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Tobacco Harm Reduction: Past History, Current Controversies and a Proposed Approach for the Future

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Abstract

Tobacco harm reduction remains a controversial topic in tobacco control. Tobacco harm reduction involves providing tobacco users who are unwilling or unable to quit using nicotine products with less harmful nicotine-containing products for continued use. The skepticism towards harm reduction is based in part on the experience with low-yield tar/nicotine cigarettes, which were presumed to be associated with lower health risks than higher yield cigarettes and marketed as such by cigarette manufacturers. Only later did the field learn that these cigarettes were a deceptive way for cigarette manufacturers to allay the health concerns over cigarette smoking. Since this experience, there has been a proliferation of tobacco products that might potentially serve as a means to reduce tobacco harm. Some members of the tobacco control community believe that these products have great potential to reduce mortality and morbidity among smokers who completely switch to them. Others believe that we will be addicting another generation to tobacco products. This paper reviews the past history, the current tobacco landscape and controversies, and an approach that might rapidly reduce the yearly half-million deaths associated with cigarette smoking in the U.S.

Keywords

Tobacco harm reduction; modified risk tobacco products; reduced nicotine cigarettes; electronic cigarettes; snus

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Introduction

The current tobacco product landscape is one in which the most toxic products, cigarettes and other combustibles, also have high abuse liability. Just in the U.S. alone, this landscape is predominantly responsible for 480,000 deaths per year, 16 million persons living with tobacco-caused diseases and the reduction in life-years among smokers by an average of 10 years[1]. This current scenario led the 2014 Surgeon General's Report (SGR) to state that, "The burden of death and disease from tobacco use in the United States is overwhelming caused by cigarettes and other combusted tobacco products; rapid elimination of their use would dramatically reduce this burden"[1]. Effective tobacco control strategies exist such as increasing the price of cigarettes, anti-smoking media campaigns, smoking bans, and providing affordable and accessible evidence-based cessation treatments; these measures have contributed to a substantial reduction in cigarette smoking[1,2]. We have less knowledge of the role of tobacco harm reduction in reducing combusted tobacco product use.

Tobacco harm reduction has been defined as "minimizing harms and decreasing total mortality and morbidity, without completely eliminating tobacco and nicotine use"[3]. Tobacco harm reduction recognizes that tobacco abstinence or never using tobacco is the ideal outcome but accepts alternative ways to reduce harm among tobacco users. Harm reduction does not take precedent over measures that prevent tobacco use and help facilitate the achievement of abstinence, but rather plays a complementary role. Harm reduction has been considered a human rights issue, where *all* smokers, whether or not they want or are able to quit tobacco use, are provided a means to reduce tobacco-related harms[4–7]. Tobacco harm reduction has also been considered a social justice issue because it can potentially benefit smokers who experience the greatest health disparities. For example, the prevalence of smoking among individuals who are below the poverty level or of lower levels of educational attainment is higher than the general population[8]. This population smokes more heavily, is as likely to make a quit attempt but less likely to successfully quit, and experiences higher risk for lung cancer than those smokers with higher incomes and education. A similar scenario is observed among smokers with mental illness[9–11]. Because of the high prevalence of smoking and difficulty in quitting experienced by these populations, access to harm reduction products may be one approach to reduce health disparities. Yet, the role of tobacco harm reduction in tobacco control is controversial.

This paper describes the evolution of harm reduction in tobacco control, the current controversies over tobacco harm reduction and concludes with a potential approach that might address these controversies.

