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CC: Brian King, PhD, MPH. Office on Smoking and Health, CDC Mitchell Zeller JD. Center for Tobacco Products, FDA

Dear sir or madam,

Re: Comments on Healthy People 2030 draft objectives related to tobacco use

We are pleased to provide comments on the draft tobacco-use indicators for the Healthy People 2030 public health measurement framework.

This comment reflects views of the National Tobacco Reform Initiative, which is an alliance of experienced public health professionals dedicated to reducing adult smoking, and the related burden of disease and premature death, as far and as rapidly as possible in the United States. The members are as listed below. In this comment, we provide overall comments on the set of objectives and comments on each of the twenty specific objectives.

We propose changes to the objectives that would rationalize and future-proof the framework. Our aim is to ensure that the objectives are closely aligned with meaningful health outcomes - ultimately reducing disease and premature death by changing tobacco-use behaviors. We suggest restoring quantified 'leading indicators' as with the Healthy People 2020 objectives.

We also suggest ways to avoid perverse incentives and unintended consequences that might arise from incomplete recognition of the very substantial differences in risk between combustible and non-combustible tobacco products. To characterize the overall burden of tobacco and nicotine use, we propose that a harm-weighted index of tobacco use would be a useful way to capture both changes in overall in tobacco use and changes in the structure of tobacco consumption over the coming decade. We suggest a focus on any form of combustible tobacco use rather than on just cigarettes, as we anticipate changes in patterns of consumption, and these could be driven in part by regulation such as reducing nicotine content.

We question whether policy implementation objectives should be included in Healthy People 2030 and make several suggestions for refinements to the indicator definitions.

We hope these views are helpful as we pursue our shared goal of radically reducing tobaccorelated disease and premature death. We would welcome the opportunity to discuss these views with relevant staff.

Yours faithfully

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Attached: Comments on draft Healthy People 2030 Tobacco Use Objectives

Comments on Draft Healthy People 2030 Tobacco Use Objectives National Tobacco Reform Initiative January 2019

This document provides comments on the twenty draft Healthy People 2030 tobacco use objectives¹ and some general comments on the design of the set of objectives. In formulating these comments, our aim has been to make proposals to simplify the set of objectives, focus on what really matters for public health, avoid perverse incentives and to try to 'future proof' the objectives - recognising potentially significant shifts in the patterns of tobacco use and regulation by 2030.

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¹ Office of Disease Prevention and Health Promotion: Healthy People 2030 [link] Draft Tobacco-Use Objectives [link] 2018

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1 Overall comments on the design of the tobacco-use objectives

1.1 Explicitly state the ultimate purpose of the tobacco-use objectives

The ultimate aim of these objectives should be made clear – the reduction of disease (principally cancer, cardiovascular disease and respiratory illness) and related premature death at the greatest possible rate. Most of tobacco policy is already geared to meeting these goals. If there are policy trade-offs with other possible objectives, for example reducing nicotine use, then these primary health goals should have primacy. We do not believe that there are circumstances that would justify accepting higher rates of disease and death in order to reduce nicotine use. In the case of cigarette smoking, these goals are aligned but in the case of non-combustible products, the concept of tobacco harm reduction may apply, and these goals could be in conflict. If other goals than disease and death are given primacy, then it would implicitly mean accepting higher rates of disease and more premature death to achieve a goal like reducing nicotine use, and we do not consider that to be an ethical approach.

1.2 The critical distinction in future is between combustible and non-combustible tobacco use

The objectives need to be relevant over the next decade, a period over which the tobacco/nicotine market will change considerably both in the diversity of products and complexity of use. Future-proofing the objectives is essential. For public health, the key distinction in characterization of tobacco/nicotine use is between combustible and non-combustible products – distinctions within these categories exist but what is most important for individual and public health is that those who need to or choose to use nicotine do so without inhaling smoke into their lungs. This distinction will become more important as the market evolves and diversifies over the next decade. We recommend, therefore, creating two broad classes of tobacco/nicotine products - combustible and non-combustible - and defining objectives for these aggregated categories, recognizing that complete substitution of high-risk combustion products by low-risk non-combustion products provides a material public health gain.

