Testimony of Thomas Cosgrove, Covington & Burling LLP (Feb. 28, 2018)
Before the House E&C Health Subcommittee on the "Tableting and Encapsulating Machine Regulation Act of 2018"

Thank you to Chairman Burgess, Ranking Member Green and Members of the Subcommittee for the opportunity to testify today. My name is Thomas Cosgrove, and until late last year, I was an official at the Food and Drug Administration (FDA) responsible for Current Good Manufacturing Practices (CGMP) enforcement and compliance within the Center for Drug Evaluation and Research (CDER). In that role, I was responsible for ensuring manufacturing and quality compliance for the thousands of drug manufacturing facilities around the world that make medicines distributed in the United States. Since December of 2017, I have been a partner at the law firm of Covington & Burling LLP. Covington represents a number of clients in the food, drug, and cosmetics industries that use tableting and encapsulating machines, the subject of the draft bill under consideration, but the views expressed today are my own.

I am here today to testify on what I think could be the unintended consequences of the draft bill, the "Tableting and Encapsulating Machine Regulation Act of 2018" and to suggest perhaps a more tailored approach. From my prior role as an FDA official, I have a perspective on the overlapping systems of regulation applicable to manufacturers of drugs, dietary supplements, and other products regulated by FDA. As the Director of the Office of Manufacturing Quality at FDA CDER, I supervised the review of FDA drug facility inspections and made decisions within CDER on whether to recommend administrative or civil enforcement actions in cases of significant regulatory violations. Many of the cases reviewed in the Office of Manufacturing Quality involved tableting or encapsulating operations in the United States and abroad. The Office of Manufacturing Quality was also responsible for enforcement decision making under the Food, Drug and Cosmetic Act (FDCA) in connection with manufacturers of approved and lawfully manufactured controlled substances.

I share Congress and the public's concern about the opioid abuse epidemic and am encouraged to see so much action in Congress and society at large aimed at ending the crisis. In my role at FDA, I was aware of the acute problem of the importation of illicit opioids and opioid analogs from overseas through international mail facilities. This appears to be a different issue, however, than the use and regulation of tableting and encapsulating machines in the United States.

The approach proposed in the draft bill is to regulate tableting and encapsulating machines the same as controlled substances. I am concerned that this approach would significantly and unnecessarily increase regulatory burdens on lawful U.S. manufacturers of tableted and encapsulated products. More importantly, it could harm patients and consumers by potentially disrupting the supply of medicines and other products, and at the very least it could increase consumer prices. I believe the Drug Enforcement Administration (DEA) should continue to investigate individuals who manufacture illicit substances using tableting machines and any future expansion of the regulation of tableting and encapsulating machines should be more narrowly tailored than the approach proposed in the draft bill.

Virtually all manufacturers of "solid oral" drugs in the United States use tableting or encapsulating machines in some form. This includes prescription, nonprescription and many animal drugs, covering everything from innovative new drugs to OTC products that people use daily. In addition, dietary supplement manufacturers commonly use tableting and encapsulating machines as part of their manufacturing processes. For instance, the majority of vitamins sold in the United States are tableted or encapsulated. One need only to walk down the

health and wellness aisle of a local supermarket to get a sense of the ubiquity of products manufactured using tableting and encapsulating machines. Furthermore, tableting machines are often used in the manufacture of candy, cosmetics and certain household products such as cleaning agents. The collective dollar value of these product sales in the United States is enormous and people use them every day.

Tableting and encapsulating machines are essential to manufacture these products. A tableting machine operates by compressing a substance, generally a granulated powder mixture, using great force into the form of a solid tablet. An encapsulating machine is used to fill soft or hard gelatin capsules with a substance, generally granules, semi-solids or liquids. These machines are carefully designed to ensure that tablets and capsules are consistently the same size, shape, and weight. With respect to drugs, one of the jobs of FDA is to ensure through inspections that manufacturers making tablets and capsules are able to consistently deliver the same dose of drug to patients across the millions of unit doses they may manufacture.

The Controlled Substances Act (CSA) and DEA's regulations have been carefully crafted to prevent controlled substances from being diverted for illegal activity while ensuring they remain available for legal medical and scientific uses. These laws designed to govern substances, however, may not be well suited to regulating tableting and encapsulating machines. The CSA requires sensible and careful control over controlled substances themselves throughout the drug manufacturing process, but it is unclear how such controls could sensibly apply to equipment used by countless U.S. manufacturers that supply necessary products to nearly all Americans.

