

IQOS MRTTP

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Reason

- Independent, non-profit, non-partisan research
- Promote choice, competition and a dynamic market economy as the foundation for human dignity and progress
- Has published extensively on risks posed by combustible cigarettes and the importance of permitting access to innovative, lower risk non-combustible products
- Reason's Vice President of Research Julian Morris has written and spoken widely on this issue

Smoking Causes Disease and Death

- Inhaling burnt tobacco leads to COPD, CVD, stroke, cancer, and other diseases
- CDC estimates that 16 million Americans living with smoking related diseases
- 480,000 Americans die of smoking related diseases each year
- Currently about 36.5 million Americans smoke
- Of those who smoke long-term, about half will die from smoking-related diseases

Harm Reduction for Those Who Can't Quit

- Majority of smokers have tried to quit, often repeatedly. Most fail or revert to smoking.
- Millions of Americans have switched to e-cigarettes, which evidence suggests are much less harmful than combustible cigarettes.
- Opportunity to encourage those who can't or won't quit smoking to switch to other less harmful substitutes.
- FDA acknowledges role of harm reduction and importance of harm reduction products:
 - Licenses NRT for long-term use
 - Regulates e-cigarettes
 - Has stated its support for less harmful products

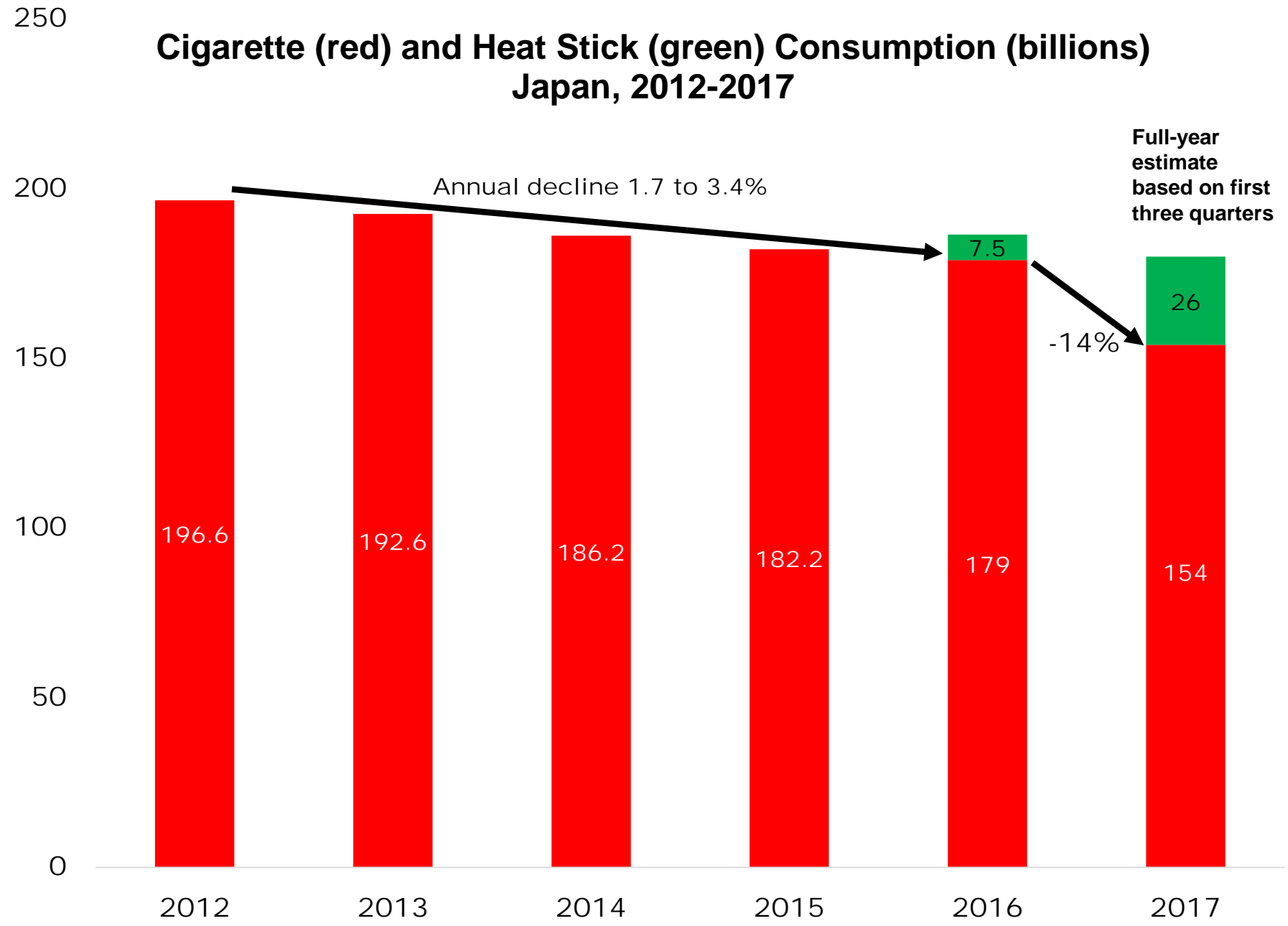
IQOS: Function and Potential Health Benefits

