

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

R.J. REYNOLDS TOBACCO COMPANY,
LORILLARD TOBACCO COMPANY,
COMMONWEALTH BRANDS, INC., and
LIGGETT GROUP LLC, and SANTA FE
NATURAL TOBACCO COMPANY, INC.,

CIVIL ACTION NO. _____

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, MARGARET
HAMBURG, Commissioner of the United
States Food and Drug Administration; and
KATHLEEN SEBELIUS, Secretary of the
United States Department of Health and
Human Services,

Defendants.

DECLARATION OF J. BRICE O'BRIEN

I, J. BRICE O'BRIEN, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

Introduction & Issues to be Addressed

1. I am the Executive Vice President of Consumer Marketing at R.J. Reynolds Tobacco Company ("RJRT"). RJRT is an indirect wholly-owned subsidiary of Reynolds American Inc. RJRT was founded in 1875 and today is the second-largest tobacco company in the United States and manufactures several leading brands of cigarettes (such as Camel, Pall Mall, Winston, Salem, Doral and Kool).

2. In my current position, which I have held since January 2010, I have responsibility for the marketing of all of RJRT's brands to consumers, including overall brand

strategic planning, product development, advertising and marketing communications with consumers, including packaging and point of sale marketing at retail.

3. I have been employed by RJRT from 1995 – 2000 and from 2001 to the present. Over the course of my employment at RJRT I have held each of the primary positions relating to the marketing of the company’s brands. During the period from 2000 – 2001 when I was not at RJRT I was employed by Suntory Water Group as Director of Marketing. I have a bachelor’s degree in Business Administration from The Citadel and a Master of Business Administration from Wake Forest University.

4. This declaration will address the steps RJRT must take to comply with the new labeling requirements imposed by the Food and Drug Administration (“FDA”) in its Final Rule implementing the Family Smoking Prevention and Tobacco Control Act, Pub. Law No. 111-31, 123 Stat. 1776 (2009) (the “Act”). *See Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36628 (June 22, 2011) (“the Rule”). In particular, the declaration describes each step RJRT must take, the cost of each step, and the timeline RJRT will follow, in order to meet the Rule’s September 22, 2012 effective date.

RJRT’s Implementation of Packaging Changes

5. The Rule requires that RJRT make major revisions to every style of packaging for every one of its cigarette products. RJRT has over 200 separate cigarette products. These products are packaged in individual packs, cartons, and cases. As a result, RJRT will need to overhaul over 480 distinct package designs. As the FDA has recognized, implementing a packaging change of this magnitude in an orderly fashion requires approximately 15 months. *See* 76 Fed. Reg. at 36703 (“The Tobacco Control Act specifies a 15-month implementation period for cigarette manufacturers to include required warnings on their packages and for all

cigarette advertisements to comply with this rule. We agree this is an appropriate amount of time for implementation of the rule.”); *id.* at 36716 (explaining that the agency included “10 percent rush charges” in calculating the cost of the Rule because “[r]esources are scarce and a large number of labeling changes [would have to be] simultaneously rushed” to meet the 15-month deadline).

6. The Rule’s labeling requirements will apply to any cigarette packaging manufactured on or after September 22, 2012, and any cigarette packaging introduced into commerce on or after October 22, 2012. In order to develop the inventory necessary to comply with these deadlines, RJRT will need to begin manufacturing cigarettes in compliant packaging beginning in July and August of 2012. If the Rule were invalidated after this point, RJRT could be stuck with an unwanted inventory of cigarettes carrying the invalidated warnings and reflecting an unrecoverable manufacturing cost of up to \$70 million.

7. In order to meet the September 22, 2012 and October 22, 2012 effective dates, RJRT has taken or plans to take the following steps:

8. First, RJRT has purchased blank metal printing cylinders, which will be engraved and used to apply the ink on the new cigarette packaging. RJRT issued a purchase order for these cylinders on June 2, 2011, at a cost of \$1.5 million.

9. Second, RJRT has hired a graphics design firm to design the new labeling beginning in June, 2011. The designers are working to revise current package designs in light of the Rule’s requirement that RJRT’s own branding and marketing be limited to the bottom half of both the front and the back of the package. RJRT estimates that the cost of this graphic design to RJRT will be approximately \$0.5 million and will be incurred from late June through mid-December, 2011.

10. Third, RJRT will need to begin the internal approval process for the new package designs in September, 2011. The approval process will be extensive given the nature of the label changes and the number of individual designs. Numerous departments—including, Consumer Marketing, Corporate Relations, Legal, Manufacturing, Operations Strategy and Innovations, Procurement, Product Services, Tax, and Trade Marketing—will need to review and approve approximately 490 individual designs. RJRT's Product Integrity team will also undertake a detailed review and approval of each pack and carton. On average, this review will require approximately 6 hours per design.

11. Fourth, RJRT will have to contract with its third-party design firm to engrave approximately 2,500 printing cylinders with the new packaging designs beginning in November, 2011. The cost of this engraving will be approximately \$3.8 million. Specifically, RJRT will incur costs of approximately \$1.2 million in November, 2011, \$0.9 million in December, 2011, \$1.2 million in January, 2012, and \$0.5 million in February, 2012.

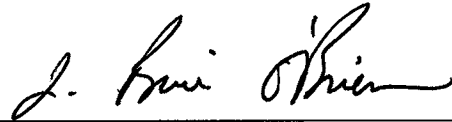
12. Fifth, RJRT will have to order new embossing for its Pall Mall packaging in December, 2011 at a cost of \$0.2 million and for its Camel packaging at a cost of \$0.5 million in January, 2011.

13. Sixth, RJRT will need to provide the engraved cylinders to its third-party packaging manufacturer and contract for the production of new packaging by March, 2012. The manufacturer must begin production in March because it will need to produce the new packaging while still producing RJRT's current packaging. The manufacturer will therefore not have its full capacity available for the new packaging. The cost of producing the new packaging will be approximately \$5.0 million.

14. In addition to the monetary costs described above, the foregoing tasks will occupy over 4,000 hours of RJRT employee time.

15. Based on its best estimates, RJRT will need to incur the foregoing costs according to the above timeline unless the effective dates of the Regulation, along with the related labeling changes tied to the effective date of the Regulation, are postponed so that RJRT may begin this implementation process after the conclusion of direct and appellate judicial review.

16. Absent a postponement, RJRT will have no choice other than to continue with its implementation even if the District Court were to invalidate the Regulation, as it could not risk the possibility of noncompliance should the District Court reject its challenge, or should the District Court invalidate the regulation but be reversed on appeal.



J. Brice O'Brien