Biomarker of Exposure Reductions Upon Switching for 5 Days from Cigarettes to a Carbon Heated Tobacco Product (CHTP 1.0)

A. Donelli, C. Tran, C. Haziza, J. Ancerewicz, G. de La Bourdonnaye, R. Weitkunat, and F. Lüdicke

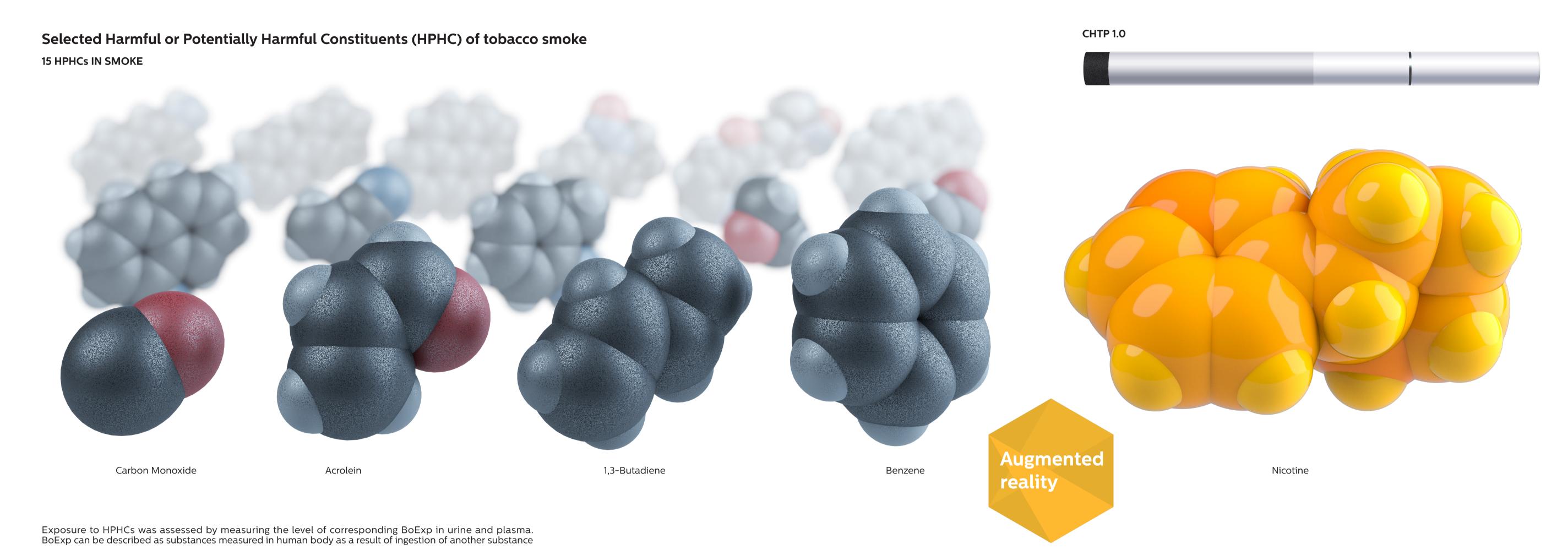
PMI R&D, Philip Morris Products S.A. Quai Jeanrenaud 5, 2000 Neuchâtel, Switzerland (part of Philip Morris International group of companies)

Intro

The Carbon Heated Tobacco Product (CHTP 1.0) is designed to heat tobacco without burning it in order to reduce formation of, and consequently exposure to, harmful and potentially harmful constituents (HPHC) as compared to cigarettes while replicating the ritual, taste, sensory characteristics and nicotine uptake of cigarette smoking. The main objective of this study was to demonstrate the reduction of biomarkers of exposure (BoExp) to selected HPHCs in smokers switching from cigarettes to CHTP 1.0 as compared to smokers continuing to smoke cigarettes for 5 consecutive days. Among other assessments the nicotine uptake and subjective effects of CHTP 1.0 use were evaluated in this study.

80 healthy adult smokers (age of 21+) were randomly assigned to two groups and asked to: (1) switch from cigarettes to CHTP 1.0 (41 participants) or (2) continue to use their own non-menthol cigarettes (39 participants). Participants were eligible if they smoked \geq 10 commercially available non-menthol cigarettes per day for the last 6 weeks prior admission and had smoked cigarettes for \geq 3 consecutive years before enrollment and were not planning to quit smoking in coming 3 months.

- 1. CHTP 1.0 is a heat-not-burn product that does not involve tobacco combustion
- 2. The product generates a nicotine-containing aerosol which has significantly lower levels of HPHCs than cigarettes
- 3. CHTP 1.0 has been designed to resemble a cigarette as closely as possible



