

The Role of Nicotine

The goal at Philip Morris International (PMI) is to develop a portfolio of products containing nicotine that are satisfying to adult smokers and significantly less harmful than smoking cigarettes — all based on rigorous scientific standards and assessment. Tobacco-related diseases are primarily associated with exposure to toxic substances in smoke at levels generated by burning tobacco, not by exposure to nicotine per se.

Progress towards improving public health by reducing death and disease caused by tobacco use requires that fewer people use traditional forms of smoked tobacco, even if nicotine use persists through use of alternative products. In fact, allowing adult smokers to continue using nicotine-containing products, with the nicotine delivered by less harmful means, has the potential to switch greater numbers of smokers away from conventional cigarettes.

For alternative products to benefit public health, three conditions need to be met:

- Smokers must find these products satisfying as alternatives to smoking conventional cigarettes. Nicotine plays an essential part in achieving this necessary consumer acceptance.
- Actual reduction in risk promised by these alternative products must be scientifically substantiated — from product development and analysis through clinical evaluations in realistic use conditions — applying assessment methods that meet recognized scientific standards.
- New alternative products should not be appealing to persons who would otherwise not smoke, particularly minors, nor should they encourage continued tobacco use by those who would otherwise quit. Premarket assessment must be complemented by postmarketing surveillance to confirm these products achieve these objectives.

Reduced-Risk
Product



Product
Acceptance
and Usage

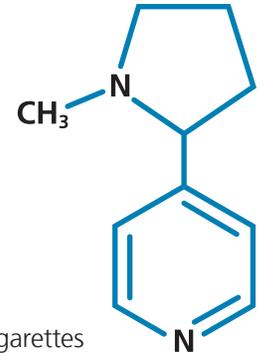


HARM
REDUCTION

What is nicotine?

Nicotine occurs naturally in tobacco and at significantly lower levels in some other plant varieties.

Nicotine used in pharmaceutical products (nicotine replacement therapies; NRTs) as well as in e-cigarettes is usually extracted from tobacco. It is possible to produce synthetic nicotine, but the process is costly.



When tobacco smoke is inhaled, nicotine is absorbed through the lungs into the bloodstream, and begins to reach the brain within about 10 seconds. There, nicotine binds to special receptor molecules, mimicking the actions of a naturally occurring brain chemical, acetylcholine. In turn, some of these nicotine receptors activate areas of the brain that are involved in producing feelings of pleasure and reward, which may explain the subjective pleasurable effects associated with smoking, but also relates to the desire for nicotine and potential for addiction. Other pathways stimulated by nicotine may contribute to its attention-enhancing and calming effects.

Through other routes, such as absorption through the skin when using a nicotine patch, or through the mouth and stomach when chewing nicotine gum, the nicotine is absorbed more slowly and takes longer to reach the brain.

Nicotine also affects other parts of the body such as the heart and blood vessels.

Nicotine is addictive and not risk free. Minors, pregnant or breast feeding women, and people with heart disease, severe high blood pressure or diabetes should not use tobacco or nicotine containing products.

“Preventable morbidity and mortality has overwhelmingly been related to combusted tobacco smoking, not to nicotine itself. Decoupled from combustion or other toxic modes of delivery, nicotine, by itself, is much less harmful.”

— Truth Initiative, America’s largest non-profit public health organization dedicated to tobacco control

How safe is nicotine use?

Experts, including the U.S. Surgeon General and the U.K. Royal College of Physicians, agree that nicotine, while addictive, is not the primary cause of smoking-related diseases. Smoking-related diseases, such as lung cancer, cardiovascular disease and emphysema, are caused primarily by inhaling harmful compounds formed when tobacco is burned.

As stated by the UK Royal College of Physicians: “Nicotine is not, however, in itself a highly hazardous drug...it is inherently unlikely that nicotine inhalation itself contributes significantly to the mortality or morbidity caused by smoking. The main culprit is smoke and, if nicotine could be delivered effectively and acceptably to smokers without smoke, most if not all of the harm of smoking could probably be avoided.”

What are the health risks associated with nicotine?

Researchers have concluded that while nicotine has not been shown to cause the chronic disease associated with tobacco use, there are risks associated with nicotine:

- Nicotine can be acutely toxic at levels much higher than what consumers are exposed to when using tobacco or nicotine-containing products.
- Nicotine can harm your baby if you are pregnant or nursing.
- Nicotine exposure can increase your heart rate and blood pressure.

PMI is committed to transparent sharing of its science. PMI’s clinical studies are registered on the U.S. National Institutes of Health website ClinicalTrials.gov. The results of PMI’s research are published in peer-reviewed publications: Since 2008, PMI has published over 250 peer-reviewed scientific articles and book chapters describing its approaches, methods and product assessment studies.

Learn more at PMIScienceUSA.com.

Additional resources

Raymond Niaura, PhD, Truth Initiative, Re-thinking nicotine and its effects (2016)

Royal College of Physicians, Harm reduction in nicotine addiction: helping people who can’t quit (2007)

Royal College of Physicians, Nicotine without smoke, Tobacco harm reduction (2016)

Surgeon General’s Report: The Health Consequences of Smoking — 50 Years of Progress (2014)

National Institute for Health and Care Excellence, Tobacco: harm-reduction approaches to smoking, NICE public health guidance no. 45 (2013)

Modifications to Labeling of Nicotine Replacement Therapy Products for Over-the-Counter Human Use, A Notice by the Food and Drug Administration, 78 FR 19718 (2013)

Ramstrom L, Wikmans T. Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report. *Tob Induc Dis* 2014;12:14. doi:10.1186/1617-9625-12-14