Chairman Hal Rogers
House Committee on Appropriations

Fiscal Year 2016 Budget Hearing – Food and Drug Administration
Wednesday, March 4, 2015
Opening Statement As Prepared

Mr. Chairman, thank you for yielding. Madame Commissioner, my deepest apologies for my tardiness this morning. Though the Committee is hosting a number of hearings simultaneously this morning, I could not miss the opportunity to bid you adieu and wish you well as your six-year tenure at the helm of the U.S. Food and Drug Administration comes to a close. Despite your imminent departure, I thank you for being here to discuss the Fiscal Year 2016 budget request for the FDA.

The FDA is a remarkable regulatory entity with numerous and far-reaching responsibilities. You have brought a public health perspective to an agency charged with ensuring the safety of our country's drugs, biological devices, our human and animal food chain, cosmetics and anything that emits radiation. We support you in this important mission, and while we certainly understand the breadth of your responsibilities, I am concerned by the size of the budget request before us today. At $4.9 billion, this is the largest FDA request in recent history. While you have indeed taken cues from Congress to utilize budget authority rather than saddling industry with the costs associated with finalizing a number of FSMA regulations this year, a $150 million increase will be tough to swallow. We look forward to hearing from you today about your plans for adhering to the terms of the FSMA court order.

While I know many of the members of this subcommittee have a number of areas of concern, there are three on which I would like to focus:

First, prescription drug abuse. As your time as Commissioner comes to a close, it gives us all an opportunity to reflect on your legacy regarding this issue, which is near and dear to my heart. The first time I approached FDA about the abuse of prescription medications was in 2000. For over a decade, my pleas for FDA to take action on this life-or-death issue fell on deaf ears. But as this problem reached epidemic proportions, I found in you a willing partner - and I am grateful for all of your efforts to address this complex public health challenge. I hope you can provide an update on the guidance for abuse deterrent formulations that hopefully will be finalized before your tenure comes to a close.

Second, your proposed tobacco deeming regulation is of interest to many – as evidenced by the 135,000 comments that were submitted in response to its publication. While you and I have discussed the regulation of premium cigars in the past, the decision FDA makes regarding e-cigarettes has the potential to be transformative for this emerging market. I know many are eager for your thoughts about how and whether these products will be regulated – and whether FDA has the adequate resources and infrastructure in place to tackle this herculean chore.

Finally, like many, I am concerned about obstacles created by the Chinese government to our inspection of foreign food and drug products. While the safety of American consumers is our paramount concern, there is also a fundamental question about fair trade practices. Domestic manufacturers and producers are

subjected to extensive regulation to ensure the safety of their products, and they should have an equal playing field with their foreign competitors. The Fiscal Year 2015 Omnibus included $2 million to speed up drug facility reviews in China, and we are looking forward to an update on this effort.

With that, Madame Commissioner, I thank you for your service to our country and I wish you all the best in your future endeavors. Thank you and I yield back.

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