

# How Outside, Real World Experiences Can Help Influence and Shape Advocacy



woodymatters

New View Conference

October 8, 2016

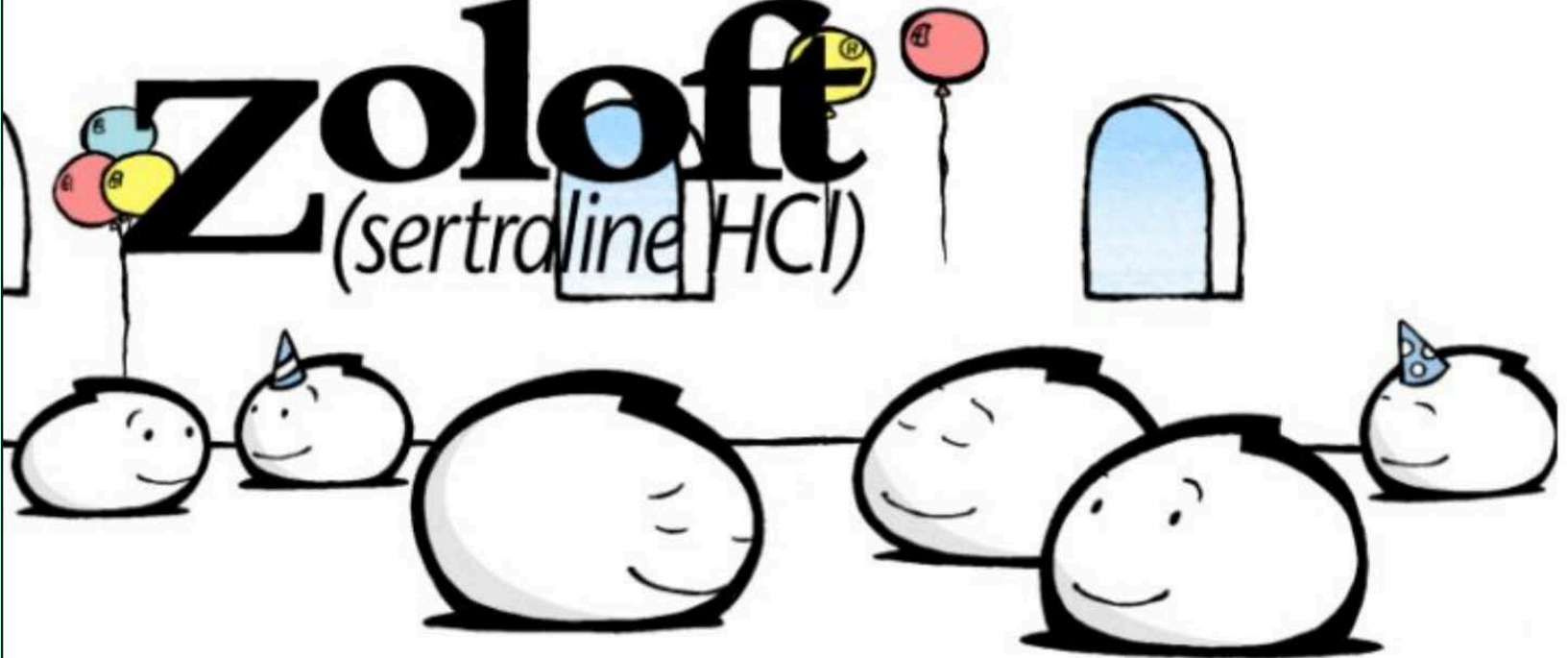
Kim Witczak

# My Life Before...

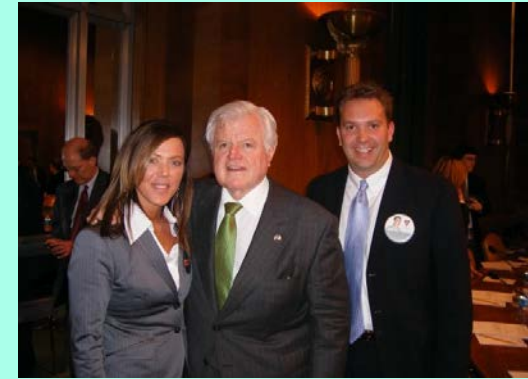


# Zoloft

(sertraline HCl)



