DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0222]

Order Granting Summary Judgment and Permanent Injunction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing in its entirety an order entitled ''Final Amended Order Granting Summary Judgment and Permanent Injunction.''

On July 28, 1999, United States District Judge Royce C. Lamberth entered an order and directed that it be published in the **Federal Register**. The agency is publishing this document to comply with that order.

FOR FURTHER INFORMATION CONTACT:

Regarding biological products and devices regulated by the Center for Biologics Evaluation and Research: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3028;

Regarding human drug products: Laurie B. Burke, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828;

Regarding medical devices: Byron L. Tart, Center for Devices and Radiological Health (HFZ–302), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4639.

Dated: August 9, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

BILLING CODE 4160–01–F

The order reads as follows:

BILLING CODE 1160–01–F–

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WASHINGTON LEGAL FOUNDATION,)

Plaintiff,

v.) Civil Action 94-1306 (RCL)

JANE E. HENNEY, in her official capacity as Commissioner, Food and Drug Administration,

and

DONNA SHALALA, in her official capacity as Secretary, Department of Health and Human Services,

Defendants.

FINAL AMENDED ORDER GRANTING SUMMARY JUDGMENT AND PERMANENT INJUNCTION

This action is before the Court on the Cross-Motions for Summary Judgment filed by Plaintiff Washington Legal Foundation ("WLF") and defendants Jane E. Henney and Donna Shalala.

Having reviewed the memorandum and other materials submitted, having heard oral argument and otherwise being fully advised;

THE COURT FINDS that there are no genuine issues of material fact and that WLF is entitled to judgment as a matter of law; accordingly,

THE COURT GRANTS WLF's Motion for Summary Judgment;

THE COURT DENIES Defendants' Cross-Motion for Summary Judgment;

THE COURT FINDS AND DECLARES that the policies, rules and regulations of the United States Food and Drug Administration ("FDA") set forth in the Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 Fed. Reg. 52800 (Oct. 8, 1996) (the "Reprint Guidance"), Guidance for Industry Funded Dissemination of Reference Texts,, 61 Fed. Reg. 52800 (Oct. 8, 1996) (the "Textbook Guidance"), and Final Guidance on Industry Supported Scientific and Educational Activities, 62 Fed. Reg. 64074 (Dec. 3, 1997) (the "Final CME Guidance"), are contrary to rights secured by the United States Constitution and therefore must be set aside pursuant to 5 U.S.C. § 706(2)(B) except insofar as they are consistent with the injunctive provisions below.

THE COURT FURTHER FINDS AND DECLARES that the policies, rules and regulations of the United States Food and Drug Administration ("FDA") set forth in the Food and Drug Administration Modernization Act, 21 U.S.C. §§ 360aaa through 360aaa-6, and in the FDA's Final Rule on the Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices, 21 C.F.R. Part 99, are contrary to rights secured by the United States Constitution and therefore must be set aside pursuant to 5 U.S.C. § 706(2)(B) except insofar as they are consistent with the injunctive provisions below.

THE COURT HEREBY ENJOINS Defendants, their successors, and all persons acting in concert with them or otherwise purporting to act on behalf of the United States (collectively "Defendants") from application or enforcement of any regulation, guidance, policy, order or other official action , as follows:

1. Defendants SHALL NOT in any way prohibit, restrict, sanction or otherwise seek to limit any pharmaceutical or medical device manufacturer or any other person:

a) from disseminating or redistributing to physicians or other medical professionals any article concerning prescription drugs or medical devices previous published in a bona fide peer-reviewed professional journal, regardless of whether such article includes a significant or exclusive focus on unapproved uses for drugs or medical devices that are approved by FDA for other uses and regardless of whether such article reports the original study on which FDA approval of the drug or device in question was based;

b) from disseminating or redistributing to physicians or other medical professionals any reference textbook (including any medical textbook or compendium) or any portion thereof published by a bona fide independent publisher and otherwise generally available for sale in bookstores or other distribution channels where similar books are normally available, regardless of whether such reference textbook or portion thereof includes a significant or exclusive focus on unapproved uses for drugs or medical devices that are approved by FDA for other uses;

c) from suggesting content or speakers to an independent program provider in connection with a continuing medical education seminar program or other symposium regardless of whether unapproved uses for drugs or medical devices that are approved by FDA for other uses are to be discussed.

2. For purposes of this injunction, a "bona fide peer-reviewed journal" is a journal that uses experts to objectively review and select, reject, or provide comments about proposed articles. Such experts should have demonstrated expertise in the subject of the article under review, and be independent from the journal.

3. For purposes of this injunction, a "bona fide independent publisher" is a

publisher that has no common ownership or other corporate affiliation with a pharmaceutical or medical device manufacturer and whose principal business if the publication and distribution of books through normal distribution channels.

4. For purposes of this injunction, an "independent program provider" is an entity that has no common ownership or other corporate affiliation with a pharmaceutical or medical device manufacturer, that engages in the business of creating and producing continuing medical education seminars, programs or other symposia and that is accredited by a national accrediting organization pertinent to the topic of the seminars, programs or symposia.

5. Nothing herein shall be construed to limit Defendants' application or enforcement of any rules, regulations, guidances, statutes or other provisions of law that sanction the dissemination or redistribution of any material that is false or misleading. In addition, Defendants may require any pharmaceutical or medical device manufacturer that sponsors or provides financial support for the dissemination or redistribution of articles or reference textbooks or for seminars that include references to unapproved uses for drugs or medical devices that are approved by FDA for other uses to disclose (i) its interest in such drugs or devices, and (ii) the fact that the use discussed has not been approved by FDA.

6. Defendants shall cause this injunction to be published in the Federal Register within 15 days of the date hereof.

IT IS SO ORDERED on this 28th day of July, 1999.

Royce C. Lamberth

THE HONORABLE ROYCE C. LAMBERTH
United States District Judge

[FR Doc. 99–20993 Filed 8–11–99; 8:45 am]
BILLING CODE 4160–01–C