Evolution of tobacco harm reduction products

The skepticisms of tobacco harm reduction are fueled by the experience with low-tar/nicotine yield cigarettes. Just prior to and particularly after the release of the 1964 SGR[12] linking smoking to disease, cigarette manufacturers were interested in finding ways to allay anxiety and concern surrounding the health risks of smoking[13]. The National Cancer Institute (NCI) was also interested in a "safer" cigarette. At that time, animal studies showed dose-response relationship between the levels of tar and the production of tumors[14] and

early epidemiological studies showed a relationship between number of cigarettes smoked and disease risk[13]. These studies were thought to support the premise that if tar is reduced in cigarettes, then health risk would also be reduced. The U.S. Federal Trade Commission (FTC) adopted a testing method that measured tar/nicotine levels through smoking machines that utilized standard smoking parameters[15]. Cigarette manufacturers began to manufacture low-yield cigarettes and aggressively market them. Health conscious smokers were encouraged to switch to low-tar cigarettes rather than quit, with statements such as, “Considering all that I’d heard I decided to quit or smoke True. I smoke True.” Other advertisements provided the appearance of U.S. government endorsement, “U.S. Gov’t Report: Carlton is Lowest.” Not only were healthy, sports-minded people portrayed as smokers, but pristine landscapes and light colors were also used to depict an image of health. In addition, descriptors such as “light,” “ultra-light” and “mild” were used to designate cigarette sub-brands.

As the science evolved, low-yield cigarettes were found not to lead to significant decreases in nicotine and toxicant exposure levels as compared to higher-yield cigarettes due to their “elasticity”[16–30]. Reduction in machine-determined yields was achieved through cigarette design features, not by reducing tar/nicotine in the tobacco filler. Filter ventilation, adding ventilated holes in the filter to dilute the smoke, was the predominant method to reduce machine-determined yields[13,31–34]. Smokers were able to alter their smoking behavior, engaging in “compensatory” smoking. Compensatory smoking involves achieving higher levels of exposure than reflected by the tar/nicotine yields of the cigarette by smoking more intensely, blocking the ventilation holes and also by increasing the number of cigarettes smoked[13,35–38]. As a consequence, the reduction in health risk was not proportional to the reduction in machine yields[39]. Filter ventilation may also have contributed to the higher rates of lung adenocarcinoma, a cancer that is typically in the periphery of the lungs[1,40]. The increased incidence of this cancer may be a result of a deeper inhalation of toxic chemicals and/or increased mutagenicity of the cigarette because of how ventilated cigarettes burn[40].

In 2006, the U.S. Department of Justice launched a racketeering case against Phillip Morris, USA (defendants included a number of other tobacco companies). In the final opinion of this case, presiding Judge Gladys Kessler stated that the tobacco industry willfully deceived the public; for decades the cigarette manufacturers knew that “low tar,” “light” and “ultralight” cigarettes did not result in any health benefits compared to full-flavored cigarettes and yet they deceived and led the public to believe that these cigarettes were a means to reduce the adverse health effects from smoking and therefore an alternative to quitting. As a result, in 2008 the FTC removed misleading tar/nicotine listings from cigarette packs. In 2010, the U.S. Food and Drug Administration (FDA) under the Family Smoking Prevention and Tobacco Control Act prohibited descriptors on tobacco packaging or in advertising that convey messages of reduced risk or exposure, including the descriptors “light,” “mild,” and “low”[41]. Unfortunately, the cigarette manufacturers still use colors (e.g., silver, gold) to depict “lightness” and use terms such as ”smooth” or “fine” perpetuating misbeliefs of less harm[32,33,38,42–45].

In light of the ill-fated attempt to create and market less harmful cigarettes, Michael Russell from the United Kingdom (U.K.) was advocating for the reduction in tar but maintenance of

moderate nicotine levels because “People smoke for nicotine but they die from the tar”[46]. He further stated, “In theory, so long as sufficient nicotine is present, reducing all the other harmful constituents to very low levels would be tolerated by smokers.” In the U.S., Benowitz and Henningfield[47] were proposing a nation-wide gradual reduction of nicotine in cigarettes. This approach had the potential to prevent the progression from cigarette experimentation to dependence in youth and facilitate cigarette cessation among smokers. Also, during the 1990s, tobacco companies continued to target health-conscious smokers through products that purportedly reduced harm. These products included cigarettes with “reduced carcinogens” but with higher nicotine levels for “premium taste” (Omni®) and cigarettes with a step-down in nicotine levels as a way to become “nicotine free” by smoking nicotine free cigarettes (Quest®), and heated not burned cigarette-like products (Eclipse® and Accord®). These products had claims of reducing health risks or addiction, with relatively little evidence. Similar products were introduced previously, but failed in the market, a similar fate for these products.

