**Subject**: Statistical Review of P180001  
      Device for treatment of insanity in FDA reviewers, Pain Inc.

**To**:   Slave Driver, Lead Reviewer  
      ODE/SOS/ZZZ

**From**:  Mathematical Statistician: Laura Thompson, Ph.D.  
       OSB/DBS/TSBII

**Date**:   November 18, 2018

# Background

This describes the background of the device, including regulatory history and device description.

# Study Design

The study was a randomized, controlled, two-arm trial. Here are some other details about the study.

## Primary Endpoints

The primary effectiveness endpoint was the subject’s score on the Happiness Index.

## Secondary Endpoints

The secondary endpoints were

* Endpoint 1
* Endpoint 2
* Endpoint 3

# Study Results

Results showed that the device was not effective.

# Statistical Issues

This section describes my issues with the sponsor’s analyses..

## Issue 1

Here is the first issue with the sponsor’s analyses.

## Issue 2

Here is the second issue.

# Deficiencies

1. Def 1
2. Def 2

# Conclusions

In this paragraph, I describe my conclusions.

If you have questions about this review, please contact me.

#### Laura Thompson