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December 4, 2023

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Re: Request for Information; Coverage of Over-the-Counter Preventative Services; File Code No.: 1210-ZA31

Dear Sir or Madam,

The Consumer Healthcare Products Association (CHPA) submits these comments on the request for information issued by the Department of the Treasury, Department of Labor, and Department of Health and Human Services on the “Coverage of Over-the-Counter Preventative Services” published on October 4, 2023. For more than 142 years, CHPA has served as a vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of over-the-counter (OTC) medicines, consumer medical devices, and dietary supplements. Our members provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases.

As the three departments continue to consider whether and/or how to cover, without out-of-pocket cost sharing, OTC preventive products for contraceptive care without a prescription by a healthcare provider, our comments cover four areas:

- (1) The value direct consumer access to OTC medicines provides today;
- (2) Healthcare trends driving the need for greater access to OTC medicines;
- (3) Market-based approaches are at the core of the OTC medicine system; and
- (4) Existing approaches may provide models or insights as the departments look ahead.

(1) Direct consumer access to OTC medicines provides strong value to consumers and the healthcare system. Access to appropriate medicines without a prescription empowers consumers to take greater control over their health and provides considerable public health benefits. In 2022, CHPA commissioned Circana (formerly IRI) to estimate the value of OTC medicines to the U.S. healthcare system. The study found

that each dollar spent on OTC medications saves the U.S. healthcare system \$7.33 in healthcare spending.¹ The overall savings to the U.S. healthcare system totals \$167.1 billion in the past year compared to alternatives. Savings from drug costs total \$56.8 billion, which are generated by the lower prices of OTC medicines as compared to more expensive branded or generic prescription medicine alternatives to treat self-managed conditions. The remaining savings come from avoided clinical visits, which represents \$110.3 billion of the total annual savings. These savings are the result of consumers making the decision to self-treat with OTCs rather than making a visit to the doctor's office for treatment.

In addition to providing value through cost savings, OTC medications also help reduce the burden on the U.S. healthcare system. This study estimates that 82 percent of consumers who treat a condition with an OTC medicine would seek professional medical treatment if OTCs were not available in the marketplace. It is unrealistic that the U.S. health system would be able to absorb additional office visits from hundreds of millions of consumers to get treatment or obtain prescriptions for mild conditions they can self-treat.

OTC products are now many consumers' first line of defense in treating everyday conditions, such as allergies to heartburn. Since 2001, there have been more than 40 different products switched over from prescription to OTC in categories ranging from chronic conditions, such as allergy and heartburn, to most recently, as mentioned in the request for information, a progestin-only oral contraceptive.

The prescription to OTC switch of nicotine replacement therapies provides a specific example of how switching a product to OTC can directly impact the health of Americans. When the nicotine replacement therapies used to quit smoking went OTC, there was a 150 percent increase in their use in the first year after the switch.² That easier access enabled tens of thousands of smokers to use these products to help quit smoking.

(2) Healthcare trends driving need for greater access to OTC medicine. Two major trends in healthcare that may be creating barriers for many Americans to access needed prescription medications are physician shortages and healthcare coverage.

The growing shortage of licensed physicians in the U.S. is making it harder for patients to get access to the doctors required to receive the prescriptions needed for treatment. A 2021 published report by the Association of American Medical Colleges

¹ *The Power of OTCs to Provide Consumer Value*, IRI and Consumer Healthcare Products Association, November 2022.

² Shiffman, S., et al., *Public health benefit of over-the-counter nicotine medications*, *Tobacco Control*, 6: 306 (1997). and Keeler, T., et al., *The benefits of switching smoking cessation drugs to over-the-counter status*, *Health Economics*, 11: 389. (2002).

projects that physician demand will continue to outpace supply. In particular, the report projects that by 2034 “there would be a shortage of primary care physicians of between 17,800 and 48,000, and a shortage of across the non-primary care specialties of between 21,000 and 77,100 physicians.”³

The shortfall could amount to 125,000 physicians within ten years. This means patients will face ever growing challenges getting timely access to appointments and treatment. This expected shortage will likely lead to rising healthcare costs as demand for treatment outstrips the available supply for physicians. These trends could raise barriers for patients attempting to access timely and appropriate treatment.

Many consumers are also facing challenges in either obtaining health insurance or having inadequate coverage. According to a report released by the PAN Foundation, about half of adults aged 19-64 are uninsured or underinsured.⁴ Last year, 12.2 percent of adults aged 18-64 did not have health insurance, and over 70 percent of the uninsured cite that coverage is not affordable as the main reason for being uninsured.^{5,6} Abundant research demonstrates that people who are uninsured have lower rates of treatment and worse patient outcomes.

Underinsured consumers usually have high health plan deductibles and high out-of-pocket medical expenses relative to their income. Similarly to the uninsured, the underinsured are likely to delay or forgo medical care and needed treatments as well as have difficulty paying medical bills.⁷

In instances of both uninsured or underinsured Americans, OTC medicines can be the first treatment option and enable the healthcare system to utilize its limited resources on the diagnosis and treatment of more serious diseases and medical conditions that necessitate the direct involvement of a physician.

(3) Market-based approaches are at the core of the OTC medicine system. OTC medicines exist in a highly competitive, market-based environment, with low barriers to entry. When prescription-only medicines have been made available as OTC products, a substantially higher number of consumers typically purchase the product compared to when it was only available through prescription. OTC medicines greatly expand access to medicine because they both remove barriers (healthcare provider visits, paperwork

³ IHS Markit Ltd. *The Complexities of Physician Supply and Demand: Projections From 2019 to 2034*, Association of American Medical Colleges. June 2021.

