

CONGRESSMAN FRANK PALLONE, JR.

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PALLONE STATEMENT AT HEALTH HEARING ON FOLLOW-ON BIOLOGIC DRUGS

Washington, D.C. --- U.S. Rep. Frank Pallone Jr., Chairman of the House Energy and Commerce Subcommittee on Health, gave the following opening statement at a subcommittee hearing this morning addressing the issue of Follow-on Biologic Drug Competition. The subcommittee hearing met to discuss a Federal Trade Commission Report on the issue.

"Good morning. Today the Subcommittee is meeting to discuss the Federal Trade Commission Report entitled, 'Emerging Health Care Issues: Follow-on Biologic Drug Competition.' This is an extremely timely report and goes to the very heart of our President and this Congress' commitment to ensuring affordable and quality health care for every American. Creating a statutory pathway for the approval of 'follow-on-biologics,' present us with an opportunity to improve millions of lives at a more affordable cost.

"Currently, brand biologics account for approximately 15 percent of total U.S. prescription drug sales and the industry is growing at a rate of around 20 percent annually. In a couple years, we could be spending over \$100 billion dollars just on biologic drugs. According to data from the Centers for Medicare and Medicaid Services (CMS), just 4 biologics account for 30% of all Medicare Part B spending. Obviously, these drugs are costing the health system a lot of money.

"It is not just the health system though, that is being burdened by these high costs. For American families, biologics can cost in the tens of thousands of dollars for the most popular drugs. In some cases, a lifesaving biologic can cost a patient over \$300,000 per year. There is no doubt that these innovative drugs provide Americans, access to groundbreaking treatments for devastating illnesses including cancer, arthritis, and multiple sclerosis. But I have heard too many stories, from my home district in New Jersey and from all around the country, of hard-working people who just can't afford the tremendous cost of these live-saving and life-improving drugs.

"In a country of the best and the brightest, I have to believe that we can do better. We must continue to innovate and push the envelope to discover more effective treatments and cures for the scourges of our time. In the same vein, we must also ensure that these innovative products are available to patients at an affordable price. We are faced with a delicate balance moving forward between ensuring reasonable drug prices and expenditures, increasing access for more Americans, and supporting innovation.

"However, these are the same principles that guided the creation of the Hatch-Waxman Act in 1984, and with great success, in my opinion. Since the passage of Hatch-Waxman, more generic drug manufacturers have entered the market, driving down costs for the consumer. Also, pioneer drug companies have been given protections that have spurred innovation, leading to advancements that are helping us live longer and healthier lives.

"In addition to driving innovation, Hatch-Waxman was also able to effectively, and without any market interference, drive down the costs of drugs. In fact, the U.S. health care system has saved over \$700 billion in the past 10 years through the use of generic pharmaceuticals. In a time where we are facing an economic crisis, partly brought on by skyrocketing health care costs, this is a staggering figure. If biologics are the future, then we should do everything we can now to control costs while aiding innovation, just like Hatch-Waxman did.

"Today, we will be hearing testimony on the newly released Federal Trade Commission (FTC) report, looking specifically at the issues of innovation, cost, and competition. The FTC has decades of expertise in this area and I value their objective and comprehensive analysis. I am anxious to hear from the FTC about what factors we must consider when moving forward with legislation and how follow-on-biologics are likely to behave in the market setting as compared to generics. I am especially curious to hear about what incentives and protections will be necessary in a biologic and follow-on biologic world, that are similar or different from the current brand and generic arena.

"I would like to welcome FTC Commissioner Harbour to the committee today who hails from the great State of New Jersey. Thank you for coming to testify before us. I would also like to welcome the author of the FTC report, Michael S. Wroblewski (Ro-bless-ky) who has been invited along with the Commission to answer our more technical questions about the report. Thank you too Mr. Wroblewski for being here. I would like to now recognize the Ranking Member, Mr. Deal for five minutes for an opening statement."

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