UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
GREENBELT DIVISION

MALLINCKRODT INC., Plaintiff, vs. UNITED STATES FOOD AND DRUG ADMINISTRATION et al., Defendants.	)	No. 8:14-cv-03607-DKC

SUPPLEMENTAL DECLARATION OF MARIO SALTARELLI

I, Mario Saltarelli, hereby declare as follows:

1. I make this Supplemental Declaration based upon my personal knowledge.

2. I previously submitted a Declaration in this matter, which was filed in support of Mallinckrodt's motion for temporary restraining order (filed on Monday, November 17, 2014). This Supplemental Declaration provides additional information relevant to the issues before the Court.

3. My prior Declaration explained that FDA's reclassification action was based on plain factual errors and unsupported assumptions. In particular, in paragraphs 28

through 35 of my Declaration, I explained that FDA had drawn faulty and illogical conclusions based on adverse event reports.

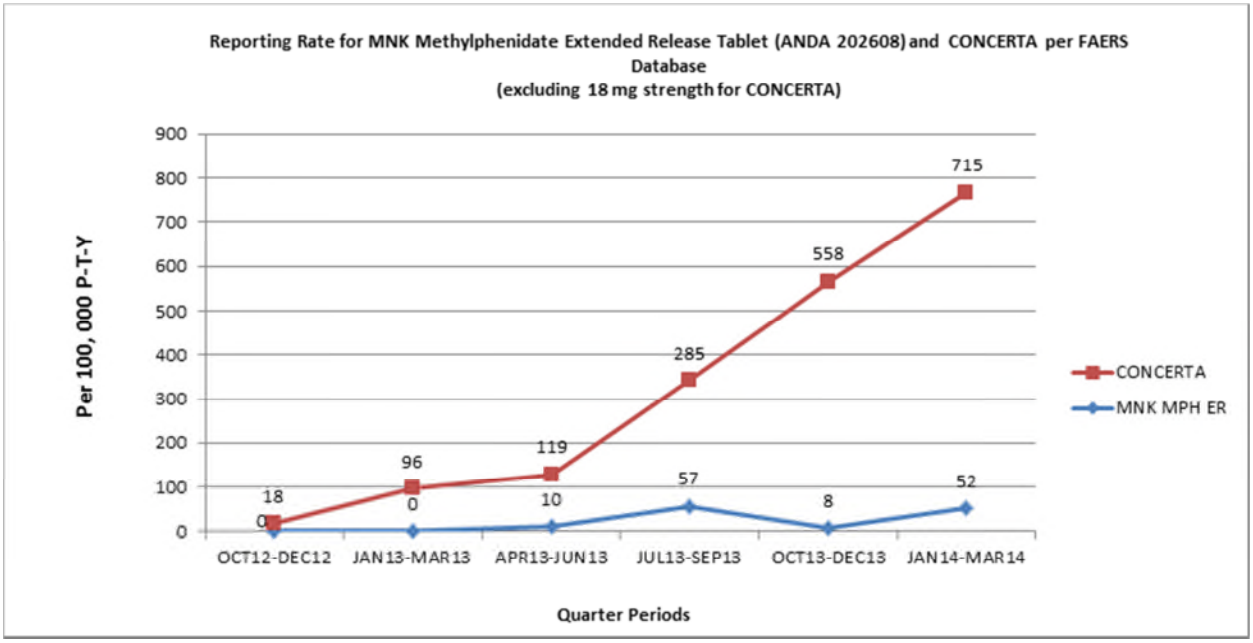
4. FDA maintains a database called the FDA Adverse Event Reporting System ("FAERS"). The FAERS database contains publicly available information on adverse event and medication error reports submitted to FDA. Relevant here, the FAERS database contains data regarding adverse event reports about Mallinckrodt's methylphenidate ER. Likewise, the FAERS database contains data regarding adverse event reports about the brand-drug Concerta®.

5. As explained in my prior Declaration and in the FDA Memo attached thereto as Exhibit D, FDA purported to base its reclassification action on information contained in the FAERS database. In particular, FDA claimed that reports in the FAERS database showed "possible therapeutic inequivalence" for Mallinckrodt's methylphenidate ER. In a related public statement (attached as Exhibit C to my prior Declaration), FDA stated that the number of reports citing lack of lack of therapeutic effect for Mallinckrodt's product was "very small compared to the overall usage of the products."

6. I have reviewed and analyzed the publicly-available information contained in the FAERS database. Specifically, I have searched for reports of "therapeutic failure", based on 16 search terms provided by FDA, both for Mallinckrodt's methylphenidate ER and for Concerta®.

7. Based on my analysis, the reporting rate of "therapeutic failure" for Concerta® is *much higher* than the reporting rate for Mallinckrodt's methylphenidate ER. In other words, FDA's own database shows a significantly higher rate of "therapeutic failure" reports for the brand-name drug than for Mallinckrodt's product.

8. I have summarized the data in the graph below. The data in the chart are normalized to 100,000 patient-treatment years—a standard measure routinely used by FDA to analyze post-marketing adverse event data—in order to allow for an apples-to-apples comparison between the two products. This analysis includes the 27, 36 and 54 mg tablet strengths of Concerta® because Mallinckrodt is not marketing an 18 mg tablet strength.



9. The above graph shows reporting rates on a quarterly basis for the time period beginning with the fourth quarter of 2012 (October-December 2012) and ending

with the first quarter of 2014 (January-March 2014). As shown throughout this entire time period, the reporting rate for Concerta® was much higher than that for Mallinckrodt's methylphenidate ER product. For example, for the period July through September 2013, FDA received 57 reports of "therapeutic failure" per 100,000 patient-years exposed to Mallinckrodt's product. During that same time period, FDA received 285 reports of "therapeutic failure" per 100,000 patient-years exposed to Concerta®. Thus, for the period July through September 2013, the reporting rate ratio for Concerta® and Mallinckrodt's product is 5 (285 divided by 57). In addition, for the period January through March 2014, the number of "therapeutic failure" reports per 100,000 patient-years exposed to Concerta® and Mallinckrodt's product are 715 and 52, respectively; the reporting rate ratio is 13.75 (715 divided by 52).

10. The data in the FAERS database further undermine FDA's conclusions regarding the Mallinckrodt product's therapeutic equivalence.

11. In its stated rationale for the reclassification action, as noted above, FDA cited data about adverse event reports for Mallinckrodt's product. However, FDA did not cite or even acknowledge data about adverse event reports for Concerta®. Thus, FDA apparently ignored that the reporting rate of "therapeutic failure" for Concerta® is much higher than that for Mallinckrodt's methylphenidate ER.

I swear under penalty of perjury that the foregoing is true and correct.

Mario Saltarelli

Dated this 19th day of November 2014.