Around this time, the harm reducing effects of snus (smokeless tobacco with lower levels of tobacco-specific nitrosamines, TSNAs, and other toxicants) in Sweden were being published. In past and current years, Swedish snus has been demonstrated to have a lower risk for some cancers[48–51], non-fatal cardiovascular disease[51–55] and pulmonary disease[56] than cigarettes. Among Swedish males, the increase in uptake of snus was associated with decrease in smoking concurrently with a decrease in rates of lung cancer and myocardial infarction[57]. The increase in snus use was primarily attributed to smokers using snus to quit smoking. Further, the risk of progression from snus to smoking was found to be significantly lower than progression from non-smoking to smoking, supporting the claim that snus does not appear to be a gateway tobacco product to smoking[58]. Sweden now has the lowest tobacco-related morbidity compared to other European Union countries that have banned smokeless tobacco[51,58]. Nevertheless, some tobacco control members are concerned because snus is not a safe product and overall tobacco use remains relatively high in Sweden[59].

The “Swedish Experience” led to cigarette manufacturers in the U.S. to begin marketing “snus” products (e.g., Camel Snus®, Marlboro Snus®) as a substitute for cigarettes in places where smoking was banned or as a means of quitting smoking. Camel Snus advertisement included captions such as “Frost the Fire,” “Cheat on an Old Flame,” “NYC Smokers, Rise Above the Ban,” or “Bar Friendly.” Other products such as dissolvable tobacco (e.g., Arriva®, Camel Orbs®) also entered the marketplace with similar marketing strategies.

Tobacco harm reduction: a benefit or risk?

The burgeoning of tobacco products with explicit and implicit claims of reduced risk led the U.S. FDA to commission the Institute of Medicine to examine the adequacy of scientific methods to determine whether and to what extent potential reduced exposure products (PREPs) reduce mortality and morbidity and the population impact of these products. In the resulting 2001 report[3], members of the committee concluded that “for many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible (page 5)”. However, at that time no PREPs had been evaluated comprehensively enough to provide a scientific basis for concluding that they are associated

with a reduced disease risk compared to conventional tobacco use (e.g., cigarettes). The report also stated the importance of assessing the toxicity, appeal, addictiveness and consumer perception of a PREP to determine its public health impact. The methods for assessment included in vitro toxicological analysis, animal studies, short-term clinical trials and epidemiological studies, and long-term epidemiological studies. Furthermore, the report indicated that reliable and validated human biomarkers of exposure and potential harm are the cornerstone for assessing potential health outcomes, and that surveillance on the health and behavioral effects of PREPs is essential.

Despite this report, some of the tobacco community remained skeptical of tobacco harm reduction. This skepticism has been in existence any time tobacco manufacturers introduced redesigned or new tobacco products with implicit and explicit marketing messages of reduced harm. There was concern that it would compromise tobacco prevention, particularly among youth, and cessation efforts as well as the goal of eliminating all tobacco use. Furthermore, questions were raised as to whether harm reduction was necessary to rapidly reduce the death and disease from tobacco use. In an effort to determine if a consensus could be reached on the role of PREPs, several meetings involving a strategic dialogue on harm reduction was convened between 2005 and 2007[60]. The invitees represented different perspectives on this topic and included scientists as well as members of tobacco control organizations and governmental agencies. Consensus was reached on the concept of a continuum of risk of nicotine-containing products, with cigarettes or combusted products being the most toxic and FDA approved medicinal products being the least toxic. It was agreed that nicotine is the main addictive chemical in tobacco products, but it is the other constituents in tobacco and tobacco smoke that are predominantly responsible for mortality and morbidity. Furthermore, although abstinence from all nicotine containing products is the ultimate goal, it was agreed that for those individuals who are unable or do not want to quit nicotine use, shifting them down the continuum of risk to a less harmful tobacco product, optimally medicinal nicotine, might benefit individual and public health. Of utmost importance was governmental regulation of reduced risk and all tobacco products in order protect to public health.

