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Division of Dockets Management

Food and Drug Administration

Department of Health and Human Services

5630 Fishers Lane, Room 1061

Rockville, MD 20852

**Comment on Citizen Petition for the U.S. Food and Drug Administration to adopt a mandatory, nutrient-specific, interpretive front-of-package nutrition labeling system for all packaged foods sold in the United States (FDA-2022-P-1832)**

I am writing as executive director of Healthy Food America **in support** of this petition calling on the U.S. Food and Drug Administration (FDA) to issue regulations establishing a mandatory front-of-package nutrition labeling (FOPNL) system for foods sold in the United States. I am also Clinical Professor of Public Health and Medicine at the University of Washington and am currently engaged in research on front of package warning labels.

**A front of package nutrition labeling system must be mandatory and nutrient-specific, include calories, and call attention to high levels of added sugars, sodium, and saturated fat *using a warning-label icon*. These nutrients are over-consumed by Americans and contribute to chronic disease. Labels must be prominently displayed. They must discourage the choice of unhealthy products (and not only identify healthier products).**

This comment describes the need for labels, evidence supporting their effectiveness, and recommendations for label design.

**Poor diet quality is driving an epidemic of chronic disease in the US.**

The widespread availability and marketing of unhealthy foods high in nutrients of concern is a key driver of the epidemic of chronic diseases in the United States. A recent FDA document reported that 63% of Americans exceed the current recommended daily limit for added sugars, 77% for saturated fat, and 90% for sodium.<sup>1</sup> Meanwhile, approximately 116 million U.S. adults (47% of the adult population) have hypertension,<sup>2</sup> 37 million Americans (11% of the population) have diabetes (and approximately 90-95% of these cases are Type 2 diabetes),<sup>3</sup> and 20 million U.S. adults (7% of adults) have coronary artery disease.<sup>4</sup> Each of these conditions is strongly linked to excess intake of added sugar, salt, and/or saturated fat.

In particular, **ultraprocessed foods** are high in added sugars, salt, and saturated fat. These foods play a key role in driving the ubiquity of unhealthy foods in American communities. A growing proportion of America adolescents and adults consume these products, and

consumption is higher in the US than other high-income countries. Nearly 60% of calories consumed by US adults come from ultraprocessed foods.<sup>5</sup> And even larger share of calories consumed by US youth – two-thirds – comes from ultraprocessed foods.<sup>6</sup> A growing body evidence links ultraprocessed foods to diabetes, heart disease, overweight and other conditions.<sup>7</sup> It is critical to inform consumers about the high levels of nutrients of concern commonly found in these products so they can make informed and healthier choices.

**Warning labels are effective in directing consumers towards making healthier food choices and warning labels are more effective than other label types for reducing choice of less healthful products.**

An substantial body of scientific evidence supports the adoption of a FOPNL system that includes mandatory warning icons about nutrients of concern to improve the nutritional quality of consumers' food choices, promote understanding of the nutritional contents of foods, and prompt food manufacturers to make healthy reformulations of packaged foods. In particular, warning labels are effective in discouraging the purchase of less healthful products.<sup>8, 9</sup>

**Labels should be easy to understand: graphic (interpretative), binary labels are grasped more readily than numeric information and more effective.**

An interpretative system was recommended by The National Academy of Medicine a decade ago.<sup>10</sup> Considerable research evidence supports using interpretative labels over numeric labels. For example, consumers often make decisions very quickly and without deep “rational” processing of information,<sup>11,12</sup> suggesting that cues such as icons, scores, words, and colors could help them assess a product's healthfulness more accurately. Consistent with this hypothesis, studies from several countries demonstrate that interpretative labels perform better than numeric labels at improving consumers' understanding of products' healthfulness.<sup>13, 14, 15, 16, 17, 18, 19, 20</sup> Studies that examine consumers' purchase behaviors also find that interpretative labels perform better at improving the overall healthfulness of people's choices compared to numeric labels<sup>8, 13,14,17, 21, 22, 23, 24, 25</sup> These objective outcomes are also supported by consumers' experience of labels. Studies that ask consumers what labels they prefer, for example, find that consumers tend to favor interpretive and easily comprehensible labeling systems.<sup>23, 26, 27, 28</sup> Labels that are easier to interpret may be particularly important for promoting health equity given that groups with lower educational attainment are less likely to use and understand numeric labels than groups with higher educational attainment.<sup>29, 30, 31</sup> A large body of evidence finds that, in contrast with the Nutrition Facts Label, interpretative food labels tend to be similarly effective regardless of race/ethnicity, income, or educational attainment.<sup>32, 33, 34, 35, 36</sup>

