Pfizer Inc
235 East 42nd Street
New York, NY 10017

January 12, 2018
The Connecticut Health Care Cabinet
Program Management Office
PO Box 1543
Hartford, CT 06144

Via Electronic Mail

Re: Cabinet Recommendations on Drug Costs

Dear Governor Wyman, Director Schaefer, and the Members of the Connecticut Health Care Cabinet:

Thank you for the opportunity to provide input on behalf of Pfizer with respect to the Health Care Cabinet's proposals. We respectfully submit the following comments regarding the Cabinet's draft recommendations.

Pfizer is a research-based global pharmaceutical company dedicated to the discovery and development of innovative medicines and treatments that improve the quality of life for people around the world.

Connecticut is home to the largest site in Pfizer's R&D network and our Groton site serves as a Center of Excellence for drug discovery and development. Pfizer employs more than 3,000 colleagues and 3,500 contract workers in Groton alone and we support an additional 11,700 jobs throughout the state. We also operate a state-of-the-art clinical research unit in New Haven, where colleagues perform clinical research studies.

Nearly every Pfizer medicine is developed in part by our Connecticut colleagues who work to translate advanced science and technologies into the therapies that matter for patients in need. Pfizer's Connecticut colleagues are leading the way in drug development, providing vital information, tools, technologies, data, drug targets, and compounds to scientists around the globe, at every level of drug discovery and development, and across all of Pfizer's therapeutic areas.

Pfizer takes great pride in being a productive and generous corporate citizen in the state. Our patient assistance program, Pfizer RX Pathways, helped over 700 Connecticut residents in 2016 by providing over 5,900 prescriptions for free or at a reduced savings. Additionally, in 2016 alone Pfizer employees and the Pfizer Foundation donated more than $4.4 million to nonprofit organizations in Connecticut through the United Way, matching gifts and volunteer programs and we have donated $230,000 to nonprofit community grants, health-related walks and STEM education scholarships.

Pfizer is committed to meeting the needs of patients and improving the health care system and, as such, we appreciate the work undertaken by the Healthcare Cabinet to identify ways to improve the

efficiency and quality of health care delivered to the citizens of Connecticut. Although Pfizer supports several of the recommendations put forward by the Cabinet, which are discussed in *Section A* of this letter, we strongly agree with each of the concerns articulated by the Pharmaceutical Research and Manufacturers of America ("PhRMA") in their comment letter, and have additional concerns that are discussed in *Section B* below. For the sake of brevity, we have not commented on each proposal put forward in the Cabinet's report; however, exclusion should not be construed as support for a given proposal.

A. Areas of Support

As we have noted in previous comments to the Cabinet, Pfizer supports a number of concepts and proposals to enhance patient access to medically necessary care and control costs that have been under discussion by the Cabinet. Below are concepts that, based on the information provided to date, we believe we could support. The concepts outlined below do not represent all approaches to improving care and controlling costs that Pfizer supports, but rather a selection of areas included in the Cabinet's recommendations that we feel merit emphasizing.

Pfizer Supports Proposals to Improve Patient Medication Adherence

Patient adherence to drug therapy is recognized as a critical component of cost-effective patient care and the Cabinet highlighted "[g]reater medication adherence can improve health outcomes and lower total medical costs." Pfizer agrees that medication adherence is a critical health care issue and supports the Cabinet's proposals that seek to improve adherence, including:

1. <u>Legislative Recommendation (d),</u> which would require PBMs to pass through negotiated discounts to consumers at the point-of-sale by ensuring that deductible and coinsurance requirements are based on negotiated prices rather than list prices;

2. <u>Administrative Recommendation (b)</u>, which would require the state to develop quality measures for medication adherence;

3. <u>Other Administrative Recommendation (j)</u>, which would promote resources that allow consumers to compare cash prices of drugs across different pharmacies; and

4. <u>Other Administrative Recommendation (o)</u>, which would promote the use of the existing All-Payer Claims Database (APCD) to illustrate trends in out-of-pocket cost.

Medication *non-adherence* is estimated to contribute to $290 billion annual in wasteful spending and the CBO credits Medicare policies that increase use of medicines with savings on other

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Medicare costs. [1-2] Each additional dollar spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes and high cholesterol generates $3 to $10 dollars in savings on emergency room visits and inpatient hospitalizations.[3] Every $1.00 invested in vaccines for vaccine-preventable diseases saves an estimated $10.20 in societal costs (direct and indirect).[4] Since 1975, the chances that a cancer patient will live five years or more have increased by 41 percent, with 83 percent of the survival gains attributable to new treatments, including medicines.[5] Reducing cancer death rates by 10% represents $4 trillion in economic value.[6]

Legislative Recommendation (d) seeks to improve medication adherence by addressing rising patient out-of-pocket cost burden, a growing barrier to care for many patients. Insured patients face increasing out-of-pocket cost burdens in the form of higher medical deductibles, more frequent use of pharmacy and combined deductibles, higher copayments, and more frequent use of co-insurance.