# The Battle for Woody.... Washington, DC





# The Battle for Woody ... The Courts

*Germany - Insulin COMAN  
Flax - Outside Security Dept*

CONFIDENTIAL  
 0107 0114 011700Z  
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0999 2003  
 ZCZC 000308 010101  
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 #REFID 01291415

MEINSTEIN, AJ (ENR) #10018 31/2  
 RUCKENSTEIN, BR (ENR) #10019/4/12  
 CCI ARDAY, DA (ENR) #10018 74/2  
 WARDEN, S (ENR)  
 HARPER, JR (NDA)  
 HORTER, J (NDA)  
 TARDIEL, DA (NDA) \*\*\*  
 TROSTMAN, DM (ENR)  
 WELLS, J (ENR) #10018 31/2  
 ZENNER, RL (ENR)

JANUARY 29, 1991

RE: FLUDAZETINE REGISTRATION

WE OFFICIALLY RECEIVED YOUR CONFIRMATION THAT FLUDAZETINE WAS DISCUSSED BY THE COMMISSION AT THE 30th ON JANUARY 21ST. TWO MAJOR CONCERNS SEEM TO BE THE REASON THAT THE REGISTRATION WAS NOT ACCEPTED.

EFFICACY QUESTIONING: THIS MAY BE DUE TO THE EXPERIENCES IN YOUR REGION AND CLASSIFICATIONS USED IN UNITED STATES VS. GERMANY.

SUICIDAL RISK

IT SHOULD BE EMPHASIZED AT THIS TIME WE HAVE ONLY PRELIMINARY CONFIRMATION, WE EXPECT THE OFFICIAL LETTERS WITHIN WEEKS WHICH WILL PROVIDE US A CLEAR UNDERSTANDING OF ALL ISSUES AND HOW WE ARE TO RECTIFY.

IN THE MEANTIME THE FOLLOWING ACTION PLANS HAVE BEEN INITIATED ON FLUDAZETINE:

- MEETING SCHEDULED ON MONDAY AFTERNOON, FEBRUARY 4TH, AT 1 P.M. WITH OUR CLINICAL EXPERT TO DISCUSS THE PROBLEMS IDENTIFICATIONS OF THE 30th'S POSITIONS TOWARDS THE PRODUCT.
- IMMEDIATE FOLLOW-UP ON ALL KEY OPINION LEADERS ON THE 30th

Page 12 of 25  
Prepared by Current Medical Divisions, Inc.

ANXIETY  
POST-TRAUMATIC STRESS DISORDER

| Author-Title                                    | Vendor  | Status   |
|---|---------|--|
| Author TBD-(640) Sertraline vs. placebo in PTSD | Painlin | Poster presented at ECNP, 1991. Paper is completed, but revisions are needed.  |
| Author TBD-(671) Tild TDB                       | Painlin | Poster presented at ECNP, 1991. First draft completed, but additional analyses needed. Both 640 and 671 studies to be submitted soon. One will go to <i>New England Journal of Medicine</i> and the other to <i>JAMA</i> . |

Page 11

ST. SUZUKI LABORATORIES

**CONFIDENTIAL**

| Country | Year | Number of Cases |
|---------|------|-----------------|
| Japan   | 1988 | 1               |
| Japan   | 1989 | 1               |
| Japan   | 1990 | 1               |
| Japan   | 1991 | 1               |
| Japan   | 1992 | 1               |
| Japan   | 1993 | 1               |
| Japan   | 1994 | 1               |
| Japan   | 1995 | 1               |
| Japan   | 1996 | 1               |
| Japan   | 1997 | 1               |
| Japan   | 1998 | 1               |
| Japan   | 1999 | 1               |
| Japan   | 2000 | 1               |
| Japan   | 2001 | 1               |
| Japan   | 2002 | 1               |
| Japan   | 2003 | 1               |
| Japan   | 2004 | 1               |
| Japan   | 2005 | 1               |
| Japan   | 2006 | 1               |
| Japan   | 2007 | 1               |
| Japan   | 2008 | 1               |
| Japan   | 2009 | 1               |
| Japan   | 2010 | 1               |
| Japan   | 2011 | 1               |
| Japan   | 2012 | 1               |
| Japan   | 2013 | 1               |
| Japan   | 2014 | 1               |
| Japan   | 2015 | 1               |
| Japan   | 2016 | 1               |
| Japan   | 2017 | 1               |
| Japan   | 2018 | 1               |
| Japan   | 2019 | 1               |
| Japan   | 2020 | 1               |
| Japan   | 2021 | 1               |
| Japan   | 2022 | 1               |
| Japan   | 2023 | 1               |
| Japan   | 2024 | 1               |
| Japan   | 2025 | 1               |

Demographic: Among treatment indication and additional data by ethnic subpopulation are provided for the positive clinical study cases with safety cases that were related to adverse reaction (Table 4).