1.3 The focus should be on reducing combustible use and avoiding unintended consequences from objectives for non-combustible use

In defining objectives, it is important not to create perverse incentives - for example, incentives that work against reducing smoking by discouraging people from switching to non-combustible products instead of smoking. The objectives for combustible products, including cigarettes, cigarillos, and roll-your-own (RYO) should always focus on reducing use and initiation. More nuance is necessary for non-combustible products, including e-cigarettes, smokeless tobacco, and modern oral products. Smokers who switch completely to a noncombustible product significantly reduce their individual risk of smoking-related diseases, contributing to the protection of public health. It follows that the Healthy People objectives should focus primarily, though not exclusively, on combustibles.

1.4 Reintroduce quantified objectives for leading indicators

The Healthy People 2020 objectives drew out two leading indicators and established quantified goals. These were: (1) to reduce adult cigarette smoking to 12% by 2020; and (2) to reduce past-30-day adolescent

cigarette smoking to 16% by 2020. The adolescent goal has been reached and surpassed (7.6% in 2017) and it is likely that the adult objective will be met by 2020 (13.9% in 2017).

This sort of ambition should be retained in the 2030 objectives. However, we suggest the following changes to the design of these indicators:

- For both adults and adolescents focus on *any combustible product*, in combination or individually. This is because the patterns of tobacco use are likely to become more complex and diverse in the next decade. If there is regulatory intervention to reduce nicotine levels in cigarettes there may be switching to other combustibles. Use of combustible tobacco ("smoking") is the most important risk behavior.
- For adults, focus on *daily* smoking as the lead indicator. Daily smoking is a sign of an entrenched, dependent behavior and involves substantially higher toxic exposures. Among adults, daily smoking is a much higher proportion of current smoking about three-quarters of adult smokers are daily smokers.
- For adolescents, retain focus on *current* smoking (any past-30-day smoking). This is because current smoking is a marker for a more instense smoking later, developing into adult daily smoking. Adolescent (high school) daily smoking is a much lower proportion of current smoking (one-fifth) than adult daily smoking.
- Because there is a much larger *stock* of adult smokers, smoking prevalence will likely change at a slower rate than for adolescent smoking, which captures the *flow* of new smokers into the smoking population and is more volatile. We recommend setting a 2030 goal for adult smoking and a 2025 goal for adolescent smoking, with an objective for adolescent smoking in 2030 to be set by 2025.

It is a realistic ambition to reduce daily use of any combustible product ["daily smoking"] to 5% by 2030 for adults and reduce current use of any combustible tobacco product ["current smoking"] to 5% for adolescents by 2025. These two new objectives would capture the aspiration to substantially reduce the population burden of tobacco use – and would codify objectives most directly related to public health and non-communicable disease outcomes.

1.5 Introduce a harm-weighted index of tobacco-use to address non-combustible products

There is a case for creating new analytical measures to characterize the changing tobacco/nicotine market that would better characterize its overall impact on public health. This would mean creating a 'harm-weighting' for each category of product (this could be as crude as a two-category combustible / non-combustible system or for each broad category of tobacco/nicotine product). There could also be weighting according to intensity of use - differentiating, for example between regular and occasional use. A harm-weighted tobacco/nicotine use composite index could provide a valuable guide to changes in overall population risk over time and would be a good singular measure of the success of a comprehensive tobacco control policy.

Overall, the focus of the objectives should be primarily on reducing use of combustible tobacco products, especially regular use, by any legitimate means. Where non-combustibles are included, the key consideration should not be numbers of users, but potential population harm or risk – including whether such products are substituting for combustible use. This would be consistent with the legal framework for tobacco control, the Tobacco Control Act, which stresses population risk as the dominant concern of policy-makers. A harm-

weighted index of tobacco use could have multiple applications – for example in pre-market tobacco applications.