**Labels should provide specific information about nutrients of concern.**

Different types of interpretative front-of-package labels have been tested and implemented globally. While some provide a summary assessment of the product's nutritional quality (e.g., a grade from A to E), others provide information on nutrients of concern (e.g., warnings signaling when products are high in these nutrients). Although evidence does not uniformly point towards a single type of interpretative labeling system outperforming all others, it is clear that nutrient-

specific labels – and especially nutrient warnings like those used in Chile – are among the labeling systems that promote consumer understanding and encourage healthier food purchases. Nutrient warnings deliver information simply. They provide a simple, clear message that a product is high in a nutrient of concern. This simplicity may be especially helpful when consumers are making a binary decision about to buy or not buy a given product.<sup>37</sup> Experimental studies indicate that nutrient warnings are perceived as effective and evoke consumer responses that are predictive of longer-term behavior change. Studies with adults in the US, for example, have found that nutrient warnings have higher perceived message effectiveness, evoke more thinking about harms and fear, and lead to lower perceptions of product healthfulness compared to control labels.<sup>38, 39</sup> In Canada, a randomized trial found that nutrient warnings led to more healthful food and beverage purchases compared to the status quo of no front-of-package labels.<sup>40</sup> Other laboratory studies from around the world – including Europe, Oceania, and South America – have similar findings in terms of consumer perceptions, comprehension, and behavioral intentions.<sup>15, 23, 41, 42, 43, 44, 45, 46, 47, 48, 49</sup>

Real-world evidence also indicates that nutrient warnings encourage healthier purchases. In 2016, Chile became one of the first countries to implement mandatory front-of-package nutrient warning labels. Longitudinal and quasi-experimental studies evaluating the Chilean policy have demonstrated that it has impacted both the supply and the demand side of food retail: consumers have reduced their purchases of labeled products (i.e., products high in sugar, saturated fat, calories, and sodium)<sup>50, 51, 52</sup> and the food industry has reformulated a substantial proportion of products to improve their nutrient content.<sup>51, 52</sup>

### **Labels should specifically discourage choice of less healthy foods.**

In the context of the FDA’s consideration of a healthy food label, it is important to note that front-of-pack labeling systems are more effective when they explicitly discourage unhealthy foods, rather than only promote healthier options. “Endorsement” or positive-only labels have several shortcomings relative to systems that discourage unhealthy foods. For example, positive-only endorsement labeling systems have been shown to impact consumers’ perception of a product’s healthfulness, but may not improve understanding of its nutritional content, and can lead to incorrect beliefs about a product’s healthfulness.<sup>53</sup> In one study comparing different types of labels, for example, participants rated a product with an endorsement logo as healthier than a product with the same nutritional profile displaying a traffic light label, which allows for a more nuanced assessment of product healthfulness.<sup>54</sup> Simple endorsement labels may also have unintended consequences for consumers, including leading to overconsumption and other unhealthy eating behaviors.<sup>55, 56</sup> Evidence also suggests that endorsement labeling systems have limited impacts on the healthfulness of food purchases. One randomized experiment found no difference in consumption or purchase intentions between cereals with an endorsement label and unlabeled controls.<sup>57</sup> Studies of the Health Star Rating labels, which rates foods only in degrees of healthfulness rather than explicitly discouraging less healthy choices, have also found that this system has no effect on the healthfulness of food purchases.<sup>58</sup>

By contrast, studies of labeling systems that explicitly discourage consumption of unhealthy foods find that these labels are likely to promote consumer understanding of food nutrition content and lead to healthier food and beverage purchases.<sup>59, 60</sup> For example, one randomized trial found that

warning labels resulted in significantly healthier packaged food purchases compared to a no-front-of-package-label control, while the positively-framed Health Star Ratings did not improve purchase healthfulness.<sup>23</sup> Another randomized experiment directly compared consumer reactions to a labeling system that only promoted healthier foods with a “healthy” label to a labeling system that only discouraged unhealthier foods with an “unhealthy” label. That experiment found that the benefits of the unhealthy labels on consumer understanding and purchase healthfulness were about twice as large as the effects of healthy labels, highlighting the importance of explicitly discouraging consumption of unhealthy products.<sup>61</sup> Of note, the unhealthy labels both increased purchases of foods with healthy nutrients while decreasing purchases of nutrients of concern.

