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February 27, 2018

The Honorable Mike Burgess
Chairman
Subcommittee on Health of the
Committee on Energy & Commerce
United States House of Representatives
2336 Rayburn House Office Building
Washington, DC 20510

The Honorable Gene Green
Ranking Member
Subcommittee on Health of the
Committee on Energy & Commerce
United States House of Representatives
2470 Rayburn House Office Building
Washington, DC 20510

Re: H.R. _____, The Tableting and Encapsulating Machine Regulation Act of 2018

Dear Chairman Burgess and Ranking Member Green:

I write you today on behalf of Catalent, Inc., a NYSE-listed advanced dosage form provider and contract development and manufacturing company, with global headquarters in Somerset, New Jersey. We produce more than 72 billion doses of prescription and consumer health products annually across more than 7,000 products on behalf of our customers, and for patients around the world.

We applaud the comprehensive approach to addressing the illicit use of opioids represented by the eight draft bills to be discussed during the **Combating the Opioid Crisis** hearing planned for this Wednesday, February 28, 2018.

We are reaching out to express some concerns regarding provisions of the initial draft of one of those bills, **The Tableting and Encapsulating Machine Regulation Act of 2018** (the "Tableting Regulation Bill" or the "Bill"). We recognize that testimony by the Drug Enforcement Administration (the "DEA") at 2016 hearings of the Committee of Energy & Commerce indicated a growing use of imported tablet presses and encapsulating machines to supply illicit drug markets in the United States. We also note that, in response to this activity, in late 2016, the DEA established expanded reporting requirements for all import, export, and domestic transactions involving such equipment, which were implemented in mid-2017.[1]

The initial draft of the Tableting Regulation Bill would reclassify **every** machine that produces either tablets or capsules in **any** domestic facility as a controlled substance, and thus subject to DEA oversight, recordkeeping, security, and other requirements—the same standards that apply to narcotic bulk drugs and finished doses. These new requirements are imposed without regard to whether any such machine is sited at a facility that is already governed by the Food, Drug & Cosmetic Act (the "FD&C Act"), or is already regulated by the Food & Drug Administration, nor does the legislation recognize the inherent differences between *machinery* and the sorts of controlled *substances* that are already regulated by the Controlled Substances Act.

[1] *See* https://www.deadiversion.usdoj.gov/fed_regs/rules/2016/fr1230.pdf.

While all the implications of the Bill's reclassification are not fully clear, the Bill is likely to impose substantial new regulatory oversight burdens on legitimate, law-abiding manufacturers of both prescription and non-prescription products, most of which **are not producing opioids or other controlled substances**. Further, the bill would drive significant additional costs for reporting, compliance management, and security, directly reducing funds currently used to invest in growth, expand employment, and drive innovation. Finally, we believe that the application of such provisions to production sites already regulated by the FDA will yield limited added enforcement value above that provided by the expanded transaction reporting requirements only recently implemented by the DEA.

Despite these significant concerns, we appreciate the enforcement benefits to be realized by applying such a status change to tableting and encapsulating production equipment that is not sited in facilities otherwise regulated by the FDA or subject to the FD&C Act. We believe that there are several possible approaches to modify the draft Bill to mitigate such concerns from regulated industry. In one such example, the application of such a reclassification might specifically exclude equipment in sites regulated by the FDA under existing sections of the FD&C Act, including but not limited to those relevant to producers of clinical and/or commercial supplies of prescription pharmaceuticals, over-the-counter monograph products, dietary supplements, and veterinary drugs. There are alternative approaches that we are discussing with industry trade associations and other companies, which we have agreed to review with the Subcommittee staff in upcoming weeks.

In closing, we reiterate our support for the efforts of the Subcommittee to address the challenges facing our country as a result of the illicit use of opioids. We recognize the difficult task before you and appreciate your consideration of our concerns and ideas to address them. For additional information, please contact either Cornell Stamoran (cornell.stamoran@catalent.com, 732-537-6408) or Steven Fasman (steven.fasman@catalent.com, 732-537-5958).

Sincerely yours,

Cornell Stamoran
Vice President, Corporate Strategy
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cc: Steven Fasman
Senior Vice President & General Counsel
Catalent, Inc.