1.6 The objectives should focus on behavioral outcomes, not policy implementation

It is questionable whether the Healthy People objectives should include policy implementation (TU-2030-[14, 15, 18, 20]). This is a matter for legislatures and, as with all policies, it involves multiple considerations, may require value judgments, some of which are political and fall outside the remit of Healthy People. The focus should be on public health outcomes - targets focused on the ends rather than the means. We recommend dropping policy objectives, especially where these are state responsibilities or have wider or potential unintended consequences.

1.7 Set goals to align relative risk perceptions more closely to reality

The public perceptions of relative risk and understanding of the continuum of risk are very poor and most of the public believe that e-cigarettes and smokeless tobacco are more harmful than would be suggested by an objective assessment of the scientific evidence. For example, in the NCI HINTS survey² only 2.6% of adults believe that e-cigarettes are much less harmful than cigarettes and only 11% of adults believe smokeless tobacco is less harmful than cigarettes, and over 50% of adults agree or strongly agree that nicotine is the primary cancer-causing agent in cigarette smoke. These misperceptions are harmful because they are likely to mean that some people continue using the most harmful tobacco products when they may, if better informed, use products that are much lower risk. CDC and FDA as the prime federal public health agencies should be aiming to align public risk perceptions with expert assessment of the evidence and thereby support informed choice. The aim should be for a significant majority (two-thirds) of adults to have risk perceptions that align with realistic scientific assessment: that smokeless tobacco and e-cigarettes are *much less harmful* than cigarettes and nicotine is not the primary harmful agent in tobacco smoke (or vapor).

1.8 Rationalize the tobacco use objective set

The number of objectives can be reduced substantially by focussing on the broad category 'use of any combustible tobacco product' and 'harm-weighted overall tobacco use' as a way of including non-combustible tobacco products in the Healthy People 2030 framework. The objectives should also be rationalized to focus on behavioral outcomes or intermediate outcomes like smoking cessation activity, rather than on particular policies.

² National Cancer Institute, Health Information National Trends Survey (HINTS) 2018. E-cigarettes compared to cigarettes [link]; E-cigarettes harm to health [link]; Smokeless tobacco compared to cigarettes [link]; Nicotine as a cause of cancer [link]

2 Comments on specific draft objectives

2.1 TU-2030-01 Reduce current use of any tobacco products among adults

This objective may generate harmful unintended consequences because there are large differences in risk between tobacco products and the total harm depends on the <u>mix</u> of tobacco product use. For example, a reduction in total tobacco product use that means that fewer smokers were switching to vaping could cause a net increase in harm. It is possible to have more tobacco/nicotine use and less harm, depending on the mix of tobacco/nicotine products in use. If a measure like this was to be used as a public health goal, then the use of each type of tobacco product would need to be weighted by its harmfulness. A harm-weighted index of tobacco and nicotine use could be useful, and harm-weighting is implicit in the public health standard ("appropriate from the protection of public health") used in the Tobacco Control Act and public statements recognizing a 'continuum of risk'. The objective set needs to be credible for more than a decade over which the patterns of tobacco/nicotine use may change very substantially. Treating all tobacco products as though they have undifferentiated risk will become less credible as the patterns of tobacco/nicotine use become more diverse.

There are also substantial measurement problems and possible need to adjust the surveys used. For example, many vapor products are sold outside of the tracked channels of convenience stores and gas stations, making it difficult to estimate the size of the market. Additionally, the use of vaping technologies may not involve tobacco use, either because it does not involve nicotine or it is used for vaping cannabis or other purposes, which may grow in the next decade.

