November 2, 2005

PRESENTATION BY THE WASHINGTON LEGAL FOUNDATION (WLF) AT FDA'S PUBLIC HEARING ON CONSUMER-DIRECTED PROMOTION OF REGULATED MEDICAL PRODUCTS

[Docket No. 2005N-0354]

WLF. My name is Richard Samp. I am Chief Counsel of the Washington Legal Foundation, a nonprofit public interest law and policy center based in Washington, D.C., with supporters nationwide. WLF devotes a considerable portion of its resources to opposing unwarranted government restrictions on commercial speech – thus our interest in the topic being considered in today's hearing. WLF has for several years tracked DDMAC's oversight of prescription drug promotional activities. In 1995, WLF filed a Citizen Petition, calling on FDA to relax restrictions on DTC advertising, and I repeated that call in testimony I gave at an FDA hearing in October 1995. In 1998, we prevailed in a federal court challenge to the constitutionality of FDA restrictions on the ability of doctors and patients to receive truthful information about off-label uses of approved drugs; the court injunction against FDA remains in place.

In June, WLF launched a new program called "DDMAC Watch." Under this program, WLF reviews and responds to, warning and untitled issued by DDMAC or by its counterpart in the biologics center, OCBQ. To date, WLF has responded to 12 DDMAC and OCBQ letters. To date, we have received no response from the agency. We nevertheless have no intention of stopping the program. WLF is firmly convinced that FDA regulation of speech about therapeutic products must be the subject of a searching inquiry – both because of the public health importance of public access to scientific information about FDA-approved products and because FDA's current policies and practices present grave statutory and constitutional problems.

Benefits of DTC. The public health benefits of DTC advertising are by now well-known. Those benefits are well-illustrated by data from FDA's 2002 national telephone survey. The survey included both health care practitioners and adult patients who had visited a healthcare provider within the last 3 months and sought to assess their exposure to, perceptions of, and attitudes toward DTC advertising. [response rate: 53%; sample size = 944.] Forty-three percent of respondents reported that an advertisement caused them to look for more information about the drug or their health. Eighty-nine percent of respondents reported obtaining information from their doctors. Seventy-two percent of physicians believe a "great deal" or "somewhat" that DTC makes patients aware of possible treatments. DTC advertisements prompted 18 percent of respondents to seek information about new or previously untreated conditions. DTC advertising thus encourages patients to seek health information, increases awareness of possible treatments, and reinforces health care practitioners as authoritative sources of information. These findings are consistent with earlier research.

In light of the enormous benefits of DTC advertising, WLF does not understand DDMAC's apparent hostility. Rather than help manufacturers fulfill their

potential to be valuable sources of health information for patients, DDMAC often works actively to repress speech that it has no basis for deeming to be false. Most alarming to WLF, DDMAC has taken to attacking scientifically valid clinical study reports and prohibiting manufacturers from disseminating study data to health care practitioners and patients.

- On June 28, 2005, for example, DDMAC sent a warning letter to Endo Pharmaceuticals objecting to the presentation of data from a clinical investigation of LIDODERM. The data were published in a reputable medical journal. Nevertheless, DDMAC demanded that Endo "immediately cease the dissemination" of information about the study because DDMAC did not like the study design.

- On July 15, 2005, DDMAC sent an untitled letter to Abbott Laboratories objecting to the presentation of data from a clinical investigation of SURVANTA. The data were published in a reputable medical journal. According to DDMAC, the study did not constitute "substantial evidence" and, therefore, could not be relied upon by Abbott to substantiate its claims.

These are but two examples of a well-established policy within DDMAC of prohibiting manufacturers from sharing valid, clinically relevant scientific information. It is paternalistic in the extreme for DDMAC to purport to forbid speech based on peer-reviewed scientific journal articles, and WLF asks the Division to change its policy immediately. This is precisely the type of information that DDMAC should encourage manufacturers to share, not only with health care practitioners, but also directly with patients. That's what's mandated by the First Amendment, and it's what's good for the public health.

Corrective Advertising. FDA has requested comment on its practice of "asking" sponsors to run corrective advertisements or issue corrective promotional materials to remedy impressions created by potentially false or misleading materials. Let's be clear what we're talking about. DDMAC does not "ask" sponsors to run corrective advertisements. Although the agency uses language suggesting a sponsor has a genuine option to reject a request for corrective messaging, what goes on between DDMAC and sponsors is not exactly an arm's-length transaction. Sponsors know that if they resist DDMAC's "request," they run the risk of souring their relationships with DDMAC, to the detriment of the company. This is not merely speculation on WLF's part. Within the past month, we have learned that DDMAC has told two sponsors that, if they press their rights, DDMAC will give "strict scrutiny" to every single one of their promotional pieces. Let there be no doubt: DDMAC expects companies to engage in corrective messaging whenever the Division desires it.

