



December 20, 2019

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Dear Ms. Johnson:

On behalf of MassBio and our 1,200+ members, please accept this letter as our testimony relative to Proposed Regulation 958 CMR 12.00, Drug Pricing Review (the “Proposed Regulations”) of the Health Policy Commission (“HPC”). MassBio represents a wide-range of member organizations, including biotech companies, teaching hospitals, and academic institutions, the majority of which are directly engaged in cutting-edge research, development, and manufacturing of innovative products that improve the lives of patients around the world.

I. Input from Manufacturers

We note as an initial matter that the enabling statute authorizing the Proposed Regulations, M.G.L. c. 6D, s. 8A (the “Enabling Law”), requires that HPC’s Drug Pricing Review Standard Reporting Form (the “Form”) “be developed by the [HPC] with the input of the manufacturers.” It appears instead that HPC has developed the Form exclusively through the Proposed Regulations and the associated notice and comment process. As far as we are aware, to date HPC has not engaged with manufacturers in developing the Form and its contents. We do not consider the current regulatory process and related opportunity for testimony as meeting the Enabling Law’s requirement that HPC solicit manufacturer input, since manufacturers, like any other members of the public, have this opportunity to testify even without this specific statutory requirement. Accordingly, we urge HPC to undertake a new, separate process to generate the Form and its contents after engaging directly with manufacturers. We would be happy to work with HPC to organize and coordinate such input from our members as part of such a separate process.

II. Transparency Requirements in Regulations and in Form

As a general matter, we note that the extent of HPC’s authority to seek transparency disclosures through regulations is not unlimited. The Enabling Law limits the first stage of transparency submissions to “information relating to the manufacturer’s pricing of a drug,” (Section 8A(b)), and the second stage of submissions to “information related to the pricing of the prescribed drug and the manufacturer’s justification for such pricing.” Section 8A(e). The Proposed Regulations appear inconsistent with these clear limitations on HPC’s discretion to seek particular categories of data, suggesting that HPC takes a much more expansive view of that authority than what is allowed by law. This is apparent not only in the various data requests compelled through the Form that we believe (as noted in more detail below) are unrelated to drug pricing or valuations, but also as reflected in language throughout the Proposed Regulations themselves. In particular, the Proposed Regulations require that manufacturers subject to the transparency process must provide “any additional information requested by [HPC]...” without reflecting HPC’s much more limited authority established by the Enabling Law. See Section 12.03(1)(c). (See Enabling Law at Section 8A(a)(4))(HPC entitled to information that it deems “necessary” to identify a proposed supplemental rebate or proposed value of the drug”)(emphasis supplied). In light of the clear

statutory directive for HPC to limit transparency disclosures to information relevant to pricing, we urge HPC to ensure that any transparency requirement contained in the Proposed Regulations and Form actually and clearly relate to data that is relevant to an analysis of the value of a drug in the Medicaid program.

III. Specific Transparency Requirements

A. 958 CMR 12.04(3)(c); Form, Part III(b) & (c): Massachusetts, National and International Prices.

This provision requires manufacturers to disclose information regarding a drug's prices, net of rebates, over the previous five (5) calendar years, reported separately by payer in Massachusetts, nationally, and internationally.

As a threshold matter, we have serious concerns about the disclosure of net pricing information. Net drug pricing data is highly sensitive, proprietary and confidential and can in many cases be precluded from disclosure by contract. The confidentiality of pricing discussions allows all parties to negotiate the best price based on a variety of factors that are unique to each engagement. Notwithstanding that data submitted under the Proposed Regulations by manufacturers would be exempt from disclosure under the Massachusetts public records law pursuant to Section 12.11, if such data were to become public there would likely be serious unintended consequences, including antitrust implications for competing manufacturers and payers. Moreover, consistent with current US practice, there is recognition outside the US that there is value in keeping country-specific discussions confidential. Additionally, it is difficult to understand how net pricing information is even relevant to a determination of whether the pricing of a drug in the Medicaid program is reasonable, given that, under the Medicaid drug rebate program, states are already entitled to the "best price" that manufacturers offer commercial payors.

We are also concerned that numerous factors render net international pricing unrelated to whether a drug is reasonably priced in a Medicaid program. For example, in terms of net international prices in particular, we note that multiple dynamics, including foreign regulatory requirements, impact the amounts paid by ExUS payors for drug products. ExUS countries have different healthcare systems and purchase drug products under vastly different regulatory structures – all of which can impact prices paid by those countries for prescription drugs. Countries also maintain different philosophies and policies regarding rationing of resources that may be available for the purchase of healthcare services and products, and these policies can dictate how a country allocates funding for prescription drugs. In many countries, access to innovative therapies is often delayed by years, if they're made available at all. Nearly 90 percent of new medicines launched since 2011 are available in the United States, compared to just 60 percent in Germany and the United Kingdom, less than half in Canada and France.

Finally, net pricing information can be unduly difficult to calculate and produce in the form required by the Proposed Regulations given restrictions on the availability of and access to this data, even for manufacturers. For this and all of the reasons set forth above, we urge HPC to strike the net pricing disclosure requirements in Section 12.04(3)(c) of the Proposed Regulations.