2.2 TU-2030-02 Reduce current use of cigarettes among adults

It would be better to have an aggregated measure of any "any combustible tobacco product". These are the most harmful products and it only makes sense to have different objectives if there is an important difference between the public health implications of each. A reduction in cigarette use is not an important health gain if it results from users switching to cigarillos or roll-your-own tobacco. The nature of transitions from cigarette smoking will be important to gauge if there is a major regulatory intervention applied to cigarettes, for example reducing nicotine to sub-addictive levels. Though that could be an argument for gathering data on all forms of combustible use individually, a more concise and future-proof objective set would focus on the broad class of combustible product use.

2.3 TU-2030-03 Reduce current use of any tobacco products among adolescents

See comment on TU-2030-01 above. A harm-weighted index of tobacco use should be created to give an overall picture of the burden of tobacco and nicotine use on youth.

2.4 TU-2030-04 Reduce current use of e-cigarettes among adolescents

This presents real dangers if e-cigarette use is substituting for smoking among young people who would otherwise smoke. Campaigns to prevent young people vaping may have the unintended consequence of causing more adolescent smoking - effectively a gateway effect induced by policymakers. We recommend that objectives for e-cigarettes are expressed through a harm-weighted index of tobacco use.

2.5 TU-2030-05 Reduce current use of cigarettes among adolescents

It would be better to have an aggregated measure of any "any combustible tobacco product". These are the most harmful products and it only makes sense to have different objectives if there is an important difference between the public health implications of different combustible tobacco products.

2.6 TU-2030-06 Reduce current use of cigars, cigarillos and little cigars among adolescents

There is little value in disaggregation of these different products and to have separate objectives, and it may be misleading. Because there is substitution possibility (for example from cigarettes to little cigars) it would be better to have an overall target for combustible use. This would also reduce the number of targets and make the objectives more closely aligned to public health outcomes.

2.7 TU-2030-07 Reduce current use of flavored tobacco products among adolescent tobacco users

All vaping products are flavored (there is no natural flavor in the various base constituents of e-liquids) and there is no merit in reducing non-tobacco flavors if it means more youth are using the tobacco flavors. Because combustible products (outside of cigarillos) are mostly not flavored, but all vaping products and many other non-combustible products are flavored, this measure would create a bias to the more harmful tobacco/nicotine products. Flavors in e-cigarettes may play a role in attracting young people away from smoking for the same reason they are important to adults. We recommend dropping this objective as it is potentially distorting across tobacco product categories in a way that could increase total harm.

2.8 TU-2030-08 Reduce the initiation of the use of cigarettes among adolescents and young adults

This would be better framed as the initiation of "any combustible tobacco product" or "smoking". There is no reason to be less concerned if a young person starts smoking bidis, hand-rolling tobacco etc. FDA's policy, which may be delivered in the 2020s, is to make cigarettes unattractive to young people by reducing nicotine levels in cigarette tobacco. For this reason, it would be wise to include the use of any combustible tobacco product to anticipate a response in which adolescents switch from one combustible product (cigarettes) to another (e.g. cigarillos and roll-your-own tobacco).

2.9 TU-2030-09 Increase smoking quit attempts among adult smokers (past year)

This measure is worthwhile as long as it recognizes smokers may switch completely from smoking to using non-combustible (i.e. smoke-free) tobacco/nicotine products and may not want to stop using nicotine completely.

2.10 TU-2030-10 Increase the proportion of adult smokers who receive advice to quit from a health professional

This is important, but it matters a great deal what advice is actually offered and that this supports broader objectives to reduce combustible tobacco product use and overall harm from tobacco and nicotine use. To that end, it should stress the public health imperative for smokers to quit smoking by any means that works for them, including switching to smoke-free products such as vaping, heated tobacco products, or smokeless

tobacco. It is particularly important to persuade dual- or poly-users of combustible and non-combustible products switch to exclusive non-combustible use by advice about the relative risks of combustion vs. non-combustion products.

Appropriate guidance is available in other jurisdictions³ and similar could be developed for an American healthcare professionals.