In 2009, the Family Smoking Prevention and Tobacco Control Act (FSPTCA), which gave the FDA regulatory authority over cigarettes, smokeless tobacco and roll-your-own tobacco, was signed into law. In the years just prior and subsequent to the passing of the FSPTCA, alternative recreational nicotine-containing products continued to proliferate in the marketplace, particularly electronic cigarettes (e-cigarettes). The introduction of a cornucopia of products seemed more of an effort on the part of cigarette manufacturers to maintain the use of tobacco products rather than to reduce harm from smoking. The FSPTCA, as initially passed, did not give FDA regulatory jurisdiction over e-cigarettes and some other products such as cigars and hookah; but on August 8, 2016 the FDA’s Center for Tobacco Products was given full authority to regulate all tobacco products not meeting the definition of a drug or medical device.

The proliferation of products like e-cigarettes led to a greater chasm between those who perceived e-cigarettes as a “disruptive” technology that could potentially replace cigarettes versus those concerned that e-cigarettes posed greater risk than benefit. Subsequently,

another set of meetings focused on a harm reduction strategic dialogue was convened between 2013 and 2014, involving participants representing broader backgrounds and more divergent opinions than the prior strategic dialogue. The overarching goal was to develop a well-reasoned tobacco control strategic plan that would maximize public health benefits and minimize tobacco-related harms in the rapidly evolving marketplace. Unfortunately, consensus was not reached. Although there was agreement on the continuum of relative risk across nicotine delivery systems, the main point of contention was whether to tip the balance towards saving millions of lives by providing access and encouraging smokers unwilling or unable to quit to use less harmful products versus protecting a new generation from tobacco addiction (Figure 1). Furthermore, among those who were inclined towards the latter stance, there was concern over whether PREPs (specifically e-cigarettes) would serve as a gateway to using more harmful products, promote prolonged dual or poly-tobacco product use and stymie quit attempts. Additionally, there was limited and conflicting research on whether or not products such as e-cigarettes are effective in helping smokers quit smoking. Despite this divisive debate, in 2017 the FDA announced a comprehensive plan for nicotine and tobacco regulation which included "…recognizing and clarifying the role that potentially less harmful tobacco products could play in improving public heath…."[61].

Shortly thereafter, the prevalence of e-cigarette use skyrocketed among youth. In 2018 the U.S. National Youth Tobacco Survey showed a 78% increase in past month e-cigarette use in high schoolers (20.8% from 11.7% in 2017) and 48% increase in middle schoolers (4.9% from 3.3% in 2017;)[62]. In 2019, the rate further increased to 27.5% among high schoolers and 10.5% middle schoolers[63]. The majority of exclusive e-cigarette users used flavored products, such as fruit, and over half of all e-cigarette users reported using JUUL (a cartridge-based device containing a high concentration of nicotine salt) as their usual brand. This increase in e-cigarette use led the U.S. Surgeon General and FDA Commissioner to declare e-cigarette use a youth epidemic. The overwhelming concern over the effects of e-cigarettes on youth began to swamp the concern over adult smokers who were seeking a means to reduce harm. Because of this increased uptake among youth, U.S. Congress, several states and local ordinances and organizations (e.g., American Heart Association[64], American Cancer Society[65] and Campaign for Tobacco-Free Kids[66]) have called for a "ban" on all non-tobacco flavored e-fluids. Prohibiting the sale of e-cigarettes altogether has also been raised, largely due to the recent incidence of a significant number of lung injuries and associated death among vapers[67]. The ban on e-cigarettes continues to be considered even though the lung injuries were strongly associated with vaping tetrahydrocannabinol (THC) which contained Vitamin E Acetate mostly obtained from informal sources[68].

