

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DONALD EDWARD BEATY, *et al.*,

Plaintiffs,

v.

Civil Case No. 11-289 (RJL)

FOOD AND DRUG
ADMINISTRATION,

and

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES,

and

KATHLEEN SEBELIUS, in her official
capacity as Secretary of the U.S.
Department of Health and Human
Services,

and

MARGARET A. HAMBURG, M.D., in
her official capacity as Commissioner of
Food and Drugs,

Defendants.

ORDER

(March 27, 2012)

For the reasons set forth in the Memorandum Opinion entered this 27th day of March, 2012, it is hereby

ORDERED that plaintiffs' Motion for Summary Judgment and Declaratory Relief on Counts I and III [#12] is **GRANTED**; and it is further

ORDERED that the defendants' Motion to Dismiss and/or for Summary Judgment [#13] is **DENIED**; and it is further

DECLARED, pursuant to 28 U.S.C. § 2201(a), that

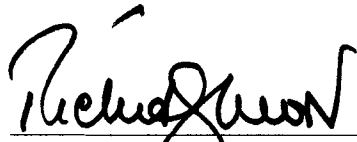
1. the foreign manufactured thiopental (or “thiopental”) imported by the importing States (e.g. Arizona, California, South Carolina, Georgia, and Tennessee) is a misbranded drug and an unapproved new drug within the meaning of the FDCA; and
2. as such, this thiopental cannot lawfully be introduced or delivered for introduction into interstate commerce or lawfully be imported into the United States; and
3. defendants’ recent actions allowing such thiopental to enter the United States were each contrary to law, arbitrary, capricious, and an abuse of discretion under the APA; and, in particular,
4. defendants’ January 4, 2011 announcement that they will allow future shipments of such thiopental to enter the United States is contrary to law, arbitrary, capricious, and an abuse of discretion under the APA; accordingly

IT IS HEREBY ORDERED that the FDA:

1. immediately notify any and all state correctional departments which it has reason to believe are still in possession of any foreign manufactured thiopental that the use of such drug is prohibited by law and that, that thiopental must be returned immediately to the FDA; and
2. be permanently enjoined from permitting the entry of, or releasing any future shipments of, foreign manufactured thiopental into interstate commerce; and

IT IS FURTHER ORDERED that the parties are hereby directed to meet and confer to determine whether further litigation is necessary, or proper, with respect to the remaining count in this Complaint.

SO ORDERED.



RICHARD J. LEON
United States District Judge