2.11 TU-2030-11 Increase use of smoking cessation counseling and/or medication among adult smokers

See comment on TU-2030-10. The counceling must embrace sound advice on the use of non-combustible tobacco products (e-cigarettes etc) as a means of quitting smoking.

2.12 TU-2030-12 Increase recent smoking cessation success among adult smokers

This objective should count switching completely to a non-combustible tobacco/nicotine product as "smoking cessation success".

2.13 TU-2030-13 Increase smoking cessation during pregnancy among females

This objective should count switch completely to a non-combustible tobacco/nicotine product as "smoking cessation during pregnancy". The public health imperative is to avoid exposure to tobacco smoke during pregnancy. While nicotine exposure during pregnancy is not desirable, the use of smoke-free alternatives instead of smoking may provide substantial benefits if the alternative is continued smoking. It may also provide an opportunity to prevent relapse to smoking after the birth.

2.14 TU-2030-14 Increase the number of states, the District of Columbia, and territories that have smoke-free policies that prohibit smoking in all indoor areas of worksites, restaurants and bars

In this case, it is important that any legislative or policy targets should focus only on smoke (i.e. emissions from combustible products) for which there is evidence of harm to bystanders. Policies that ban vaping or other forms of non-combustible use should remain the responsibility of the property owner or manager, not the states.

2.15 TU-2030-15 Increase the number of states, the District of Columbia, and territories that have smoke-free policies that prohibit smoking in all indoor areas of multiunit housing

In this case, it is important that any legislative or policy targets should focus only on smoke (i.e. emissions from combustible products) for which there is at least some evidence of harm to bystanders. Policies that ban vaping or other forms of non-combustible use should remain the responsibility of the property owner or manager, not the states. A prohibition should apply only to common areas. To have a smoke-free home in multi-unit housing should be a choice and captured by objective TU-2030-16

³ See for example, National Centre for Smoking Cessation and Training (UK) briefing: E-cigarettes, 2016 [link]

2.16 TU-2030-16 Increase the proportion of smoke-free homes

It is unclear what is intended here: does it refer to homes where no-one is a current smoker? Or does it refer to homes with a self-imposed smoking ban in which adult smokers do not smoke within the confines of the indoor areas of the home? The former objective does not add much. The latter objective captures important behavioral responses to messaging about combustible tobacco use. It should be focused on homes with a voluntary, self-imposed ban on smoking in the home

2.17 TU-2030-17 Reduce the proportion of children, adolescents and adults exposed to secondhand smoke

This objective needs an improved definition of 'exposed', as this could mean any contact with secondhand smoke, no matter how trivial. The greatest risk to young people from second-hand smoke is exposure in the home. This would capture both the effects of exposure and the normalizing effects of smoking at home – a risk factor for smoking initiation. It would be preferable to address this objective with a subset of TU-2030-16 for homes with children and adolescents. This would be to "increase the proportion of smoke-free homes where children or adolescents live". It would reduce data collection and simplify the objectives set while making the objective more relevant.

2.18 TU-2030-18 Increase the national average tax on cigarettes

Taxation is a complex and multi-facted issue. While increasing tax provides a fiscal incentive to change behavior, there are other tax objectives. These include aligning tobacco taxation with risk, to avoid creating perverse fiscal incentives for manufacturers and consumers, to reduce the variance in tax levels between states. Though taxation is important, we recommend that it is taken out of the Healthy People objective set and addressed in a different way.

2.19 TU-2030-19 Reduce the proportion of adolescents in grades 6-12 who are exposed to tobacco product marketing

It is unclear what 'exposure' would mean in this case (seeing one advertisement or point-of-sale display?), and whether this would be a meaningful public health measure. It would be better to differentiate between exposure to adverting for combustible tobacco products and non-combustible products – it is quite possible, for example, that advertising for e-cigarettes functions as anti-smoking or smoking cessation advertising.