In January of 2019, the FDA announced removing enforcement discretion for non-menthol or non-tobacco flavored cartridge-based e-cigarettes due to the popularity of flavored cartridges among youth. Also, FDA prioritized enforcement against all e-cigarettes for which the manufacturer has failed to take measures to prevent minors' access to these products or has targeted their use to minors. For tank-based and other non-cartridge systems, flavors such as fruit continue to be allowed if they are not targeted or promoted to youth. This allows adult smokers who want to switch or former smokers to continue using flavored e-cigarettes. Health and Human Services Secretary Alex Azar stated, "By prioritizing enforcement against the products that are most widely used by children, our action today

seeks to strike the right public health balance by maintaining e-cigarettes as a potential off-ramp for adults using combustible tobacco while ensuring these products don't provide an on-ramp to nicotine addiction for our youth[69]".

Moving forward in tobacco harm reduction

Former Surgeon General C. Everett Koop once stated, "We must not focus our efforts so narrowly on preventing tobacco use by youth that we send the message to smokers' that we have abandoned them—that their action is their own fault and we don't care about them[70]". How can we maximize complete cessation of combusted tobacco use with less harmful alternative nicotine delivery systems (ANDS) including medicinal nicotine among smokers unable and unwilling to quit nicotine use *and* at the same time minimize uptake of ANDS among youth and the potential gateway effect? The answer to this question might be an integration of the proposal made by Benowitz and Henningfield[47] to reduce nicotine in cigarettes (and optimally other combusted products) and the proposal by Michael Russell to have products with moderate doses of nicotine but significantly less tar[46]. This is an approach that was described by the FDA as part of a comprehensive tobacco and nicotine regulation strategy. That is, the FDA is "envisioning a world where cigarettes would no longer create or sustain addiction" along with a world "where adults who still need or want nicotine could get it from alternative and less harmful sources[71]. In the U.S. alone, this approach is estimated to reduce the prevalence of smoking to 1.4% and avert cigarette-caused death by 8.5 million by the year 2100[72]. In 2018, an advanced notice of proposed rulemaking was issued on a tobacco product standard for nicotine level in combusted cigarettes[73].

To date, there is substantial scientific data that shows that reducing nicotine to about 95% of what is found in conventional cigarettes could result in public health benefit[74]. Clinical trials have shown that daily smokers assigned to very low nicotine cigarettes show decreases in the number of cigarettes smoked, exposure to toxicants and carcinogens and dependence, and increases in quit attempts[75–77] and cessation[76,78,79] compared to those who smoke normal nicotine cigarettes. Reductions in smoking and dependence have been observed in non-daily smokers[80,81], young adults[82,83], menthol smokers[84], and those with depressed mood[85] or serious mental illness[86,87]. Reductions in the reinforcing effects of cigarettes has been observed in laboratory studies among youth[88] and in populations likely to experience health disparities such as persons of lower socioeconomic status, with a diagnosis of substance use disorder, and who experience mental health disorders[89]. Regarding potential unintended outcomes of such an approach, reducing nicotine in cigarettes was not associated with changes in depressed mood[85], alcohol[90] or cannabis[91] intake. Weight gain, however, may be experienced in some smokers[92], as typically observed when smokers quit smoking. The best approach to reducing levels of nicotine in cigarettes is to have a target date at which time all cigarettes cannot exceed a certain threshold of nicotine[78,93]. However, such an immediate reduction in nicotine versus a stepped-down approach is likely to result in a greater number of smokers seeking nicotine from other sources[78]. These sources include alternative combusted products (e.g., little cigars or cigarillos), medicinal nicotine products, non-combusted ANDS (e.g., e-cigarettes) or cigarettes obtained through the black market. Alternative combusted products with nicotine are the most likely product to be used, which

would not result in a public health benefit[94]. If all combusted products were reduced in nicotine, then smokers are likely to seek products like e-cigarettes[94], especially if strong regulations are enforced on illegal combusted products[95].