### **Labels should be mandatory - mandatory labels are more effective than voluntary labels.**

Research evaluating the voluntary Health Star Rating system in Australia and New Zealand, for example, found that two years after the implementation of this system, only 5% of packaged foods and beverages displayed the Health Star Rating labels.<sup>62</sup> This figure increased somewhat by three years after implementation, but was still low, at just 28%.<sup>63</sup> The limited uptake of voluntary labels is problematic because customers cannot determine if a product lacks a label because it is unhealthy or because the manufacturer simply chose not to label the product. Indeed, evaluations of the voluntary Health Star Rating labels, for example, find that retailers primarily display labels on healthier products that earn higher scores (more stars) and leave less unhealthy products unlabeled. One study found that >75% of all products with the HSR label received  $\geq 3$  stars (out of a possible 5), and that the mean score for products displaying the HSR was significantly higher than the mean of products not displaying the labels (3.4 stars vs. 2.7 stars).<sup>63</sup> Similarly, a study of packaged foods marketed to children in Australia found that 28.5% of products displayed the HSR label, with >80% receiving  $\geq 3$  stars.<sup>64</sup> By contrast, evaluations of mandatory labeling systems find very high compliance – the vast majority of products required to bear mandatory labels display these labels.<sup>65</sup>

In addition to guiding consumers, front-of-pack labels can also incentivize manufacturers to reformulate products to reduce the amount of nutrients of public health concern.<sup>66</sup> Voluntary labeling systems, however, have been found to spur only very small changes to the food supply. Implementation of voluntary HSR labels, for example, was associated with minimal product reformulation, resulting in only small changes in energy density, sodium, and fiber content.<sup>62</sup> By contrast, mandatory labeling systems provide much stronger incentives for companies to reformulate their products to be healthier.<sup>60</sup> In Chile, after a mandatory warning label was implemented, many retailers removed unhealthy nutrients from products to avoid exceeding the “high in” thresholds that triggered the warnings; the prevalence of products high in sugar and sodium, for example, dropped from 80% to 60% and 74% to 27%, respectively.<sup>67</sup> Reformulation appears to be concentrated around products that are close to the thresholds specified by the labeling,<sup>51, 68</sup> suggesting that tightening thresholds over time could be useful to spur continued reductions in unhealthy nutrients in the food supply.

Mandatory labels can also facilitate implementation of other policies and regulations. For example, if the government implements mandatory nutrition labels based on specific nutritional criteria (e.g., requiring warnings for products that exceed certain thresholds for sodium, saturated fat, or added

sugars), then government buildings and institutions like schools, hospitals, and universities can use the same regulatory criteria in their policies regulating what foods they serve and sell on their premises. For example, Chile’s Law of Food Labeling and Marketing required front-of-package warning labels on products that are “high in” calories and nutrients of concern, with the added stipulation that products with warning labels cannot be promoted to children under 14 years of age and cannot be sold at schools or provided as part of school food programs.<sup>67</sup> The unified suite of policies reinforces the message that consumption of these products should be limited.<sup>69</sup>

### **Many consumers already use front of pack labels and they are more effective than the nutrition facts panel.**

Research shows that many consumers rely on information presented on the front of food and beverage packaging,<sup>70, 71, 72</sup> perhaps because consumers make food purchasing decisions very quickly.<sup>73</sup> Eye tracking studies confirm the importance of front-of-package labels for drawing attention to nutrition information, finding that when products display both front-of-package labels and Nutrition Facts Labels, consumers pay more attention to the front-of-package labels than the Nutrition Facts Labels.<sup>74, 75</sup> Eye tracking studies have also found that when front-of-package food labels are added to products, consumers are more likely to notice nutrition information, find nutrition information more quickly, and pay attention to that information for longer periods, compared to when only the back-of-package Nutrition Facts Label is present.<sup>76</sup> In-person laboratory studies and real-world natural experiments confirm that adding front-of-package labels to products can lead to beneficial changes in consumer perceptions and food purchase behavior.<sup>50, 41, 77, 78, 79,</sup>

### **The current nutrition fact panel is not widely used nor understood – more effective means for informing consumers are needed.**

Use and understanding of the nutrition fact panel are low. For example, an FDA study with a nationally representative sample of 4,398 Americans found that only 20% reported always using the Nutrition Facts Label when buying a food for the first time, and 1 in 8 said they never look at these labels.<sup>80</sup> Even when consumers do look at the Nutrition Facts Label, systematic reviews show that they often have difficulty understanding its content.<sup>81</sup> Moreover, use and understanding of the Nutrition Facts Label are lower among groups with lower income and educational attainment,<sup>81, 82,</sup> <sup>83</sup> potentially contributing to sociodemographic disparities in dietary quality.

## **SUMMARY**

Diet-related disease remains a leading public health concern in the US. Evidence indicates that appropriately designed food labels can play a useful role in addressing this challenge by encouraging consumers to make healthier purchases and prompting the food industry to reformulate their products to remove unhealthy nutrients. But food labels will only meet their potential to promote population health if companies are required to display them and consumers can easily use and understand them. New food labels should therefore be mandatory, shown prominently on the front of package, interpret product healthfulness graphically for consumers in relation to nutrients of concern (rather than only providing numeric information), and explicitly discourage unhealthy products (rather than only promoting healthier options).

The time has come for FDA to take bold action to improve our nation's diet and health. Please prioritize this evidence-based policy and develop a mandatory FOPNL system for the United States.

Sincerely,

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