2.20 TU-2030-20 Increase the number of states, the District of Columbia, and territories that establish 21 years as the minimum age for purchasing tobacco products

It is questionable whether Healthy People targets should be set for policies, rather than just for behavioral outcomes. The age of majority, at which adult responsibility is assumed, is a complex issue that is broader than tobacco use and requires value judgements that are properly the concern of legislators. Any objective of this nature should focus on combustible products. For some young people, non-combustible products may be used as an alternative to smoking and there are potential harms arising from denying access to lower risk products.

3 Additional, replacement and unnecessary objectives

In one sense, there can never be enough data and indicators and it would be possible to add endlessly to the list. But on the basis that indicators should be a focus of policy and communications, there is merit in rationalizing the set to only those with the most impact and least risk of unintended consequence. Some rationalization is suggested in the discussion below, but it is not our intention to suggest any particular data is unimportant, but to suggest some prioritization.

3.1 Harm-weighted index of tobacco use (research required)

Because there is a substantial variation in risk/harm between different forms of tobacco/nicotine use, the public health impact can only be approximated by factoring in the harmfulness of each broad category of tobacco/nicotine product. Even if this involves conservative approximations, it is superior to the implicit assumption that all tobacco products are equally harmful when unweighted aggregations are used to characterize tobacco use. This should be used to incorporate relatively low-risk tobacco and nicotine products into tobacco-use objectives without creating distorting incentives. It could be measured for both adolescents and adults, but if harm is properly characterized it could be a singular measure.

This objective would replace: TU-2030-1 and TU-2030-3 on total tobacco use; TU-2030-4 on ecigarettes; TU-2030-7 on flavors.

3.2 Current use of any combustible tobacco product among adults

Self reported regular use of any product involving combustion of tobacco in the last 30 days gives a broad measure. It could also be compared with non-combustible tobacco product use. This could replace measurements of cigarette use or other individual tobacco categories, for example TU-2030-2 on cigarettes.

3.3 Daily use of any combustible tobacco product among adults

Use of any product involving combustion of tobacco every day. If a single number was to be used to characterize the public health problem of tobacco use, then this would be it. The aim should be to reduce this figure to 5% or lower by 2030. This should form the basis of a new leading indicator.

3.4 Current use of any combustible tobacco product among adolescents

Use of any product involving combustion of tobacco in the last 30 days gives broad measure of those at most significant risk. It could also be compared with non-combustible tobacco product use. The aim should be to reduce this to 5% or lower by 2025. This could replace individual tobacco product objectives TU-2030-5 on cigarettes and TU-2030-6 on cigars, cigarillos etc, and would form the basis of a new leading indicator.

3.5 Reduce the initiation of the use of any combustible tobacco product among adolescents and young adults

This would replace the exclusive focus on initiation with cigarettes in TU-2030-8 to cover initiation with any combustible products. Use of combustible tobacco products other than cigarettes has been increasing over time.

3.6 Risk perceptions

Three indicators of risk perception drawn from the NCI HINTS survey would track the alignment of perceptions:

- The proportion of adults who believe that e-cigarettes are <u>much less harmful</u> than cigarettes (HINTS)
- The proportion of adults who believe that smokeless tobacco is <u>much less harmful</u> than cigarettes (HINTS) this requires modification of the HINTS answers to allow 'much less harmful' as an option.
- The proportion of adults who disagree that the nicotine in cigarettes is the substance that causes most of the cancer caused by smoking (HINTS)

3.7 Opportunities to drop objectives

Those objectives focused on policy outcomes, rather than behavioral outcomes could be removed: these include TU-2030-14 (smoke-free policies in workplaces), TU-2030-15 (smoke-free policies in multi-unit housing), TU-2030-18 (tax) and TU-2030-20 (age 21). This is not to argue that such policies are unimportant, but to question whether they are appropriate for inclusion in a national health indicator framework.