     | 5          | 3.2  | 3         |
| –                        | <b>Disinhibition</b>                             | <b>211</b> |      | <b>37</b> |
| <input type="checkbox"/> | Attention-seeking behaviour                      | 1          | n/a  | 1         |
| <input type="checkbox"/> | Compulsive hoarding                              | 0          | n/a  | 0         |
| <input type="checkbox"/> | Compulsive shopping                              | 0          | n/a  | 0         |
| <input type="checkbox"/> | Disturbance of conduct, not elsewhere classified | 6          | 1.6  | 1         |
| <input type="checkbox"/> | <a href="#">Emotional instability</a>            | 54         | 4    | 12        |
| <input type="checkbox"/> | Impatience                                       | 8          | 3    | 7         |
| <input type="checkbox"/> | Impulse-control disorder                         | 19         | 6    | 2         |

|                          |                                     |            |      |          |
|--------------------------|-------------------------------------|------------|------|----------|
| <input type="checkbox"/> | <a href="#">Impulsive behaviour</a> | 58         | 8.3  | 6        |
| <input type="checkbox"/> | Intermittent explosive disorder     | 6          | 17.4 | 3        |
| <input type="checkbox"/> | Kleptomania                         | 0          | n/a  | 0        |
| <input type="checkbox"/> | <a href="#">Loss of inhibition</a>  | 37         | 12.4 | 5        |
| <input type="checkbox"/> | Necromania                          | 0          | n/a  | 0        |
| <input type="checkbox"/> | Pathological gambling               | 13         | 1.1  | 0        |
| <input type="checkbox"/> | Poriomania                          | 3          | 3.2  | 0        |
| <input type="checkbox"/> | Pyromania                           | 6          | 16.2 | 0        |
| <b>-</b>                 | <b>Dreams</b>                       | <b>373</b> |      | <b>8</b> |
| <input type="checkbox"/> | <a href="#">Abnormal dreams</a>     | 134        | 2.1  | 4        |
| <input type="checkbox"/> | Nightmare                           | 239        | 4.1  | 4        |
| <b>-</b>                 | <b>Injury</b>                       | <b>62</b>  |      | <b>0</b> |
| <input type="checkbox"/> | <a href="#">Injury</a>              | 62         | 0.2  | 0        |
| <b>-</b>                 | <b>Irritability</b>                 | <b>449</b> |      | <b>8</b> |
| <input type="checkbox"/> | <a href="#">Irritability</a>        | 449        | 4.7  | 8        |
| <b>-</b>                 | <b>Mania</b>                        | <b>281</b> |      | <b>5</b> |
| <input type="checkbox"/> | <a href="#">Hypomania</a>           | 68         | 10.5 | 2        |
| <input type="checkbox"/> | <a href="#">Mania</a>               | 213        | 6.4  | 3        |
| <b>-</b>                 | <b>Paranoia</b>                     | <b>346</b> |      | <b>8</b> |
| <input type="checkbox"/> | Delusional jealousy                 | 4          | 9.3  | 1        |

|                          |   |             |      |           |
|--------------------------|---|-------------|------|-----------|
| <input type="checkbox"/> | <a href="#">Drug psychoses</a>                | 175         | 2.8  | 3         |
| <input type="checkbox"/> | <a href="#">Paranoia induced by drugs</a>     | 162         | 4.1  | 3         |
| <input type="checkbox"/> | <a href="#">Paranoid personality disorder</a> | 1           | n/a  | 0         |
| <input type="checkbox"/> | <a href="#">Psychotic behaviour</a>           | 4           | 2.1  | 1         |
| –                        | <b>Personality Change</b>                     | <b>1122</b> |      | <b>28</b> |
| <input type="checkbox"/> | Abnormal behaviour                            | 397         | 3.9  | 3         |
| <input type="checkbox"/> | Abusive behaviour                             | 534         | 4.7  | 13        |
| <input type="checkbox"/> | Antisocial behaviour                          | 9           | 3.9  | 0         |
| <input type="checkbox"/> | Antisocial personality disorder               | 0           | n/a  | 1         |
| <input type="checkbox"/> | Belligerence                                  | 6           | 4.9  | 2         |
| <input type="checkbox"/> | Borderline personality disorder               | 7           | 5.8  | 0         |
| <input type="checkbox"/> | Conduct behaviour disorder                    | 0           | n/a  | 0         |
| <input type="checkbox"/> | Intermittent explosive disorder               | 6           | 17.4 | 3         |
| <input type="checkbox"/> | Oppositional defiant disorder                 | 5           | 6    | 1         |
| <input type="checkbox"/> | <a href="#">Personality change</a>            | 112         | 5.7  | 3         |
| <input type="checkbox"/> | Personality disorder                          | 43          | 8    | 0         |
| <input type="checkbox"/> | Physical abuse                                | 3           | 6.1  | 0         |
| <input type="checkbox"/> | Psychological abuse                           | 0           | n/a  | 2         |
| <input type="checkbox"/> | Psychopathic personality                      | 0           | n/a  | 0         |

Based on 4,441 reports where Sertraline was the suspect drug for the zone side effects.

FDA reports are based on 4.4 million reports submitted to the FDA's MedWatch from January 1, 2004, to December 31, 2012. These contain 5.9 million suspected drugs, suspected of causing 16.5 million side effects. About a third of these reports come from outside the United States.