Since 2006, the percentage of covered workers in employer-sponsored health plans with a general annual deductible has increased from 55 percent to 81 percent, with an average general annual deductible of $1,505 in 2017.[7] Between 2011 and 2016, deductibles in employer-sponsored health plans increased 7 times faster than wages.[8] The proportion of commercial health plans with pharmacy deductibles grew by 100 percent between 2012 and 2015.[9]

During the deductible phase of an insurance benefit, the patient typically pays the full cost of the service or drug. However, unlike medical services, patients are often required to pay the full list price for prescription drugs during the deductible phase rather than the lower negotiated price that accounts for discounts and rebates negotiated by the payer, such as the PBM. This practice increases patients' out-of-pocket burden and should be addressed. Therefore, Pfizer supports Legislative Recommendation (d), which would allow patients to benefit from discounts negotiated by the payer with a manufacturer, as they currently do for all other medical services.

Administrative Recommendation (b) seeks to improve medication adherence by adding medication adherence quality measures to the core quality measure set adopted by the State Innovation Model

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[1] NEHI, *Improving Patient Medication Adherence: A $290 Billion Opportunity.* http://www.nehi.net/bendthecurve/sup/documents/Medication_Adherence_Brief.pdf

[2] Congressional Budget Office, "Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services," November 2012. Available at: https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/reports/MedicalOffsets_One-col.pdf .

[3] M.C. Roebuck et al. "Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending." Health Affairs, January 2011.

[4] Centers for Disease Control and Prevention (CDC) -- Immunizations and Respiratory Disease Fact Sheet, 2014. Available at: https://www.cdc.gov/budget/documents/fy2016/ird-factsheet.pdf.

[5] E. Sun, et al., "The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology, and End Results (SEER) Database," *Journal of Clinical Oncology,* May 2008 Suppl(Abstract 6616); http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-044552.pdf.

[6] National Cancer Inst. & Murphy and Topel, via http://www.phrma.org/sites/default/files/pdf/infographic-value-of-cancer-medicines-2014.pdf

[7] Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2017. Available online at: https://www.kff.org/report-section/ehbs-2017-section-1-cost-of-health-insurance/.

[8] Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 1999–2016. Bureau of Labor Statistics, Consumer Price Index, U.S. City Average of Annual Inflation (April to April), 1999 -2016; Bureau of Labor Statistics, Seasonally Adjusted Data from the Current Employment Statistics Survey, 1999-2016 (April to April).

[9] IMS Institute for Healthcare Informatics, "Emergence and Impact of Pharmacy Deductibles," September 2015.

(SIM) program established under a CMMI grant from the Centers for Medicare & Medicaid Services. As noted in the 2016 Report of the Quality Council on a Multi-Payer Quality Measure Set for Improving Connecticut's Healthcare Quality:

"Quality measures play an essential role within shared savings programs and other value-based payment arrangements. Payers generally use quality measures to establish expectations, evaluate performance, and reward attainment of value – improvements in clinical quality and health outcomes and/or reductions in the total cost of care."[10]

Given the importance of medication adherence to patient care and controlling health care costs, Pfizer supports exploration and possible adoption of quality metrics related to adherence, provided development of such metric(s) is conducted in an open and inclusive manner with active participation by all stakeholders.

Other Administrative Recommendation (j) proposes to promote the availability of "existing resources that allow consumers to compare the cash price of [a] prescription across pharmacies so consumers can reduce their personal expenses for prescription drugs." Pfizer agrees that patients who are paying cash or a coinsurance for a drug would benefit from greater understanding of how much different pharmacies charge.

Lastly, with regard to medication adherence, Pfizer supports Other Administrative Recommendation (o), which would encourage the state to use its existing APCD to monitor and evaluate trends in patient out-of-pocket cost. APCDs are powerful tools for understanding market-wide trends, including patient cost-sharing exposure, but given their nascence are often under-utilized. We support efforts to enrich and deepen policymakers' understanding of changes in insurance benefit design, which we believe this proposal could help achieve.

B. Areas of Concern

As noted above, Pfizer supports a number of proposals included in the Cabinet's most recent set of recommendations; however, we also have significant concerns with some of the recommendations, many of which are reflected in PhRMA's comments that we agree with. Below are areas of concern that we believe warrant additional emphasis.

