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May 10, 2002

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Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20875

Re: National Abortion Federation's Response to Citizen Petition of  
Mr. Gene Koprowski, Docket No. 02P-0171

Dear Sir or Madam:

On behalf of the National Abortion Federation ("NAF"), we submit this response in opposition to the above-referenced petition filed by Mr. Gene Koprowski ("Koprowski Petition"). FDA should deny Mr. Koprowski's petition, because—as Mr. Koprowski admits in his own petition—the Agency lacks jurisdiction or authority to regulate the speech of independent third parties, like NAF, relating to prescription drugs or to amend unilaterally the Federal Food, Drug, and Cosmetics Act ("FDCA"). Moreover, FDA cannot establish regulations or conduct an investigation in an area, such as this, where the Agency lacks statutory authority or jurisdiction.

Mr. Koprowski has requested that FDA take the following actions:

- (1) Investigate the speech of third parties, including NAF, relating to mifepristone (RU-486);
  - (2) Amend section 301 of the FDCA relating to misbranding;
  - (3) "Refer the matter, with urgency, to any other federal regulatory body which has the authority" to regulate the speech of third parties relating to the sale of "regulated drugs"; and
  - (4) amend a "regulation" to restrict the speech of third parties with respect to food, drugs, and cosmetics. (Koprowski Petition at 2.)
- For the reasons stated below, FDA should deny the Koprowski Petition in its entirety.

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**I. AS MR. KOPROWSKI ADMITS IN HIS PETITION, FDA LACKS JURISDICTION TO REGULATE THE SPEECH OF THIRD PARTIES RELATING TO PRESCRIPTION DRUG PRODUCTS.**

Mr. Koprowski admits in his petition that FDA lacks jurisdiction under the FDCA to regulate third party speech relating to prescription drug products. Mr. Koprowski

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characterizes this limitation on FDA's authority to regulate the speech of third parties as "a lacuna in the law" (Koprowski Petition at 1.) In recognition of the fact that he seeks from FDA that which the Agency has no legal authority to deliver, Mr. Koprowski then requests that FDA "[r]efer the matter, with urgency, to any other federal regulatory body which has the authority" over such matters he is concerned about. (Koprowski Petition at 2.)

The plain text of the FDCA makes clear that Congress has not authorized the Agency to regulate third party speech. As Mr. Koprowski acknowledges, FDA's advertising, labeling, and misbranding provisions are "generally interpreted to regulate the activities of manufacturers of drugs." (Koprowski Petition at 1.) In fact, the FDCA makes clear that FDA's statutory authority to regulate prescription drug advertising extends only to manufacturers, packers, and distributors of drug products. See 21 U.S.C. § 352(n) (establishing restrictions on prescription drug advertising "issued or caused to be issued by the manufacturer, packer, or distributor" of a drug); see also 21 C.F.R. § 202.1(l)(2) (defining labeling as items "supplied by the manufacturer, packer, or distributor" of a drug). Mr. Koprowski admits as much.

In addition to having no textual basis in the FDCA, Mr. Koprowski's petition raises serious concerns under the First Amendment. As the Supreme Court recently observed while striking down FDAMA's advertising restrictions on pharmacy compounding: "If the First Amendment means anything, it means that regulating speech must be a last—not first—resort." *Thompson v. Western States Medical Center*, 535 U.S. \_\_\_\_ (2002). In fact, NAF's non-commercial and public service-oriented speech, about which Mr. Koprowski complains, would be entitled to an even higher level of constitutional protection than the commercial speech at issue in *Western States*.

Because FDA lacks the authority to regulate the speech of third parties with respect to prescription drug products, any investigation into such speech is not authorized by the FDCA. Conducting an investigation in an area plainly outside FDA's statutory mandate would be unlawful and would waste the precious resources of the Agency. Moreover, since Mr. Koprowski has failed to request action for which FDA may provide relief, the Agency is obliged to deny Mr. Koprowski's request.

## **II. FDA LACKS AUTHORITY TO AMEND THE FDCA UNILATERALLY.**

Mr. Koprowski also requests that FDA "amend Section 301" of the FDCA to allow the Agency to regulate third party advertising relating to drug products. Again, Mr. Koprowski requests that FDA take an action that would be contrary to law. Neither FDA, nor any other Executive Branch agency, holds the power to create or amend

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legislation without the approval of both houses of Congress. See U.S. CONST. art. I. Moreover, Mr. Koprowski's request, again, is an admission that FDA lacks statutory authority to restrict such third party speech. Therefore, FDA should deny this portion of Mr. Koprowski's petition as well.

### **III. FDA LACKS AUTHORITY TO ESTABLISH A REGULATORY REGIME AS MR. KOPROWSKI REQUESTS.**

Finally, Mr. Koprowski requests that FDA "amend" its "regulation" to prohibit certain forms of third party speech relating to prescription drugs and other products. As discussed in Section I above, and as Mr. Koprowski admits in his petition, FDA lacks statutory authority to regulate third party speech with respect to prescription drugs. Thus, the Agency may not restrict such speech by regulation or any other means. Establishing such a regulation would be an unlawful action "in excess of statutory jurisdiction" under section 706(C) of the Administrative Procedure Act. 5 U.S.C. § 706(C). Thus, Mr. Koprowski has requested that FDA take action for which it is unable to provide relief under law.

For the reasons stated above, NAF requests that FDA deny Mr. Koprowski's petition in full. Mr. Koprowski has petitioned the Agency to take actions that are unauthorized by statute. Given the nature of these requests, any further consideration of this matter would constitute a waste of the Agency's valuable resources.

Respectfully submitted,



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