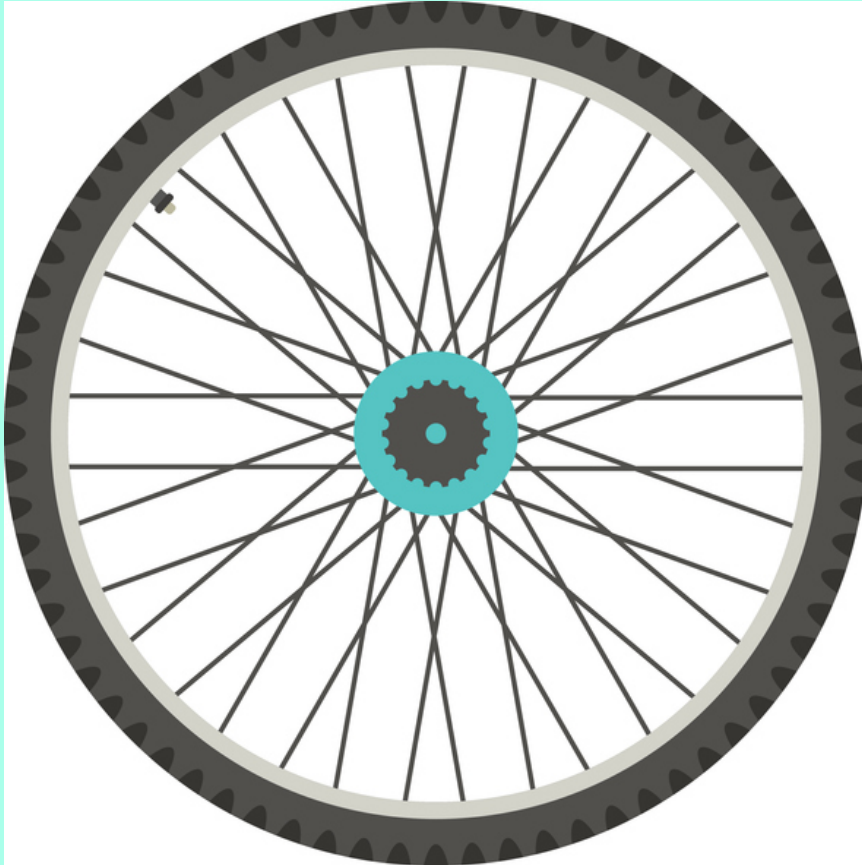
Table 4. Summary of adverse reaction from clinical study cases with events related to sertraline

| Case Characteristics  | Number of Cases |
|---|-----------------|
| Gender  |                 |
| Female  | 12              |
| Male  | 1               |
| Age   |                 |
| 18-29 years   | 1               |
| 30-39 years   | 1               |
| 40-49 years   | 1               |
| 50-59 years   | 1               |
| 60-69 years   | 1               |
| 70-79 years   | 1               |
| 80-89 years   | 1               |
| 90-99 years   | 1               |
| Unknown   | 1               |
| Sertraline Daily Dose   |                 |
| 50mg  | 1               |
| 100mg   | 1               |
| 150mg   | 1               |
| 200mg   | 1               |
| 300mg   | 1               |
| 400mg   | 1               |
| Unknown   | 1               |
| Approximate Duration of Treatment   |                 |
| 1 day   | 1               |
| 2-7 days  | 1               |
| 8-14 days   | 1               |
| 15-30 days  | 1               |
| 31-60 days  | 1               |
| 61-90 days  | 1               |
| 91-180 days   | 1               |
| 181-360 days  | 1               |
| 361-720 days  | 1               |
| 721-1080 days   | 1               |
| 1081-1440 days  | 1               |
| 1441-2160 days  | 1               |
| 2161-3600 days  | 1               |
| 3601-7200 days  | 1               |
| 7201-10800 days   | 1               |
| 10801-14400 days  | 1               |
| 14401-21600 days  | 1               |
| 21601-36000 days  | 1               |
| 36001-72000 days  | 1               |
| 72001-108000 days   | 1               |
| 108001-144000 days  | 1               |
| 144001-216000 days  | 1               |
| 216001-360000 days  | 1               |
| 360001-720000 days  | 1               |
| 720001-1080000 days   | 1               |
| 1080001-1440000 days  | 1               |
| 1440001-2160000 days  | 1               |
| 2160001-3600000 days  | 1               |
| 3600001-7200000 days  | 1               |
| 7200001-10800000 days   | 1               |
| 10800001-14400000 days  | 1               |
| 14400001-21600000 days  | 1               |
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| 720000000000000000000000000000001-10800000000000000000000000000000000 days  | 1               |
| 1080000000000000000000000000000001-14400000000000000000000000000000000 days | 1               |
| 1440000000000000000000000000000001-21600000000000000000000000000000000 days | 1               |
| 2160000000000000000000000000000001-3600000000000                            |                 |

