Chairman Frank Pallone, Jr.
Subcommittee on Health
Hearing:
Programs Affecting Safety and Innovation in Pediatric Therapies

Opening Statement

May 22, 2007

Good morning. Today the Subcommittee is meeting to hear about "Programs Affecting Safety and Innovation in Pediatric Therapies".

Today's hearing is of critical importance, because above all else, we must ensure that the prescription medications and devices our children use are in fact tested appropriately and deemed safe. I believe that we all agree, regardless of our party affiliation, that we have an enormous responsibility to our children to ensure that they have access to the best possible medical treatment.

Today we will hear about two existing programs designed to facilitate better testing of drugs in children. They are the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). Combined, these two programs are often referred to as a "carrot and stick" approach used by FDA to encourage and direct drug manufacturers to test their products for pediatric use. We will also discuss the need to encourage better research and development of medical devices in pediatric populations.

Under BPCA, in exchange for completing a pediatric study requested by the FDA, a drug manufacturer can receive a six month extension of market exclusivity for the product it is studying. This model has proven successful in providing new and valuable information about the appropriate pediatric use of many drugs.

According to the Government Accountability Office (GAO), who we will hear from later today, drug manufacturers agreed to the pediatric studies requested by FDA for on-patent drugs eighty one percent of the time. These studies have resulted in important labeling changes that help providers and parents determine the best course of treatment for a child stricken by a particular illness or chronic condition.

In the past, I have raised concerns about the financial impact an additional six months of market exclusivity has on American consumers. While the incentive under BPCA is clearly working to encourage companies to conduct the studies that FDA requests, at the same time this type of patent extension serves as an obstacle that blocks access to generic drugs for consumers, forcing them to pay higher prices because lower cost alternatives are kept off the market.

Looking over how the program has worked over the past five years, I am concerned about the amount of earnings drug manufacturers receive in exchange for completing these studies. The financial gain that drug makers receive from the market exclusivity under BCPA usually far exceeds the cost incurred of completing the pediatric trials requested by FDA. There may be a better way to balance the need to provide incentives for drug manufacturers to conduct pediatric studies and ensuring that consumers have timely access to lower-cost prescription drugs.

The Pharmaceutical and Research Equity Act (PREA) is the other component of this approach, which gives FDA the regulatory authority to require certain pediatric assessments for a particular drug in which a drug maker is submitting an application. The regulatory authority granted to FDA under PREA is linked to the expiration of BPCA, and thus will also expire at the end of this fiscal year.

This makes little sense to me. Why should we put a time table on providing FDA with the regulatory power to ensure drug companies conduct the research necessary to ensure that our children have access to safe and effective medicines? We don't place such limits on FDA when it comes to conducting research on adult populations, and so we shouldn't do it for our children either.

Aside from drugs, we also have a responsibility to ensure that children have access to appropriate medical devices. The problems that we face in encouraging pediatric studies in drugs are parallel to the problems we face in encouraging similar research in the device world.

There are few medical devices designed to be used in kids. Instead, doctors are often forced to jury-rig devices that are designed to treat adults. We need legislation that will encourage device manufacturers to do the research and development necessary to provide our children with devices that will fit their small and growing bodies.

Again, I cannot emphasize enough that testing of drugs and devices for pediatric use is essential. As a father of three young children, I know how critical it is that we ensure our children have access to the treatments and therapies they need to live happy and healthy childhoods.

I also want to say that I know how important these issues are to the members of this Subcommittee on both sides of the aisle. Ms. Eshoo and Mr. Waxman have been critical voices in the debate about encouraging pediatric studies for prescription drugs. While Mr. Markey and Mr. Rogers have been strong advocates on the need for medical devices that our appropriate for kids. I am going to work with all of you to ensure that we pass legislation that improves access to the medical treatment our nation's children need.

I want to thank all of our witnesses for being here today. We are looking forward to hearing your testimony. I now recognize our Ranking Member, Mr. Deal of Georgia, for five minutes for the purpose of making an opening statement.