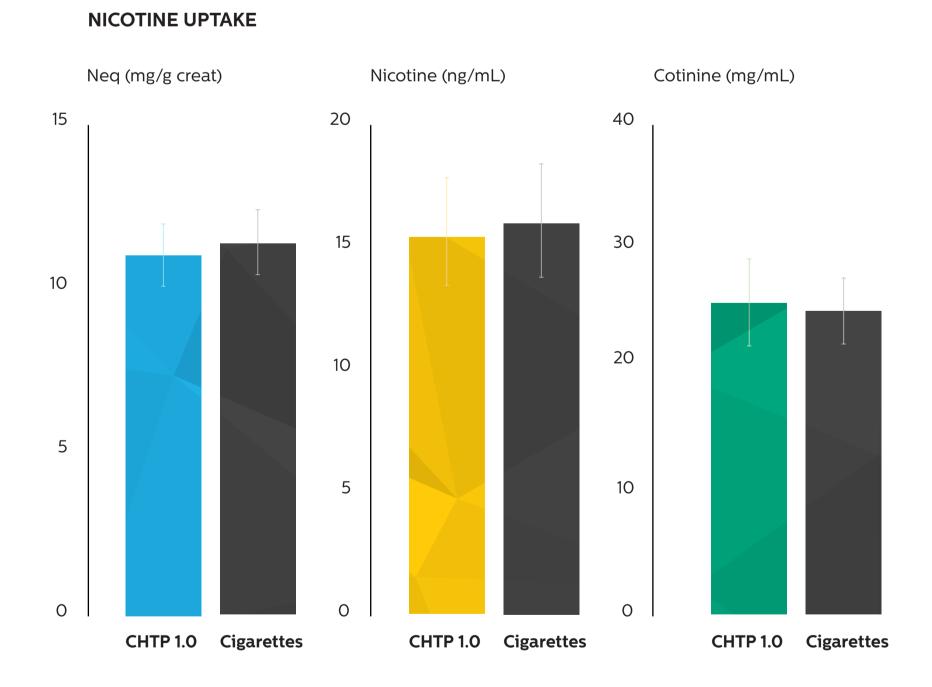
Results

the brochure.

Constituent: NNN

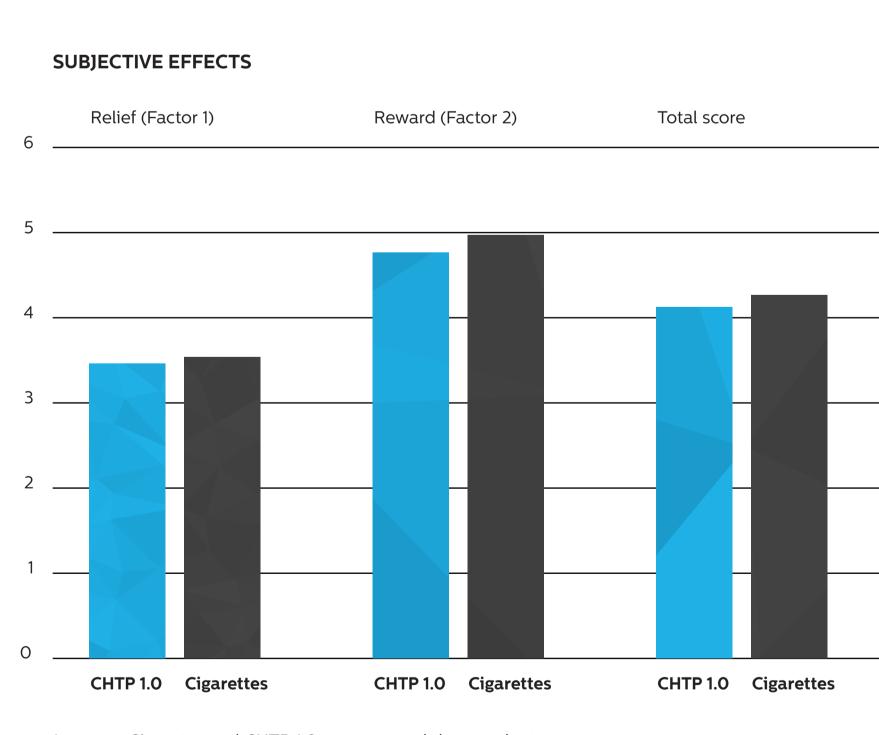
REDUCTION IN HPHCs EXPOSURE: CHTP 1.0 VS CIGARETTES (DAY 5) Day 5 levels were reduced, relative to cigarettes, by 58.8% to 88.1% in primary biomarkers COHb, MHB-MA, 3-HPMA and SPMA. Other biomarkers were reduced by 55.6% to 97.1%. For more information see

Level of Biomarkers in the group smoking cigarettes	100 %
CUTD 1 O	
CHTP 1.0	50.00
COHb ————————————————————————————————————	-58.8 9
Constituent: Carbon Monoxide	
B-HPMA ├── <mark>──</mark>	-63.5 9
Constituent: Acrolein	
MHBMA	-82.8 9
Constituent: 1,3-Butadiene	
S-PMA	-88.19
Constituent: Benzene	
Total 1-OHP	-55.6 °
Constituent: Pyrene	
4-ABP	-78.9°
Constituent: 4-aminobiphenyl	
I-NA	-97.1°
L	
2-NA	-90.1
Constituent: 2-aminonaphthalene	
o-toluidine	- 72. 1°
——————————————————————————————————————	/="
Constituent: o-toluidine	-85.8°
	65.0
Constituent: Acrylonitrile	CE 14
HEMA	-65.1°
Constituent: Ethylene Oxide	
B-HMPMA	-75.5 °
Constituent: Crotonaldehyde	
Total 3-OH-B[a]P	-77.1 °
Constituent: Benzo[a]pyrene	
Total NNAL	-57.7
NNK	
Total NNN	-70.2 %



1. NEQ level was 3.0% lower for the CHTP 1.0 group compared to the cigarette group over all time points.

2. On day 5, plasma nicotine and cotinine levels were respectively 3.0% lower and 2.6% higher in CHTP 1.0 group than in the cigarette group.



1. Cigarette and CHTP 1.0 users scored the products similarly in the urge-to-smoke assessment questionnaire of relief, reward and total scores.

The scoring scales of CHTP 1.0 were close to those of cigarettes over the whole study period.

Conclusions

At the end of the 5 day exposure period biomarkers of exposure to HPHCs were markedly reduced upon switching to CHTP 1.0 use, whereas nicotine levels were similar to cigarette smoking.

Smoking urge questionnaire scores indicate similar responses for CHTP 1.0 as for CC, which is encouraging for CHTP adoption as an alternative to CC.