Vanda Pharmaceuticals Comments on FDA's Recently Announced Guidance on Communication with Health Care Professionals Regarding FDA-Approved Drugs

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WASHINGTON, Jan. 12, 2024 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) submitted a comment letter (here) on January 5, 2024, regarding the FDA's recently announced policy—by way of a draft guidance document—that substantially restricts drug manufacturers' ability to communicate truthful, non-misleading information about FDA-approved drugs.

Communication of novel scientific findings and emerging therapies is crucial to inform healthcare providers about new treatment options that did not exist at the time of their medical training. Innovators who conduct this research play a significant role in communicating this new information to healthcare providers. The FDA's guidance document, *Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products (October 2023)*, threatens drugmakers with criminal misbranding liability when they share truthful, non-misleading scientific information about unapproved uses of FDA-approved drugs—like the results of a new clinical trial—with healthcare providers unless the communication satisfies vague and nebulous FDA standards for both form and scientific substance. The FDA's assertion of such broad authority to censure the scientific information that drug manufacturers may share with healthcare providers—doctors and others who are working tirelessly to find innovative solutions for individual patients suffering from a wide range of afflictions—is of grave concern, as it encroaches on freedom of speech, hastily attempts to coerce manufacturers into compliance without due process, and imposes rules without clear direction from Congress in addressing major questions that broadly affect the practice of medicine and public health.

Vanda's comment argues that there are four problems with the FDA's approach:

- The FDA's guidance imposes content-based burdens on drugmakers' protected commercial speech in violation of the First Amendment.
- The FDA's standards are too vague to satisfy the minimum requirements of due process.
- The Federal Food, Drug and Cosmetic Act does not give the FDA the authority to regulate marketing of approved drugs for off-label use.
- The FDA's guidance in fact sets binding standards, even though the FDA describes the guidance as a "nonbinding statement of policy."

Vanda's full comment is publicly available and also on Regulations.gov here.

About Vanda Pharmaceuticals Inc.

Vanda is a leading global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com and follow us on Twitter @vandapharma.

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