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Opening Statement
Rep. Jackie Speier, Ranking Member

Subcommittee on Energy Policy, Health Care and Entitlements Hearing on "FDA Checkup: Drug Development and Manufacturing Challenges"

December 12, 2013

Mr. Chairman, Thank you for holding this important hearing.

I also want to thank the witnesses, and particularly Paul Hastings, CEO of OncoMed Pharmaceuticals for being here. OncoMed is located in my district, and is doing groundbreaking work on stem cell therapeutics that could provide important alternatives for the treatment of cancer. He brings a crucial understanding of the FDA approval process, and the successes and challenges that remain in that process.

I also want to thank Dr. Woodcock for being here, and for the great work she is doing to improve the pathway for drug approvals and manufacturing, and for working with us to understand the challenges the FDA faces to ensure that our innovative bio-technology sector remains just that—innovative, and able to efficiently move new products from early stage developments, through the clinical trial process, and to approval and full scale manufacturing. I know she expected to focus on the modernization of drug manufacturing, but I would also like to discuss some of the initiatives underway at FDA under the PDUFA (Prescription Drug User Fee Act) reauthorization and the Food and Drug Safety and Innovation Act (FDASIA)—both passed last year.

Last night I hosted a special order hour to highlight the critical work of the NIH in funding basic research and providing grants to fund early stage groundbreaking treatments. All that is for nothing if the newly discovered drugs and treatments cannot be brought efficiently and safely to market.

I am very proud that the biomedical industry really started in my district with the founding of Genentech in South San Francisco in 1976. Since that time, the biotech industry has grown dramatically in my district and across the country. Over the years its growth has also posed a challenge to the FDA, and its ability to assess and approve these new drugs and devices for both safety and efficacy. I have facilitated several meetings with the FDA and companies in

my district to discuss their concerns with the process, and how that process needed to improve. FDA listened.

In the past the FDA was criticized for being unpredictable and risk adverse, to the point of discouraging beneficial products and biomedical innovation. The industry has consistently pushed for more transparency and a predictable process, with better Agency communication. FDA listened.

While we must make sure this industry --in both development and manufacturing-- is not crippled by either government action or inaction, we must also make sure that the FDA has the resources to properly do its job.

I am very concerned that as a result of the sequester, a portion of the new fees that the industry agreed to pay under the Prescription Drug User Fee Act reauthorization in 2012 to help improve and speed the process are being withheld. This is unconscionable, and we must pass the bi-partisan Food and Drug Administration Safety Over Sequestration Act (FDA SOS) immediately.

The Agency clearly recognizes the need to modernize and improve its record, and FDA Commissioner Hamburg launched an innovation initiative soon after she took command in 2009. In 2011 the FDA cleared 35 "innovative" drugs, including advances in treating hepatitis C, lupus, pneumonia, and several different cancers and orphan diseases. According to the FDA, all but one of these drugs was approved on or before the target dates set by the statute. But others still lagged, faced delays and unexpected demands for additional clinical trials.

We must make sure that FDA does not shortchange its attention of drug applications from one therapeutic area while it concentrates on other high priority areas. Oncology, for instance, is a high priority and the Agency has used various procedures to accelerate the approval of cancer drugs. Indeed, the FDA and others have highlighted recent approvals of oncology products as evidence of its commitment to biomedical innovation. There are also other areas with serious disease burdens – obesity and diabetes are good examples – where regulatory standards remain unclear and the Agency's performance may have lagged. Disorders like Alzheimer's, Parkinson's and multiple sclerosis impose widespread suffering, but their complex biology has made them notoriously elusive targets for drug development, and the regulatory process seems to mirror this complexity.

Importantly, FDASIA (fuhdaysia) contained measures to help foster more timely patient access to new medicines; enhance FDA's regulatory science capacity; encourage future innovation and strengthen the FDA's high safety standards. FDASIA also provided FDA with a novel accelerated drug development instrument, known as the "breakthrough therapy" designation, allowing FDA to assist drug developers to hasten the development and evaluation of new drugs utilizing preliminary clinical evidence that a drug may offer a significant improvement over currently available therapies for patients with potentially fatal or life threatening diseases.

This is all good news.

But let's be clear, part of the problem lies with us here in Congress. Every time something goes wrong, or appears to go wrong with an FDA approved product, the first thing we do is haul them before a committee and excoriate them for approving the drug or product. They are damned if they do and damned if they don't. I appreciate the fact that this hearing is intended, much credit to you Mr. Chairman, not so much to criticize the FDA, but to find constructive ways to further improve the drug development and manufacturing processes.

Today we will also discuss initiatives to modernize pharmaceutical manufacturing, and to keep this manufacturing here in the U.S. instead of watching these jobs go overseas.

A key element of this effort is "Quality by Design." I look forward to learning how these new innovations can reinvigorate the manufacturing sector here in the United States, and what else we can do to spur that effort.

I also look forward to hearing from our witnesses how the steps the FDA has taken in the past several years to improve the drug approval and manufacturing process are working, and what additional changes are in the works, or still needed.

Thank you Mr. Chairman, I yield back

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