# The Personal Experience Lens

# How Professional Experience Influences

# Wheel Hub



- Collaborate
- Many different roles needed
- Importance of relationships

# NO Is Not Option



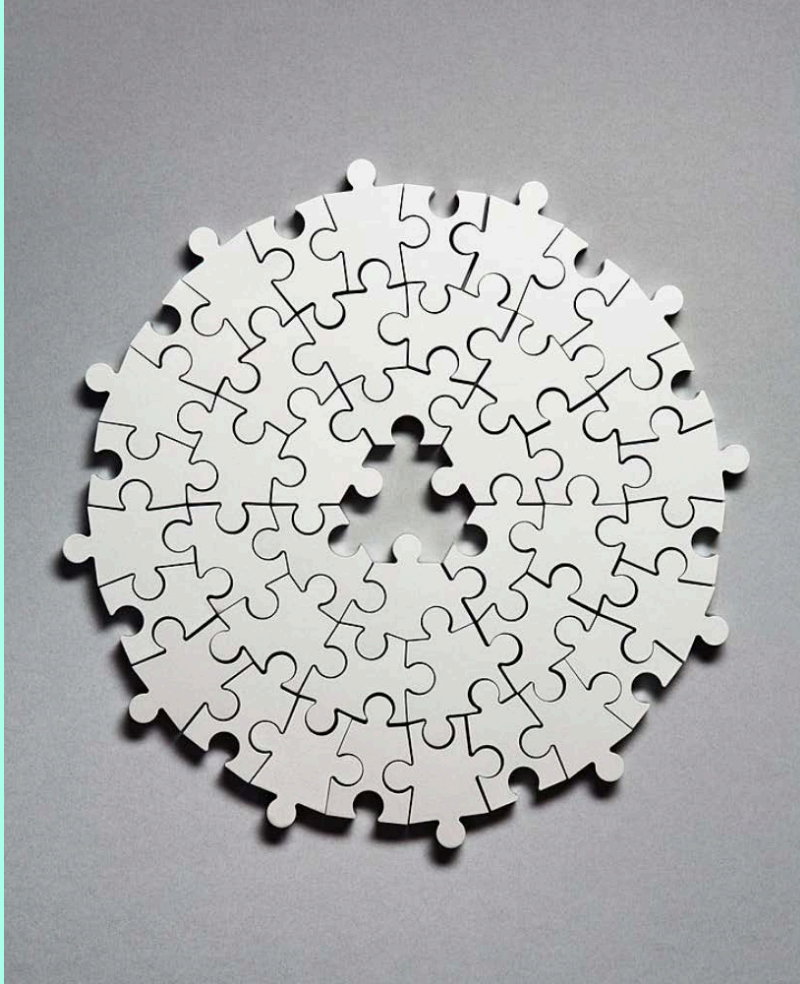
- Resourceful
- Ask for help, guidance, advice
- No rule book

# Think Outside The Box



- Research
- Look at all sides – Good, Bad, Ugly
- Strategy matters: Disruption of Narrative.

# Connect The Pieces



- Make it relevant
- Tell a different story
- Build on learning

Thank you!!!

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