These results suggest that an integral part of the public health benefit of nicotine reduction in combusted products is the availability of *regulated* non-combusted ANDS along with greater innovation in medicinal products. FDA regulation of non-combusted ANDS can either be achieved through the premarket tobacco product application (PMTA) process or through product standards. To date, two non-combusted products have received FDA authorization for marketing through the PMTA process: General Snus (Swedish Match) and IQOS (Phillip Morris International, PMI). General Snus has lower levels of TSNA and other toxicants compared to other brands of smokeless tobacco products sold in the U.S. IQOS is a tobacco heating system that is considered to be appropriate for the protection of public health because the product has fewer or lower levels of toxicants and toxicant exposures compared to cigarettes, level of nicotine delivery is close to cigarettes which would permit complete switching from cigarettes, and only menthol and tobacco-flavors are available[96]. In addition, the FDA determined that few non-tobacco users, including youth, would use IQOS. The FDA required PMI to conduct post-marketing surveillance of IQOS to determine who and how these products are being used and the effects of their marketing and also to provide sales data. Additionally, PMI was required to submit plans on how the product will be marketed, advertised and labelled. Warning labels were required, and PMI needed to limit youth access and exposure. To date, PMI requires that IQOS customers be at least 21 years old and identify as currently smoking.

Similar requirements can be imposed on e-cigarettes. The National Academy of Science, Engineering and Medicine[97] issued a report stating that completely switching from smoking cigarettes to using e-cigarettes reduces exposure to numerous toxicants and carcinogens found in tobacco smoke and results in reduced short-term adverse health outcomes. However, long term consequences are unknown. Furthermore, the report stated that nicotine and toxicant delivery is highly variable and depends on several product characteristics and how the e-cigarette is operated. The report also stated that youth uptake is a major concern. Given these conclusions, approaches to regulating e-cigarettes should consider: 1) toxicity including e-fluid constituents, coil composition and other materials, amperage/voltage/wattage, and battery type; 2) appeal including eliminating certain flavors and descriptors and potentially the design of the device based on the extent of youth appeal; 3) addictiveness such as a cap on nicotine level or type of nicotine used (e.g., nicotine salts); 4) packaging, labelling, advertising and marketing directed towards to youth or non-smokers; and 5) youth product access.

Regulations for smokeless tobacco might also be considered because of the tremendous variability in levels of TSNA and polycyclic aromatic hydrocarbons[98]. In 2017, the FDA issued an advanced notice of proposed rulemaking for a product standard for N-Nitrosonornicotine (NNN), a TSNA associated with increased risk for oral and esophageal cancer. The proposal was to establish the level of NNN to no greater than 1 microgram per gram of tobacco dry-weight, which was estimated by the FDA to potentially avert approximately 12,700 new cases or oral cancer and 2,200 oral cancer deaths within a 20 year

period after implementation[99]. Unfortunately, nothing has come out of this proposed rulemaking to date. In 2020, PMTAs are being submitted by Swedish Match and Altria for nicotine pouches, ZYN and On!, respectively. Nicotine pouches are placed between the upper lip and gum and are available in different flavors (e.g., mint, citrus, coffee, cinnamon) and doses of nicotine, with the highest doses (6 mg for ZYN and 8 mg for On!) exceeding the highest nicotine dose (4 mg) approved by the FDA for medical nicotine gum and lozenges[100]. Furthermore because nicotine pouches do not contain tobacco leaf and are not combusted, they have potential to be a reduced risk tobacco product[101]. A recent study on the appeal of ZYN among adults found that non-tobacco users had very little interest and smokeless tobacco users represented the largest group of regular ZYN users[100]. Thus this product may potentially be used as a substitute for smokeless tobacco. However, due to the limited available data on nicotine pouches among adults and no data among youth, more research is needed to determine the role of nicotine pouches in the tobacco landscape, including as a harm reduction product in adult smokers.