What's more, DDMAC never, and I mean never, has an empirical basis for determining that corrective messaging is necessary. DDMAC does not survey consumers to determine whether a particular promotional piece has, in fact, been misleading. If it uses any criteria at all, they have not been, to our knowledge, disclosed to the public. This is extremely troubling to WLF from a "good government" perspective. The lack of empirical data is also constitutionally suspect.

It is a bedrock principle of constitutional law that the First Amendment limits not only government restrictions on speech, but also government compulsion to speak. WLF has seen no indication that FDA has considered whether its "requests" for corrective advertising comport with the First Amendment as a general matter. And we view it as highly unlikely that anyone in FDA engages in a First Amendment analysis each time DDMAC sends a warning letter seeking corrective advertising.

It is far from certain that DDMAC's use of corrective advertising would survive First Amendment scrutiny. DDMAC does not ascertain the extent to which the audience was actually misled or how effective, if at all, "corrective" advertising would be in redressing the alleged harm. The efficacy of this remedy is questionable because of the long period that usually lapses between initial use of the promotional message and issuance of the corrective advertising. It is entirely possible, even likely, that the corrective messages themselves are misleading to consumers. Does DDMAC do copy testing of the messages it requires sponsors to disseminate?

There is another problem with DDMAC's use of corrective messaging: the lack of statutory authority for it. The FDCA establishes a very specific set of tools that the agency can use to remedy statutory violations. Corrective advertising is not among them. It is an unsettled question whether the agency's authority to seek injunctive relief in a court under the FDCA includes the authority to impose corrective advertising administratively, without judicial involvement. As the Supreme Court has taught us, judicial involvement is an important safeguard against unlawful government interference with the exercise of speech rights. We call on DDMAC to curtail or eliminate all efforts to seek "corrective" advertising.

Established Policies/Procedures (DDMAC). It is abundantly clear to WLF that DDMAC has in place many policies and procedures that drive its decisions on promotional materials but that have not been made available for public review. The FDCA and FDA's own regulations require the agency to announce new regulatory expectations to regulated industry by going through the notice-and-comment rulemaking or guidance processes. Anyone conversant with DDMAC regulatory practice knows that you could be an expert on the statute, the regulations, and the guidance documents and still know only a tenth of the rules governing drug promotion.

For example, it is clear from DDMAC's warning and untitled letters that there are limitations on the length of time a company can say that its product is "new." But you would be hard-pressed to find any authoritative document in which that "rule" appears. It is also obvious that there are circumstances in which "breakthrough" is not allowed. We learned from recent corrective messaging required with respect to ENBREL that "breakthrough" can only be used if sponsors conduct head-to-head comparative studies.

WLF has pointed out numerous examples of de facto rules in our correspondence to DDMAC and OCBQ under the DDMAC Watch program. We expect and hope that FDA will reexamine DDMAC's modus operandi and ensure that the only

rules that are relied upon in reviewing promotional materials are those that have gone through the statutorily prescribed procedures.

Excessive Information. Earlier this morning, I read over my October 1995 testimony to FDA on DTC. Much of that testimony focused on burdensome disclosure requirements that require that consumers be provided information that they cannot possibly understand because it is really intended for health professionals. Unfortunately, 10 years later, DTC print promotion is still burdened by many of those same requirements. To take one example, suppose a manufacturer wishes to convey the following message: "you have been prescribed Drug X for your disease; take Drug X exactly as your doctor prescribed." It makes little sense that, under current FDA rules, the manufacturer who conveys that message will also have to provide the full PI as well as comply with "fair balance" and FDA's many other requirements. FDA needs to streamline its disclosure requirements in order to ensure that the information being conveyed to patients is useful and meaningful.

Suggested Reforms. WLF has repeatedly communicated with FDA concerning our views on the ways in which the agency's regulation of speech should be changed. We are submitting for the record copies of those previous suggestions. Our main message for you at this important meeting is that there remains much work to be done to ensure that DDMAC's policies and procedures respect the First Amendment and are consistent with the agency's statutory authority. Rather than clamp down on consumer-directed advertising, as the meeting notice implied should be done, FDA should find ways of getting more health information to patients. That is the only approach that accords with the Administration's expressed commitment to treating consumers as partners in their own health care. It is the only approach that accords with the First Amendment. And it is the only approach that truly promotes the public health.

Thank you for the opportunity to speak.