⁴ *Issue Brief No. 14: Being Uninsured and underinsured in the U.S.*, PAN Foundation. September 2020.

⁵ Cohen, R., et al, *Health Insurance Coverage: Early Release of Estimates From the National Health Interview Study, 2022*. National Center for Health Statistics. May 2023.

⁶ Cha, A., et al, *Reasons for Being Uninsured Among Adults Aged 18-64 in the United States, 2019*. National Center for Health Statistics, September 2020.

⁷ *Issue Brief No. 14: Being Uninsured and underinsured in the U.S.*, PAN Foundation, September 2020.

burdens, and, in some cases, the removal of stigma or embarrassment), and expand available places of sale, ie, retail outlets (including e-retailers).

Most OTC medicines exist in pre-existing therapeutic categories, and thus face competition immediately upon entry. Even when an OTC medicine switched from prescription status creates a new direct consumer access therapeutic category, it can receive a maximum of three years of data exclusivity, and then only if FDA determines the prescription-to-OTC switched was based on the conduct of essential new clinical studies to support the Rx-to-OTC switch application. OTC medicines therefore exist in a willingness-to-pay model, largely directly from out-of-pocket. And in this model, Americans appropriately elected to purchase OTC medicines over 5 billion times in 2022. Why? Because, in addition to the medical benefits they provide, the time and access savings have value unto themselves.

In contrast, acquiring a medicine through the prescription pathway requires a greater number of steps, any one of which can reduce adherence to therapy: visiting a provider, receiving a prescription, receiving any relevant authorization from the insurance plan, finding an in-network pharmacy, and being aware of out-of-pocket costs. This process requires a patient's time commitment and an awareness of those steps and relevant information (e.g., how to access and understand the plan's benefit design). Conversely, acquiring an OTC product without the involvement of a health insurance plan provides patients with a more direct access route.

As a result of the different access pathways, including the time and awareness elements, some individuals may choose to acquire a product as an OTC even where its availability as a prescription medicine could provide out of pocket drug cost savings under many Medicare and commercial plans.

Finally, in a proposed rule on technology-enabled Rx-to-OTC switches, the Food and Drug Administration estimated the greater access to switch drugs and reduction in costs to consumers saves consumers \$26.70 per consumer per purchase (within a range of \$0 - \$53.40).⁸ Past switches have repeatedly underscored the increased utilization that flows from nonprescription availability. For instance, Stomberg, *et al.*, found utilization increased 27 percent when a new OTC therapy is introduced.⁹ In the era of several switches for allergy symptoms, the percentage of allergy sufferers using OTC medicines increased from 66 to 75 percent.¹⁰ As noted above, the introduction of OTC smoking

⁸ 87 Fed. Reg. 38313, 38325 *June 28, 2022).

⁹ Stomberg C., *et al.*, *Utilization effects of Rx-OTC switches and implications for future switches*. Health. 2013.

¹⁰ Nielsen for CHPA, *Assessing consumer benefit of allergy Rx-to-OTC switches*. 2017.

cessation products provides the most powerful example, with utilization increasing 150 percent in the first-year post-switch.¹¹

Significant disruption in this market-based model may have the unintended consequence of undercutting incentives for future products to enter the OTC space.

(4) Existing approaches may provide models or insights as the departments look ahead. While OTC medicines exist in consumer choice and market-driven system, the departments may wish to promote programs that reduce or cover the cost of select OTC medicines to Americans today. We highlight three:

(a) Medicaid. Medicaid in many state programs covers a number of OTC medicines, thus making it the only common type of insurance that does so. In order to purchase an OTC product under Medicaid coverage, patients require a physician prescription or fiscal order. In this situation, OTC transactions still flow through the benefit adjudication process. That could continue to take place in the future.

(b) Medicare Advantage supplement benefits. While the Medicare-eligible population is of course largely outside of the departments' request for information on OTC contraceptives, the expansion of Medicare Advantage supplement benefits programs may provide analogies of interest. As of 2021, nearly 18 million consumers had access to health-plan funded and administered OTC benefits at an average of \$400 in OTC allowances per enrollee.¹² These OTC benefits are typically structured on an allowance basis where enrollees are provided with an allotted annual, quarterly, or monthly allowance. A number of Medicare Advantage OTC programs use retail and pre-paid payment cards, with a catalogue of approved OTC products available for enrollees to purchase using the allocated allowances. Existing retail scanner systems can readily accommodate fields for eligibility.

(c) Tax-advantaged status. While not a zero out-of-pocket option, Flexible Savings Accounts and Health Savings Accounts (FSAs and HSAs) are the third area that can reduce the cost of OTC medicines. In March 2020, Congress restored eligibility for OTC medicines in FSAs and HSAs, allowing Americans to purchase these products as tax-advantaged qualified medicine expenses. This, then, saves consumers money and increases access. In many instances, an FSA or HSA debit card can be used with many retailers to pay for eligible products. As with the Medicare Advantage OTC benefit cards, this again synchs with existing retail scanner systems.

¹¹ Shiffman, S., et al., *Public health benefit of over-the-counter nicotine medications*, Tobacco Control, 6: 306 (1997). and Keeler, T., et al., *The benefits of switching smoking cessation drugs to over-the-counter status*, Health Economics, 11: 389. (2002).

¹² Healthscape and Pareto Intelligence for CHPA, *Using the Medicare Advantage Over-the-Counter Medicines Program as a Consumer Engagement Tool*, 2021.

We appreciate the opportunity to submit these comments and are available for further information.

Submitted,

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