



April 30, 2018

The Honorable Rosa DeLauro
United States House of Representatives
Washington, DC 20515

Dear Congresswoman DeLauro,

As a nonprofit physicians' advocacy group that puts patients first, with a core principle of not taking any pharmaceutical or medical device company funding, we at the National Physicians Alliance thank you and offer our support for your pressuring the FDA to scrutinize the unprecedented number of deaths reported as associated with Nuplazid.

Several of our members have worked at the FDA and others sit on advisory committees for the agency. We understand the nuances of the FDA approval process, and that unfortunately, approval does not necessarily mean that a drug or device is safe or effective. We are concerned about the lowering of the FDA's standards as illustrated by the example of Nuplazid. The drug never should have been approved, as noted by the FDA physician primarily responsible for evaluating it, but who was overruled by his superiors. After three failed clinical trials, the company tweaked their study design and analysis, and was able to come up with a positive study. This is but one flaw in our approval system for drugs.

We will continue to fight against any expansion of indications of this drug, and we hope you will too.

Sincerely,

A handwritten signature in cursive script that reads 'Susan Molchan, MD'.

Susan Molchan, MD
Chair of the Board of Directors
National Physicians Alliance

The National Physicians Alliance is a non-partisan, non-profit organization that offers a professional home to physicians across medical specialties. We create research and education programs that promote health and foster active engagement of physicians with their communities. The NPA accepts no funding from pharmaceutical or medical device companies.

Learn more at NPAlliance.org