- IQOS uses blade to heat tobacco stick to a maximum of 662°F – about half the temperature of a burning cigarette (1300°F).
- Releases vapor with nicotine and tobacco flavor without combustion
- PMI research found that for IQOS:
 - Levels of 18 HPHCs reduced by 90% compared to reference cigarette.
 - Levels of IARC Class 1 carcinogens reduced by 95% compared to ref. cigarette.
 - IQOS aerosol dramatically reduces the impact on biological mechanisms and disease endpoints associated with COPD and compared to cigarette smoke.
 - Comparing exposure of IQOS vapor to cigarette smoke over an eight month period show IQOS use reduced exposure to HPHCs to the same degree as smoking cessation.
 - Clinical trials lasting 90-days carried out in Japan and the U.S. show smokers who switched exclusively to IQOS saw reductions in levels of 15 HPHCs similar to levels seen in smokers who ceased cigarette use for the duration of the study.
- Independent research by Dr Konstantinos Farsalinos found that for IQOS:
 - Levels of most toxins reduced by at least 90% compared to ref. cigarette.
 - Nicotine delivery greater than e-cigarette but less than combustible cigarette.
- UK Government Committees On Toxicity investigated two heat not burn products (PMI's IQOS and BAT's Glo) and concluded that compared to a reference cigarette:
 - “For both products, there were some HPHCs where the reduction was approximately 50%, and the reduction in other HPHCs was greater than 90%.”

IQOS: Population Health Effects

- Evidence from locations where IQOS is being sold suggests that a large number of smokers would be willing to switch:
 - In Japan, the only country where IQOS is sold nationwide, IQOS already accounts for 10% of the tobacco market and 72% of those using IQOS are doing so exclusively, after little more than a year on the market.
 - IQOS is also being sold in cities in an additional 29 countries.
 - According to PMI, nearly 4 million adults worldwide so far have switched to IQOS from cigarettes to IQOS.
- There was substantial interest from current adult U.S. smokers but no evidence to suggest IQOS would significantly appeal to never smokers. PMI's premarket Perception and Behavior Assessment found:
 - Among current adult U.S. smokers, between 20% and 39% said they intended to use IQOS.
 - Among U.S. never-smokers aged 18-25, the proportion stating an intention to use IQOS was between 0% and 1.1%.
- Under Section 911(g) of the TCA, FDA is mandated to consider whether the use of the product by consumers will significantly reduce harm and the risk of tobacco-related disease to individuals who use the products and benefit the health of the population as a whole, considering both users of tobacco products and those who do not currently use them.
- High interest from smokers to switch from combustible cigarettes to IQOS and minimal interest from non-smokers suggests a large net gain to public health from allowing IQOS onto the market.

Cigarette (red) and Heat Stick (green) Consumption (billions) Japan, 2012-2017



IQOS: Support for MRTTP

- PMI surveys of adult U.S. smokers suggests there is substantial demand from smokers to know the relative risks of different products so as to make an informed choice about how to reduce their risks from smoking-related harms:
 - 98% of survey respondents said it is important adult smokers are informed about the benefits of a reduced risk product.
 - 95% agreed the FDA has an obligation to allow these products onto the market.
 - 89% said they would be more likely to switch to a potentially less harmful product if the government provided clarity on the relevant health benefits.
- There is also significant support among healthcare providers for a tobacco harm reduction approach that allows smokers to switch to less harmful products. In a survey conducted on behalf of PMI, 82% of healthcare providers support communicating the relative risks of new tobacco products to adult smokers.
- Americans should have access to honest, accurate, scientifically-valid information about different products upon which to make informed decisions. The Modified Risk Tobacco Products (MRTTP) application process exists to enable manufacturers to make specific, truthful claims about the risks of specific tobacco products.
- The MRTTP is important given the well-established harm from combustible cigarettes.

IQOS: Approach to MRTP

- It is important to avoid misleading consumers into thinking alternative products are without any risks at all.
- However, available scientific evidence suggests that use of most noncombustible nicotine products offers a significantly less risky way to consume nicotine than smoking combustible cigarettes. Restricting adult smoker access to this important information poses a greater risk than allowing it.
- An FDA order allowing a MRTP is not permanent and is set for a fixed period of time specified in the order. Upon the end of the set term, the company would need to seek renewal of the order. Additionally, if FDA later concludes that the determinations necessary to satisfy requirements cannot be made, it must withdraw the order.
- Given the known risks of death and disease that result from smoking combustible cigarettes and the temporary nature of the MRTP order, TPSAC should encourage the FDA to exercise its wide discretion in liberally interpreting the requirements necessary for an MRTP.
- Noting the temporary nature of the MRTP order, the current findings of the CDC that over 400,000 Americans die prematurely every year from smoking-related causes and the fact that no MRTP orders for reduced risk products are currently on the market and available to 30-40 million U.S. smokers, we strongly encourage TPSAC to avoid applying the most stringent burden of proof (i.e. “beyond a reasonable doubt”) and instead use another recognized standard (i.e. “a preponderance of the evidence” or “more likely than not”) to permit valuable information to be shared with inveterate smokers who are currently at risk of premature death and disease as a result of smoking.
- We encourage you to recommend approval of the MRTP in this instance and where questions exist to work with the applicant reasonably to resolve those questions. By approving this MRTP application, the FDA would ensure that consumers have access to more accurate and reliable information concerning the relative risk of IQOS. Approval would also likely encourage additional MRTP applications, which if approved would ensure that consumers have more accurate information about a wider selection of innovative noncombustible products.