Disclosure Mandates

A primary concern for Pfizer is proposals under Legislative Priorities Recommendation (a) that include disclosure mandates. We oppose mandates that require prescription drug manufacturers – or any other entity – to report proprietary information such as pricing, research and development,

[10] Connecticut Health Care Innovation Plan, Connecticut State Innovation Model (SIM) Report of the Quality Council on A Multi-Payer Quality Measure Set for Improving Connecticut's Healthcare Quality, FINAL REPORT, Approved by The Healthcare Innovation Steering Committee. November 10, 2016. Available at http://www.healthreform.ct.gov/ohri/lib/ohri/work_groups/quality/report/qc_report_11102016_final.pdf.

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manufacturing, and marketing costs over and above the extensive information already disclosed in financial filings and publicly available.

Drug prices and development costs are readily available from a variety of public sources, including securities filings. List prices are publicly available. Information on Research and Development (R&D) expenses, Selling, Informational and Administrative (SI&A) expenses, and cost of sales information for drugs collectively manufactured by Pfizer is provided on an aggregate basis in quarterly and annual reports (Forms 10-Q and Forms 10-K). These additional disclosure mandates neither improve patient care nor lower health care costs. Rather, they will raise the administrative costs of developing and delivering life changing medicines.

We also oppose mandating that manufacturers signal price changes in advance, which can have negative implications on the prescription drug supply chain, which can reduce access for patients and put quality at risk. Stockpiling of prescriptions drugs occurs today when price changes are announced. Further advanced notice of price changes would create more incentives and opportunity for stockpiling, potentially resulting in drug shortages not only within the state, but nationwide. Additionally, stockpiling and shortages can result in medicines being sold by unauthorized distributors or on the gray market, disrupting a manufacturer's processes for maintaining high quality assurance of its products.

Disclosure mandates gather only a narrow slice of information and miss the larger drivers of health care spending. Cost-focused initiatives should instead be system-wide. All health care stakeholders – prescription drug manufacturers, insurers, pharmacy benefit managers (PBMs), hospitals and health care professionals – have a role to play in ensuring a high-quality, cost-efficient system.

Given that prescription drug costs represent a small fraction of health care spending overall (< 20%)[11] and are a proportionally small contributor to premium growth,[12] focusing disclosure mandates on medicines is short-sighted and could lead to incomplete and poorly designed policies. Policymakers interested in making improvements to the health care system and reducing health care costs should seek information that provides a holistic picture of health care, and promote a definition of value that considers impacts to health over time and across all appropriate stakeholders.

In fact, Connecticut's own Department of Social Services recently cautioned the Governor's Health Care Cabinet about approaches to controlling drug costs that "examines drug costs outside of the context of other health costs and health needs," and that such approaches fail "to account for the substantial clinical and financial benefits generated by medications and related treatments."[13] They further noted that, "[m]edications save money <u>and</u> lives. PhARMA (sic) is correct in its assertion that medications are largely why heart disease rates decreased 46% in the U.S. between 1991 and 2011."[14]

[11] Centers for Medicare & Medicaid Services, National Health Expenditure Projections 2014-2024 (2015).
[12] Avalere, *Health Insurance Premium Increases Largely Mirror Spending*, Nov. 16, 2015, http://avalere.com/expertise/managed-care/insights/health-insurance-premium-increases-largely-mirror-spending.
[13] CT Department of Social Services, Presentation to the Connecticut Healthcare Cabinet, February 14, 2017.
[14] *Ibid.*

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We believe that information gathered by policymakers should improve health care decision-making and patient care, and should not impart burdensome reporting requirements on companies that yield data that is of little use to patients and health care professionals. In particular, we need to focus on providing information that can be used by patients to improve their health care and insurance enrollment decision making (e.g., plan-level information on coverage and out-of-pocket cost-sharing requirements).

The American Institute for Research has noted that, "[l]acking health insurance-related knowledge and skills—or health insurance literacy—puts people at risk of choosing an insurance product that could fail to provide needed benefits or protect them financially. And, previous research has shown that consumers who struggle to understand how health insurance works and how to estimate out-of-pocket costs are at risk of going without needed care even if they are covered." [15]

They also noted that, "[w]hen comparing plans, most people (79%) were moderately or very likely to check which hospitals and physician are covered in each plan," but, "only slightly more than half of people were moderately or very likely to 'look to member services to tell you what medical services your health plan covers.'"[16]

An Avalere Health analysis of the consumer shopping experience in health insurance exchanges revealed that, "thirty-eight percent of plans had no drug formulary data available, presenting significant obstacles to consumers who are shopping for insurance and attempting to assess the value of their coverage."[17]

Given the vital role medicines play in preventing the onset or worsening of many conditions, as well as preventing the need for more intensive, higher cost health services, rather than mandating disclosure of information that will not help patients, we believe Connecticut should ensure that up-to-date and accurate drug formulary information is available to its residents. To choose the plan that best fits their needs, patients need to know which drugs are listed on the plan's formulary; tier placement and associated cost sharing levels; and utilization management (UM) restrictions, such as prior authorization, step therapy, or quantity limits.

