Comments on S 2211 (2017)

SECTIONS 4 and 29. Definition of Pharmaceutical Manufacturer (Amending Section 1 of Chapter 6D and Section 1 of chapter 12C)

- **Please amend to conform with federal law:**

  "Pharmaceutical manufacturing company", an entity engaged in the production, preparation, propagation, **compounding**, conversion or processing of prescription drugs, directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or an entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that "Pharmaceutical manufacturing company" shall not include a wholesale drug distributor licensed under section 36B of chapter 112 or a retail pharmacy registered under section 39 of said chapter 112.

SECTIONS 8 and 33. Assessment (Amending Section 6 of Chapter 6D (HPC) and Section 7 of Chapter 12C (CHIA)

The bill would require the assessment to be applied in the same manner as Section 68 of Chapter 118 E, which is the same as methodology used for insurers. While industry understands that other health care entities contribute to the costs of data analysis, **any assessment must be fairly apportioned across brands and generics alike to cover CHIA and HPC analyses of information submitted under Section 10A of Chapter 12C; the proposed methodology for the assessment would be problematic for calculating the pharmaceutical industry assessment.**

- The methodology would require hospitals and ambulatory surgical centers to calculate the assessment based on medicines prescribed for Medicaid patients in those settings.
  - There are many more brand and generic pharmaceutical companies than the number of payors paying for medical assistance claims.
  - Requiring acute hospitals and ambulatory surgical centers to assess each brand or generic manufacturer would be an undue burden for these clinical entities.
  - Many medicines utilized in the hospital inpatient and outpatient settings are not reimbursed separately and are often bundled with the services linked to treating the primary reason for the patient's care (e.g., treatment for heart attack, hip replacement, etc.). Therefore, it will be difficult for hospitals and surgical centers to assess the surcharge.
- In addition, most patients purchase their medicines at the retail pharmacy rather a hospital or surgical center. By restricting the assessment to medicines delivered at a hospital or surgical center, some manufacturers would shoulder a higher surcharge amount, rather than having the surcharge spread over the entire pharmaceutical industry.

SECTION 11. HPC Cost Trends Witnesses (Amends Section 8 of Chapter 6D (HPC))

- Adds representatives of the pharmaceutical industry to the cost trends hearing.
- Industry is supportive of adding a large pharmaceutical company, a generic manufacturer and a company in existence less than 10 years to the witnesses that could be called for the HPC cost trends hearing.

SECTION 14. HPC Public Testimony (Amends Section 8 of Chapter 6D)

- The legislation requires that pharmaceutical companies testify about confidential and proprietary information including factors underlying prescription drug costs and price increases, the impact of manufacturer rebates, discounts and other price concessions on net pricing, the availability of alternative drugs or treatments and any other matters as determined by the commission.

- The pharmaceutical industry was supportive of being included in the cost trends hearing in the initial version of the Senate bill (S2202 in 2017), under which the pharmaceutical industry would become a formal part of the cost trends hearing, on level footing with other health care industry actors such as hospitals and provider organizations.
    - Under the initial version (and existing statute), the Commission would be required to examine, through the testimony, health sector prices and cost trends, with a particular focus on factors that contribute to cost growth.
- However, the latest proposed amendments go too far by expressly specifying the content of pharmaceutical industry's testimony. No other health care entity in Massachusetts has its testimony prescribed in such a manner.
    - S2211 would undermine the Commission's ability to engage with the various stakeholders, on grounds that it deems appropriate, in order to seek appropriate testimony regarding prices and cost trends.
    - These amendments may also require pharmaceutical manufacturers to reveal competitively sensitive information. The Federal Trade Commission has acknowledged that disclosure of competitively sensitive information could lead to less competition and facilitate collusion.

SECTIONS 16, 36 and 41. HPC and CHIA Reports.

- Industry is supportive of being included in HPC and CHIA reports.
- Industry opposes the significant increase in penalties from $50,000 in current law to $200,000 (SECTION 36).

SECTION 25. Academic Detailing and Studying Pipeline Drugs, Generics and Biosimilars (Section 15A and 15B of 6D (HPC))

- 15A moves the current academic detailing law from DPH to HPC; the language should repeal (Section 4N of Chapter 111).
- This does not include patient protections to ensure data examined considers the needs of different patient populations and the individual preferences of patients.
- Industry is generally supportive of providing the Commonwealth with information about brand, generic, and biosimilar medicines in the FDA pipeline. The program should be funded by the marketing fee already required by the Commonwealth rather than a new assessment.
- HPC should keep the information confidential.

SECTION 35. Pharmaceutical Transparency (Amending Section 10A and 10B of Chapter 12C (CHIA)

- The expanded disclosure provisions of this section will not provide patients and consumers with meaningful information to better understand the cost of their medicine at the pharmacy counter. The request for such information ignores that there are many stakeholders including pharmacy benefit managers, insurers, government payers, and employers that determine the price a patient pays for a medicine.
- The biopharmaceutical industry is one of the most heavily regulated industries in the United States. Companies already report extensive information to the federal government about costs, sales, clinical trials, and total research and development (R&D) expenditures. This section of S2211 (2017) goes further and focuses on the costs of approved medicines while ignoring a large portion of the drug discovery and development process—failure.
- Requiring information on production and distribution costs for individual products also may not be feasible, as R&D is a long-term process and manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug. Accounting for these related discovery costs could be nearly impossible.
- Much of the information this section requires to be disclosed is considered protected, confidential corporate information; and this information falls under federal protections for trade secrets and includes substantial competitive information.
    - Disclosing such proprietary information, even in the aggregate only chills the ability of insurers and PBMs to negotiate drug pricing.
    - In fact, the Federal Trade Commission (FTC) has indicated that disclosure of proprietary information would not lead to lower prices but would likely lead to increased prices. Simply put, revealing competitors' pricing and discount information removes incentives to provide discounts in the marketplace. In a letter to the New York legislature in 2009, the FTC's Office of Policy and Planning, Bureau of Competition and Bureau of Economics cautioned that disclosure of similar information would jeopardize the competitive market and

remove incentives to provide discounts and additional rebates and "…may increase pharmaceutical prices."

- Manufacturers generally consider many factors in determining an appropriate price for a drug, including but not limited to the value of a medicine in improving a patient's life and helping minimize costs elsewhere in the health care system. Further, companies use revenue from current products on the market to fuel future innovation. Indeed, the biopharmaceutical industry invests more in research and development (R&D) than any other industry in the U.S., with industry accounting for one in every five dollars spent on innovation in the U.S.