Finally, the lowest harm is likely to be associated with FDA regulated medicinal nicotine products. Yet, the FDA has been conservative in approving any medicines that might have appeal and compete with the addictiveness of cigarettes, resulting in modestly effective medications and stagnation of any innovative pharmacological treatments. An easier pathway for approval of novel nicotine replacement treatments (NRTs) may bring products such as pulmonary delivery of nicotine, which is currently readily available for recreational use in the marketplace, as a medication for cessation without compromising standards for efficacy and safety. The need for appealing and more effective products is reflected by the greater uptake of e-cigarettes as compared to NRT for smoking cessation, particularly among young adults[102], and a clinical trial conducted in the U.K. that showed higher quitting among smokers assigned to e-cigarettes as compared to combination NRT[103]. In addition, more flexible instructions for use and indications need to be considered, including a combination of short and long-acting forms of nicotine replacement[104], potentially pre-quit NRT use[104–106] and possibly long-term use for harm reduction in the smoker unwilling or unable to quit nicotine. As early as 1991, Michael Russell wrote that selective nicotine replacement products should be “as palatable and acceptable as possible and actively promoted on the open market to enable them to complete with tobacco products”. (page 656)[107]

Communication of Relative Risk.

In order for tobacco harm reduction to be successful, communicating accurate information about relative risks across different tobacco and nicotine products is essential and has even been considered a human right. For example, Koslowski once wrote, that it is a human right for both youth and adults to have accurate health-relevant information to make informed decision. Access to accurate information is grounded in the principles of justice and respect for persons[108,109]. To this day, significant misperceptions exist for the toxicity associated with nicotine and the relative risk of a variety of non-combusted products, including the belief that nicotine causes cancer and that smokeless tobacco and nicotine replacement products are just as or more harmful than cigarettes[110–114]. Not providing unified and accurate information to smokers may lead them to continue to use cigarettes and other

combusted products. In 2019, FDA approved a modified risk tobacco product (MRTP) claim for eight PMTA approved General Snus products manufactured by Swedish Match[115]. This approval allows manufacturers to market these products with the claim, “Using General Snus instead of cigarettes puts you at lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis” for a five-year period. MRTP claims could begin to alter the misperceptions of the relative risk of products compared to cigarettes but keeping in mind the goal of minimizing any promotion or marketing to youth or perceptions that the products are safe.

Summary and conclusion

Much has been learned from the low tar/nicotine experience and we have better knowledge and tools to determine which products have the potential to reduce harm in smokers who are not interested in quitting use of nicotine. Nevertheless, there is continued divisiveness about weighing the benefits and risks in youth versus smokers and using abstinence versus cigarettes as a comparator for a reduced risk tobacco product. The most rapid way to reduce the tobacco-related death and disease would be to “devalue” cigarettes and other combusted products by reducing nicotine to minimally addictive levels. At the same time non-combusted products should be regulated for toxicity, appeal, addictiveness and marketing and promotion in an effort to minimize youth uptake of these products while still providing smokers with the means to completely switch to a less harmful product. Additionally, bringing innovation to medicinal products would allow access to more effective evidence-based tools for tobacco cessation. This approach has great potential to: 1) lead to the rapid elimination of combusted products, 2) allay the concerns about the gateway effect of non-combusted products to combusted product use; 3) reduce dual use; 4) minimize the uptake of combusted products among youth; 5) assure that non-combusted products are indeed reduced risk products; and 6) provide smokers and other tobacco users with more effective medications. To date, more attention has been paid on the virtues or vices of potential harm reduction products such as e-cigarettes with less focus on cigarettes, which prematurely kills half of its long-term consumers. Most in the tobacco control community would agree that an immediate main goal is to rapidly eliminate tobacco-related death and disease. To effectively achieve this goal, a more cohesive and unified approach is urgently needed before million more lives are lost to tobacco use. Perhaps this approach could be achieved by convening yet another strategic dialogue on harm reduction that is led by one of the governmental agencies, a scientific organization and/or by respected scientists who are not strongly associated with one particular ideology. At this meeting, the current and evolving science, modeling that projects population health effects under different scenarios, identification of research gaps and consensus on a potential path towards a sensible and agreeable harm minimization approach can be developed. Keeping focus on how best to regulate combusted tobacco products and ANDS *and* allowing tobacco harm reduction as a component of a comprehensive tobacco control program would be one such approach.

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Highlights

- The controversy over tobacco harm reduction is in part based on the experience with low-yield cigarettes.
- Present controversy involves providing smokers with reduced risk products vs potentially addicting youth to these products.
- Future approach includes strong regulation of combusted and reduced risk products and innovation of medicinal nicotine.

