Chairman Frank Pallone, Jr.
Subcommittee on Health
Hearing
Reauthorization of the Medical Device User Fee and Modernization Act

Opening Statement

May 16, 2007

Good morning. Today the Subcommittee is meeting to hear about the Reauthorization of the Medical Device User Fee and Modernization Act, otherwise known as MDUFMA.

Recent innovations in medical devices have provided us with new possibilities in treating illness and delivering health care services. Today, we are witnessing medical innovations that would have been considered unthinkable just a few years ago, but now are considered commonplace. New breakthroughs in medical device technology have empowered patients and providers to achieve better clinical outcomes with less invasive procedures and shorter recovery times.

As the medical device industry continues to innovate, we as policy makers have a responsibility to ensure that the FDA has the financial and human resources necessary to provide for a timely review of the latest inventions in medical technology.

In an attempt to achieve this goal, Congress passed the Medical Device User Fee and Modernization Act (MDUFMA) of 2002, which established for the first time a user fee program for medical devices that was modeled after the prescription drug user fee program, which we are also working to reauthorize this year.

This legislation was necessary due to inadequate resources at the Food and Drug Administration (FDA). As applications began to pile up, it became clear that there was a need to implement a new revenue stream to improve the time in which new and innovative medical devices could be approved by FDA. That is as true today as it was five years ago.

While FDA has been meeting its performance goals under MDUFMA I, the demand on FDA to ensure that devices are safe and effective has grown significantly in the past few years, and will continue to do so. Innovations in the medical device industry that will transform our health care system will continue to rapidly develop and will likely require even greater resources from the FDA. Accordingly, it is important that this Committee reauthorize MDUFMA so that FDA can continue to fulfill its job of regulating medical devices and safeguarding the public health.

While I want to thank all the people that worked hard to bring this proposal together, having had the chance to review it, I do have some concerns. First and foremost, noticeably absent from this proposal appears to be any provisions relating to post-market surveillance of medical devices.

In MDUFMA I there was an authorization for appropriations for post-market surveillance activities. Even though these funds were never appropriated under the previous Republican led Congresses, at least there was some recognition about the need to fund post-market surveillance activities. There are no such provisions in the MDUFMA II proposal that I am aware of.

This obviously raises some concerns for me. Most importantly, for anyone who has been paying attention to the Prescription Drug User Fee Act (PDUFA) which has been reauthorized a number of times, you should know that in the first few reauthorizations of that program, user fees were mostly set aside to fund pre-market activities, largely ignoring any of the post-market responsibilities of FDA to ensure that drugs are safe once they are already on the market.

Under the MDUFMA II proposal, I see a recurring pattern where once again FDA and the industry have managed to agree on performance goals for achieving expedited review of medial devices, but fail to address the post-market surveillance issues, which are equally as important. We will have to take a long and hard look at this, and it may be necessary to ensure some of the user fees collected under MDUFMA II are designated for post-market surveillance activities.

On another issue, I am very concerned about the reprocessing of single use devices (SUDs). MDUFMA I attempted to address the potential risks of infection and device malfunction that might arise from the reprocessing of single use devices. Over the past year, I have been following this issue very closely, especially in my home state of New Jersey.

I continue to be alarmed about the reprocessing of SUDs, and at a minimum believe that patients should be made aware of when a single use device that has been reprocessed is being used on them during a procedure. As this problem persists, I am worried that the MDUFMA II proposal does not focus on SUDs at all, with the exception that SUD re-processors pay the proposed annual establishment fee. Further regulation may be required.

In closing, I just want to say that I know during the first MDUFMA authorization there was tremendous bipartisan support within our Committee to reach an agreement on behalf of patients, providers, and the industry. I hope that we can proceed in a similar fashion as we move forward with reauthorizing this program. The health and well being of many of our friends, family, and constituents depends upon it. I would like to now recognize my friend from Georgia, Mr. Deal, for five minutes for the purpose of making an opening statement.