B. 958 CMR 12.04(f): (Standard Reporting Form – Part V: Financial Information – R&D Expenditures; R&D Funding Sources; Manufacturing, Production, and Distribution Budget and Expenditures)

1. R&D Expenditures

This section of the Proposed Regulations would require manufacturers to disclose financial information at a product and aggregate level, including R&D expenditures and funding; manufacturing, production, and distribution budget and expenditures; and marketing expenditures. We recommend that this requirement be stricken. As an initial matter, the calculation of product-level disclosures can be extremely time and resource intensive to complete, if they can be reasonably calculated at all, and contain sensitive and proprietary information that requires special management. We have significant concerns about the implications for a

manufacturer that is unable to provide such information within the required timeframe, or is otherwise unable to calculate such information due to lack of access to necessary data. The ramifications for manufacturers that have difficulty producing such data are particularly concerning to us given the significant penalties under the Proposed Regulations associated with providing “incomplete” data to HPC. See Section 12.12. Moreover, utilizing product specific R&D expenditures (assuming they can even be calculated) to estimate the “value” of a drug can be highly misleading. In particular, reliance on such information will negatively impact young, start-up companies which typically have lower estimates of R&D expenditures since they likely have undertaken a single-therapeutic, high-risk approach to developing a compound.

In addition, the R&D expenditures related to one product (again, assuming they can even be calculated) may not account for all of the losses generated to fund significant R&D activities for drugs that have failed due to efficacy or toxicity. Larger manufacturers may have several related targets in development, with only one ultimately making it successfully to launch. Thus, the costs of failure are important to assess, but this may position larger manufacturers more favorably to smaller start-up firms.

2. *Acquisition costs*

Utilization of acquisition cost data as required by the Proposed Regulations does not bear any reasonable relationship to whether the pricing of an acquired drug is reasonable to a Medicaid program. Multiple factors impact acquisitions by manufacturers. First, the business case for an acquisition is, in many cases, not exclusively about the purchase of a therapeutic asset. Often an acquisition will bring to the manufacturer scientific and leadership expertise that can help a company advance the new asset but also develop future targets in similar therapeutic areas. Moreover, many acquisitions target entire companies with extensive commercial and prospective product lines, and are consummated with the expectation that only some of the therapeutic assets in development will actually reach patients, and others will fail. For all of these reasons the acquisition “cost” for a particular drug, even if such information can be reasonably calculated, generally bears no relation to the value of that drug.

3. *Manufacturer expenditures*

The financial information regarding manufacturing, production and distribution expenditures, and marketing expenditures bears no relation to whether the pricing of a manufacturer’s drug is reasonable because they are business-related and commercially-oriented decisions. Indeed, small and mid-sized companies with limited manufacturing operations and associated expenditures could unfairly be penalized by this approach—even for products with extraordinary value.

In addition, the expenditure data requested by the Proposed Regulations cited above are highly company, competitive and therapeutic area dependent. For example, manufacturers with therapeutics in more highly competitive markets may spend more on marketing expenditures, but the additional spend may be due to competitive factors that are not fundamentally based on value. In fact, additional marketing in a competitive environment may ultimately result in lower costs for the healthcare system and patients due to increased competition within a class. Again, such factors cannot accurately provide a reasonable estimate of value, and therefore should be eliminated as data transparency requirements in the Proposed Regulations.

4. *Lobbying Expenditures*

Manufacturers, like other businesses, may lobby policymakers on a number of different policies that may impact the industry. The lobbying expenditures disclosure requirement in the Form appears to assume that all lobbying expenditures are solely related to drug pricing. For this reason alone, HPC cannot demonstrate that, as is required by the Enabling Law, lobbying expenses represent a disclosure category that is reasonably related to the pricing of a particular drug product. In any event, it is unclear how, if at all, a manufacturer’s lobbying expenses can at all be a meaningful factor in any determination of whether the cost of the manufacturer’s drug to MassHealth is reasonable.

III. Other Concerns

Last but certainly not least, we are concerned that the Proposed Regulations do not require HPC to take into consideration in any meaningful way the impact of a drug or biologic on unmet medical need and the beneficial impact the drug may have on the well-being of patients as compared to existing standard of care (if any). For example, the Proposed Regulations do not require HPC to support its valuation conclusions with meaningful input from patients and caregivers affected by the condition or disease being studied. That is, factors that are critical to a fair and balanced assessment of the value of a drug product should include caregiver burden, the value of treating patients with unmet medical needs, and any other non-health related issues including but not limited to societal impact.

In addition, the Proposed Regulations also do not provide sufficiently robust guidance for HPC relative to the standards to be applied in conducting the complex task of valuing a drug product. In our view HPC's process and valuation criteria must be informed by meaningful input by external experts on topics such as the impact of particular coverage, cost-sharing, tiering, utilization management, prior authorization, medication therapy management, or other utilization management policies on adherence by patients to the prescription drug, and on access to the prescription drug. We also believe that the demographics and the clinical description of patient populations treated by the prescription drug are crucial to any value assessment. Relevant data should include, for example, for prescription drugs approved for the treatment of a rare disease, the severity of and the unmet medical need associated with the rare disease, the benefits and risks of the prescription drug as a treatment for the rare disease, and factors that may be limiting access by patients requiring treatment from or consultation with a rare disease specialist. It is critical that HPC's valuation procedures be informed by all of these factors in order to ensure as much as possible fair, reasonable and unbiased drug pricing determinations.

Thank you for the opportunity to comment on the Proposed Regulations. Please do not hesitate to contact me with any questions or comments about the above, or if you would like MassBio to organize sessions with its members to provide meaningful input on the contents of the Form consistent with the requirements of the Enabling Law.

Sincerely,

A handwritten signature in black ink that reads "RK Coughlin". The signature is written in a cursive, flowing style.

Robert K. Coughlin
President & CEO, MassBio