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Pursuant to Food and Drug Administration's Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products Notification of Public Hearing, attached is a draft of the testimony that I intend to provide to FDA at its November 9, 2016 hearing.

Sincerely,

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I would first like to thank the Food and Drug Administration and its staff for allowing me an opportunity to testify on this important topic on behalf of Washington Legal Foundation. Since WLF first reintroduced the First Amendment rights of pharmaceutical manufactures to communicate truthfully about their products to FDA nearly twenty years ago, we have often needed to remind FDA about the agency's constitutional responsibilities to the various entities it regulates. Today marks another one of those occasions. Although we are encouraged by this effort to review FDA's off-label communication policies, we are disappointed that FDA has once again forgotten to mention the First Amendment. It is utterly inexplicable that FDA's Notice of Public Hearing and Request for Comments on the topic of Manufacturer Communications Regarding Unapproved Uses of Approved Medical Products would completely fail to mention the First Amendment—but it did. WLF hopes that this omission was simply an oversight and not a return to a policy of restricting speech about off-label uses, which has consistently been rejected by the courts for the last two decades. As the Administration reviews its regulations and policies regarding off-label communications, WLF encourages it to keep the First Amendment rights of patients, doctors, and health care companies uppermost in its mind.

Starting in the late 1990s with the *Washington Legal Foundation* cases, courts have consistently upheld corporations' and their representatives' First Amendment rights to communicate truthfully and non-misleadingly about the effects of their products. Courts have held that such a right is not limited by FDA approval of the use that is under discussion. Rather, the limiting factor on a company's speech is a classic First Amendment test: whether the communication is false or misleading. Therefore, the FDA may only restrict health care companies' speech regarding both approved *and* off-label uses if it is untrue or misleading to the listener. This test is grounded in both the Constitution and sound public policy. Pharmaceutical and medical device companies and their representatives possess the same rights to free speech under the First Amendment as other individuals, and patient care is strengthened by increased access to truthful information and innovation regardless of its origins.

While FDA must play an important role in preventing false and misleading information, it must also work to ensure patients, physicians and health care companies maintain access to the latest information and most current innovation. To accomplish this, the agency must be careful not to limit the free flow of information. It must not encroach on the First Amendment rights of various health care stakeholders.

When reviewing its off-label communication regulations, FDA should be mindful that any speech's ability to mislead depends significantly on its audience. Based on a multitude of factors, some audiences are more equipped to parse the subtleties of an academic journal's recent article or a new scientific study. Doctors and other qualified healthcare professionals are not misled by the same information that might confuse members of the general public, and therefore do not require the same protections. Even when an off-label use described in a commercial targeted at the lay public might be considered misleading, that very same statement when made to a room of doctors might well not be. FDA's regulations should reflect that fact and allow

health care companies more latitude to discuss the off-label uses of their products when addressing medical professionals.

Further, American doctors have the right to practice medicine as they see fit and a duty to act in the best interest of their patients, subject only to regulation by state medical boards. As a result, many doctors believe that standards of care and/or best practices require them to prescribe medication because of its non-approved effects on their patients. Failure to do so could be considered malpractice in some circumstances. Any FDA policy limiting information about potentially life-saving off-label uses could seriously compromise the medical profession and interfere with its duty to patients.

So, while the First Amendment clearly permits FDA to restrict false or misleading speech, it must be careful in how it attempts to codify those restrictions. Of importance, too, is the way in which FDA seeks to define truthful information. FDA's approval process requires studies to be "adequate and well controlled." That high standard might be ideal for the approval process, but it would be a mistake to conflate it with the test for falsity under the First Amendment. A clinical trial might not have been "well controlled" because, for example, its supervisors decided not to give sick participants a placebo, but that does not mean that its results would be considered "false" under the First Amendment. Courts have been clear that a communication is not false unless it is of absolutely no scientific value. Many valuable studies have passed through the peer-review process and been accepted for publication in reputable journals without meeting FDA's restrictive definition of "well-controlled" study. Moreover, it is well accepted that these studies can impart valuable information. Should FDA try to use its "well controlled" definition as its test for First Amendment falsity, it would not only infringe on health care companies' constitutional rights, but it would also prevent doctors from learning about potentially lifesaving treatments and keep their patients from receiving the best care possible.

That is not to say that FDA has no role in protecting consumers from suspect research and unscientific studies. FDA's requirement of disclaimers attached to disseminated journal articles, which grew out of WLF's litigation with the agency, is a well-reasoned approach to ensure that medical professionals have the information they require when deciding the best treatment for their patients. Disclaimers can provide doctors with the necessary context to fully understand the trials and the effects of a product's non-approved uses. However, disclaimer requirements can become burdensome on health care companies and medical professionals if they are required too liberally. Expansive disclaimers can overwhelm the recipients of the communications and obscure the most important information. Even worse, unreasonable burdens placed on pharmaceutical manufacturers can be so extensive as to discourage dissemination from occurring in the first instance. Such disclaimer regulations become *de facto* prohibitions on speech, suspect under the First Amendment, and they unlawfully impede doctors from learning about important and lifesaving treatments. It would therefore be both bad policy and a violation of the First Amendment to require more disclaimers on communications regarding non-approved uses

than are necessary to give medical professionals the context they need to make decisions about their patients' care.

Finally, on behalf of Washington Legal Foundation, I would like to again thank FDA for the opportunity to testify today. We appreciate the Administration's continued work in this area and hope that it learns to balance the real needs for regulation with the First Amendment rights of health care companies. In addition to today's testimony, WLF will be submitting written comments later in the year. We trust that FDA will take seriously our constitutional concerns, and we hope that it will pursue policies that are consistent with its constitutional duties. Thank You.