For example, were the draft bill to be enacted as now written, lawful domestic manufacturers using tableting and encapsulating machines to produce legally marketed, non-controlled products (including non-drug products) would be subject to the CSA's strict requirements for controlled substances. A straightforward reading of the draft bill at hand would appear to require manufacturers to register with the DEA and with state authorities in each location they hold or operate a machine. Manufacturers apparently would need to store tableting and encapsulating machines in secured areas such as the ones used to safeguard controlled substances themselves, such as electronically monitored safes, steel cages, or vaults that meet certain specifications. Manufacturers hoping to dispose of or replace malfunctioning machines could need to transfer machines to companies specifically registered by DEA to render the machines "non-retrievable." In addition, manufacturers might need to comply with additional recordkeeping and paperwork requirements each time they move a machine from one location to another, even between two company-owned properties within the same state. These requirements could be unworkable for manufacturers operating large industrial tableting and encapsulating machines integrated within production lines.

Such requirements if enacted would greatly increase regulatory burdens for domestic manufacturers and make everyday products less available to consumers. For instance, although manufacturers of drugs and dietary supplements are already used to a high degree of regulation by FDA, additional requirements imposed by the draft bill could be costly and unwieldy. FDA inspects manufacturing facilities to ensure that equipment such as tableting machines are operating within the scope of Current Good Manufacturing Practices under applicable law and regulations. FDA does not, however, require registration of individual pieces of equipment. Drug, dietary supplement, and other manufacturers have a great deal of flexibility in selecting or changing out the equipment they use, which flexibility could disappear if this bill were enacted as drafted.

Regulating this equipment itself as a controlled substance could be a fundamental and expensive change. Domestic manufacturers could incur direct costs of machine registration, recordkeeping, security, and disposal and indirect costs from training, education, and audits to ensure compliance with the CSA. These additional burdens could increase the costs for manufacturers to produce their products in the United States compared to manufacturing their products abroad, where tableting and encapsulating machines would not be subject to the CSA's controlled substance requirements. We live in a time where there is already enormous pressure on drug manufactures to move their operations overseas for cost reasons. In fact, one of FDA's main challenges today is keeping up with the explosion of drugs manufactured overseas in places like India and China.

Ironically, the draft bill would burden most the companies that have nothing to do with opioids or other controlled substances. Existing manufacturers of medicines that are controlled substances should already have systems in place to ensure that the controlled substances themselves are handled in accordance with DEA rules. Companies that have nothing to do with controlled substances now, which constitute the vast majority of companies that use tableting and encapsulating machines, would have to develop CSA-compliant systems from scratch. This could lead to higher costs to consumers and potentially even drug shortages.

Furthermore, Congress has already amended the CSA to give DEA special authority to regulate tableting and encapsulating machines. In 1988, Congress passed the Chemical Diversion and Trafficking Act (CDTA). Under the CSA as amended by the CDTA, DEA already has a role in connection with the distribution, importation, or exportation of a tableting machine or encapsulating machine. Under existing law, each person selling a tableting or encapsulating machine must report the transaction to DEA. Each person must also file a report to DEA before importing or exporting a machine. DEA may deny entry to any unregistered shipment of tableting or encapsulating machines.

The FDA also has broad powers to regulate drug manufacturing facilities using tableting and encapsulating machines under existing provisions of the FDCA. FDA regularly inspects manufacturing facilities to ensure that equipment, including tableting and encapsulating machines, is functioning properly and being used for legal activities. FDA has authority to take action if it encounters drugs being counterfeited, including counterfeited opioids and other controlled substances. From my own experience, I believe that FDA would be poised to take quick action in concert with DEA if it found a manufacturer under its jurisdiction illegally manufacturing a controlled substance.

If Congress decides that enhanced regulation of tableting and encapsulating machines is needed, I would encourage a more tailored approach that builds on existing authorities. First, I would want to understand better why DEA's existing CDTA authorities are not sufficient. One potential further approach would be to consider amending the CDTA, such that companies would also register equipment with DEA beyond only reporting transactions. This could be tethered with an appropriately crafted exemption for firms regulated by FDA. This way, DEA could develop a more robust database of tableting and encapsulating machines, but perhaps thousands of companies around the United States would not suddenly be regulated as if they were holding controlled substances. If Congress decides to move forward on this or any similar proposal, I would be happy to serve as a resource in deliberations going forward.

Thank you again for the opportunity to testify and I would be happy to take any questions.