Opening Statement of Chairman Greg Walden
Subcommittee on Health
Hearing on "Examining Medical Product Manufacturer Communications"
July 12, 2017

(As prepared for delivery)

Thank you Chairman Burgess for holding today's hearing on an increasingly important topic – one that has been a topic amongst our members for some time.

Approximately 40 percent of prescriptions in this country are for indications or uses not included in the FDA-approved product labeling. Although "off-label" uses of drugs and devices are often the recognized standard of care for treating many conditions, the lack of clarity in the statute and implementing regulations has stifled important information about such uses from being communicated in a responsible, non-promotional manner by manufacturers.

FDA has attempted to address this issue in a piecemeal fashion over the last two decades with various non-binding guidance documents and policy statements that fall woefully short, particularly given the criminal penalties in play.

Since the Supreme Court affirmed in 2011 that First Amendment commercial speech protections extend to medical product manufacturers, every subsequent judicial decision has raised significant questions about the extent of FDA's authority to restrict truthful and non-misleading off-label communications.

So, where are we today? The regulators and the courts have spoken. Everyone is left with a vast amount of uncertainty that does nothing to protect or benefit patients.

It is past time for Congress to act, and as FDA's authorizing committee it is our job to clarify the statute.

Which brings us to this hearing. Neither of these bills are new to my fellow committee members. We discussed an earlier version of both bills during a markup in this subcommittee back in May, and we reviewed these updated

versions at the full committee markup of the FDA Reauthorization Act (FDARA) last month.

Both bills were ultimately withdrawn as amendments to FDARA, with a commitment from our Democrat colleagues to continue to work together to iron out a compromise on moving these important policies forward. I look forward to continuing that work today.

I believe Morgan Griffith's bill, H.R. 1703, is a serious, well-thought-out policy proposal that responsibly sets the rules of the road in a constitutionally sound manner. I greatly appreciate his willingness to continue to address concerns he has heard about the legislative language. I am also appreciative of Ranking Member Pallone's commitment at the user fee markup to work with us on this issue through regular order, which starts with this important hearing.

In addition, Rep. Guthrie's amended version of H.R. 2026 would clarify how drug and medical device companies can share health care, economic, or scientific information related to investigational uses of their products with payers and similar entities.

These bills do not provide manufacturers with free rein to communicate any and all information about their products. They establish targeted statutory boundaries within which manufacturers may responsibly disseminate accurate, and up-to-date information about medical products. These clarifications will lead to a better-informed health care system and will ensure that patients receive high-quality care based on current, sound scientific and clinical information.

Today we continue the dialogue, and I look forward to a productive discussion.