Greater access to insurance coverage information, *conveyed in a manner that average consumers can easily understand*, enhances the ability of consumers and businesses to make informed decisions among available coverage options. It also allows providers and their patients to identify optimal treatment programs. For patients to make effective health care and financial choices, they must be able to understand and compare health plans' medical and formulary coverage and costs relative to their current and expected future healthcare status.

Pfizer Opposes Weakening Protections for Medicaid Patients

[15] American Institutes for Research, "Many Americans Lack Health http://aircpce.org/2014/10/many-americans-lack-health-insurance-knowledge-skills/
[16] *Ibid.*
[17] Avalere Health, LLC, "Exchange Consumer Experience: Study finds lack of transparency on drug coverage in exchanges, but better data on provider networks." April 25, 2014. Available at http://avalere.com/expertise/managed-care/insights/avalere-analysis-exchange-consumer-experience. Last accessed March 23, 2015.

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Other Administrative Recommendation (l) suggests that the state evaluate using exclusions or "more onerous prior authorizations" to the Medicaid formulary. Pfizer is concerned that this proposal would fail to meet certain basic requirements for Medicaid waivers under Social Security Act ("SSA") section 1115,[18] and thwarts the Congressional intent underlying the Medicaid rebate statute,[19] which reflects a pact between government and industry to provide deep rebates in exchange for patient access. Further, formulary exclusions (even if they were allowable) would block the neediest patients from accessing cutting-edge care that the patient and his or her physician has selected as medically necessary and that the FDA has approved as safe and effective. Instead, Connecticut should consider ways to do more with the cost containment tools that it already possesses under existing law.

Under the Medicaid rebate statute, Connecticut can exclude drugs from its Medicaid formulary that are not used for medically accepted indications—if these key requirements are all met: (1) the drug does not "have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome" over a drug on the formulary; (2) the state provides a publicly-available written explanation of the basis for the exclusion; (3) the excluded drug is available using prior authorization; and (4) the formulary is developed by a committee of medical experts that meets the composition requirements specified under the statute.[20]

Under existing law, Connecticut may use utilization management restrictions to seek rebates that supplement the deep Federal Medicaid rebates that are automatically payable on covered outpatient drugs. Therefore, we believe that Connecticut should explore these options fully before it considers seeking the ability to exclude drugs from its formulary.

Pfizer Opposes Weakening of Cost-Sharing Protections

As previously noted, patients are facing ever-increasing out-of-pocket cost burdens with more frequent use of and higher deductibles, and high cost-sharing requirements. The number of tiers health plans use has been steadily increasing. In 2016, 14 percent of exchange plans nationally used 6-tier formularies and 5 percent used 7-tier formularies.[21] Similar trends are occurring with the use of high coinsurance. In 2015, 52 percent of bronze plans had specialty tier coinsurance of greater than 30 percent.[22] The Cabinet correctly notes that "even small changes in member cost share for pharmaceuticals can have significant impacts on medication adherence."

Administrative Recommendation (e) proposes to "[s]et co-payment and co-insurance maximums per month of $250 for most plans ($500for bronze ACA plans), per 30 day supply." While we

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[18] Codified at 42 U.S.C. § 1315.
[19] Codified at 42 U.S.C. § 1396r-8.
[20] 42 U.S.C. § 1396r-8(d)(2).
[21] Avalere PlanScape®, a proprietary analysis of exchange plan features, December 2015.
[22] Avalere PlanScape®, a proprietary analysis of exchange plan features, December 2014. Avalere analyzed data from the FFM Individual Landscape File released November 2014 and the California and New York state exchange websites.

support policies that protect patients from high or excessive cost-sharing requirements, we are concerned that this approach would *weaken* protections already established in Connecticut. As we understand regulatory guidance issued by the Insurance Department, Connecticut already limits copays for branded drugs to $60.[23] Therefore, we are concerned that adopting Administrative Recommendation (e) would have the unintended consequence of raising cost-sharing requirements for patients, and thereby reduce medication adherence.

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Pfizer appreciates the opportunity to comment on the preliminary recommendations to control prescription drug costs, and we welcome further discussion. Please do not hesitate to contact me if I can be of further assistance. We look forward to working with the Office of the Lieutenant Governor, the Cabinet, and other stakeholders to enhance health care for the residents of Connecticut. If I can be of any assistance please do not hesitate to contact me at 860.287.4603 or at ken.hiscoe@pfizer.com.

Sincerely,

Ken Hiscoe
Director, Government Relations

[23] Insurance Department, State of Connecticut. *Bulletin HC-109.* February 5, 2016.