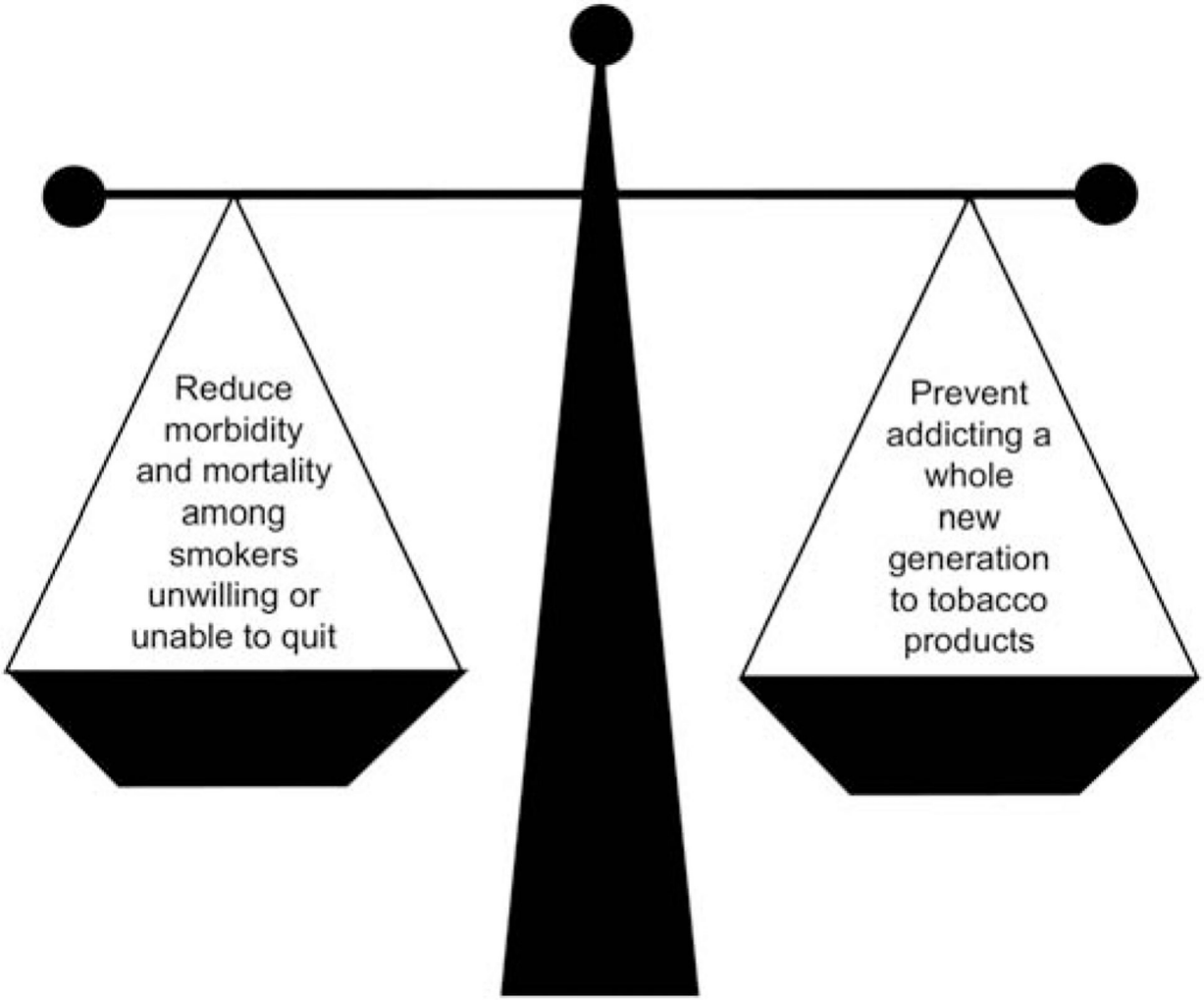

Fig. 1.
Tobacco harm reduction: a public health benefit or risk?