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ONE HUNDRED FIFTEENTH CONGRESS

# Congress of the United States

## House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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WASHINGTON, DC 20515–6115
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April 5, 2018

Mr. Thomas Cosgrove
Partner
Covington & Burling LLP
860 10th Street, N.W.
Washington, DC 20001

Dear Mr. Cosgrove:

Thank you for appearing before the Subcommittee on Health on February 28, 2018, to testify at the hearing entitled "Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on April 19, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

## Attachment — Additional Questions for the Record

### The Honorable Michael C. Burgess, M.D.

I agree that the current pill press proposal – in discussion draft form – needs to be more narrowly tailored. This concept was raised in the President's Commission as a recommendation – it's number 25. Here's what it says: "The importation of tableting machines (pill presses) is regulated by DEA. DEA has recently enhanced importation regulations by replacing paper reporting with an electronic process. However, the active use of pill presses remains unregulated."

While DEA currently can inspect a registrant's use of controlled substances in their usable form to verify they are properly stored and used for their stated, registered purposes, the DEA currently cannot inspect pill presses to verify that the equipment is not being used to produce counterfeit drugs.

The intent of the draft legislation (the Tableting and Encapsulating Machine Regulation Act of 2018) is to capture criminal practices of pill presses being used to produce counterfeit drugs and not create a burden on legitimate industries.

1. Do you have any creative ways we could do this without causing unnecessary harm on legitimate industries, like over-the-counter products or dietary supplements?

You point out that under existing law, each person selling a tableting or encapsulating machine must report the transaction to DEA. A quick search on eBay yesterday produced 572 results. Some of these machines can produce 5,000 pills per hour.

2. Is the DEA requiring transaction reports on these products?

3. What is the difference in a pill press bought on eBay to tablet or encapsulate illicit synthetic fentanyl versus one used by a legitimate licensed manufacturer?

You also note that existing manufacturers of controlled substances have systems in place be sure they're in compliance with DEA standards and rules. But this proposal is targeting illicit drugs.

4. Do you have any suggestions on how we can differentiate between the legitimate and counterfeit use of these machines?