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Pallone Voices Concern About Off-Label Medical Product Communications Legislation at Health Hearing

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Washington, D.C. – *Energy and Commerce Ranking Member Frank Pallone, Jr. (D-NJ) delivered the following opening remarks at a Health Subcommittee hearing titled, "Examining Medical Product Manufacturer Communications:"*

Mr. Chairman, I want to thank you for holding today's hearing. The issue before us today is an important one, and I hope that our discussion will help to inform whether or not it would be appropriate for this Committee to take further action at this time.

Today, under current law, medical product manufacturers are required to demonstrate the safety and effectiveness of each intended use of their medical product. This review process has been critical to protecting and promoting public health by ensuring that the benefits of medical products that are prescribed to patients outweigh the risks. It is also commonsense – just because a medical product approved for one use may be found to be safe and effective for that use, does not necessarily mean that it will be safe and effective for another use or for another population.

Recognizing that physicians may prescribe treatments off-label in response to individual patient needs, FDA allows the communication of truthful and non-misleading scientific or medical information regarding unapproved uses of medical products that may assist physicians in making treatment decisions. In these instances, FDA has allowed for manufacturers to respond to requests from physicians about unapproved uses and provide peer-reviewed journal articles, scientific or medical texts, and clinical practice guidelines. Following 21st Century Cures, manufacturers are also now able to share health care economic information with payors to help them better understand the economic benefits of an approved treatment.

These are commonsense approaches that allow doctors to address the individual needs of a patient, but also ensure that patients are not unnecessarily exposed to unproven or harmful medical products.

Today, we are here to examine discussion drafts from Representatives Griffith and Guthrie that would greatly expand the types of scientific information that manufacturers could share without any FDA oversight. While I understand that medical product manufacturers have voiced concern about their ability to communicate with doctors about their products, I am concerned that these drafts would severely undermine the current protections against marketing unsafe and ineffective medical products. During this hearing, I hope to hear what materials manufacturers want to share with health care professionals and payors today that they feel they cannot under current law.

The scientific exchange discussion draft would severely restrict the types of evidence the FDA has always relied on to determine the intended use of a medical product. It would also hamstring the agency from holding bad-actors who distribute dangerous drugs or medical devices accountable.

The preapproval communication discussion draft would blow a hole in the current approval process by allowing the communication of any scientific evidence or health care economic information to payors or formularies without any recourse for the FDA to prevent bad actors from communicating false or misleading information. Allowing manufacturers to communicate about unapproved products and unapproved uses of their products, reduces the incentive to go through FDA's approval process. This is grossly irresponsible.

For example, the proposed discussion draft would allow for a manufacturer to publish a biased scientific study in any medium to constitute "scientific exchange." This could include simply posting results of a non-peer reviewed study on a company's own website, and there is no requirement that this information be truthful.

I am concerned these two discussion drafts could expose more patients to medical products that have never been proven to be safe or effective. One study found that 81 percent of medications prescribed for off-label purposes had poor or no scientific support, while another found that patients who received off-label prescriptions were 54 percent more likely to experience an adverse event as compared to on-label use. These are risks that we simply cannot ignore.

If there is a need for greater certainty and clarity on the types of communications that manufacturers are permitted to use under current law, I am willing to have that discussion. However, broadening communication in the ways proposed under these discussion drafts would undermine FDA's regulatory review process and the safety and effectiveness approval standard.

Thank you.

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