Abuse Liability Assessment of JL Electronic Nicotine Delivery System (ENDS) in Two Nicotine Concentrations Compared to Usual Brand Cigarette, Nicotine Gum and a Comparator ENDS

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Disclosures

NIG, EMA and MLR are full-time employees of JUUL Labs, Inc. (JLI)

ARB and JEH are full-time employees of PinneyAssociates and advise JLI on abuse liability related to JLI ENDS products.

Participants and Experimental Design

- Adult smokers (N=146; mean age=41.2 years; 46% female; JL ENDS-naïve)
- Randomized, parallel-cohort, crossover, open-label design
- 4 study arms (cohorts) – Virginia Tobacco, Menthol, Mint, Mango
- 35-38 subjects per cohort

- Within each cohort subjects were randomized to a 5-product within-subjects cross-over sequence
    1. JL END 5.0%
    2. JL ENDS 3.0%
    3. Usual brand (UB) cigarette
    4. 4 mg Mint Nicotine Gum (Nicorette® White Ice Mint)
    5. Comparator ENDS (VUSE Alto 5.0%)

- Subjects puffed the ENDS and cigarettes *ad lib* for 5 minutes
- Gum was chewed *ad lib by "chew and park" method* for 30 minutes.

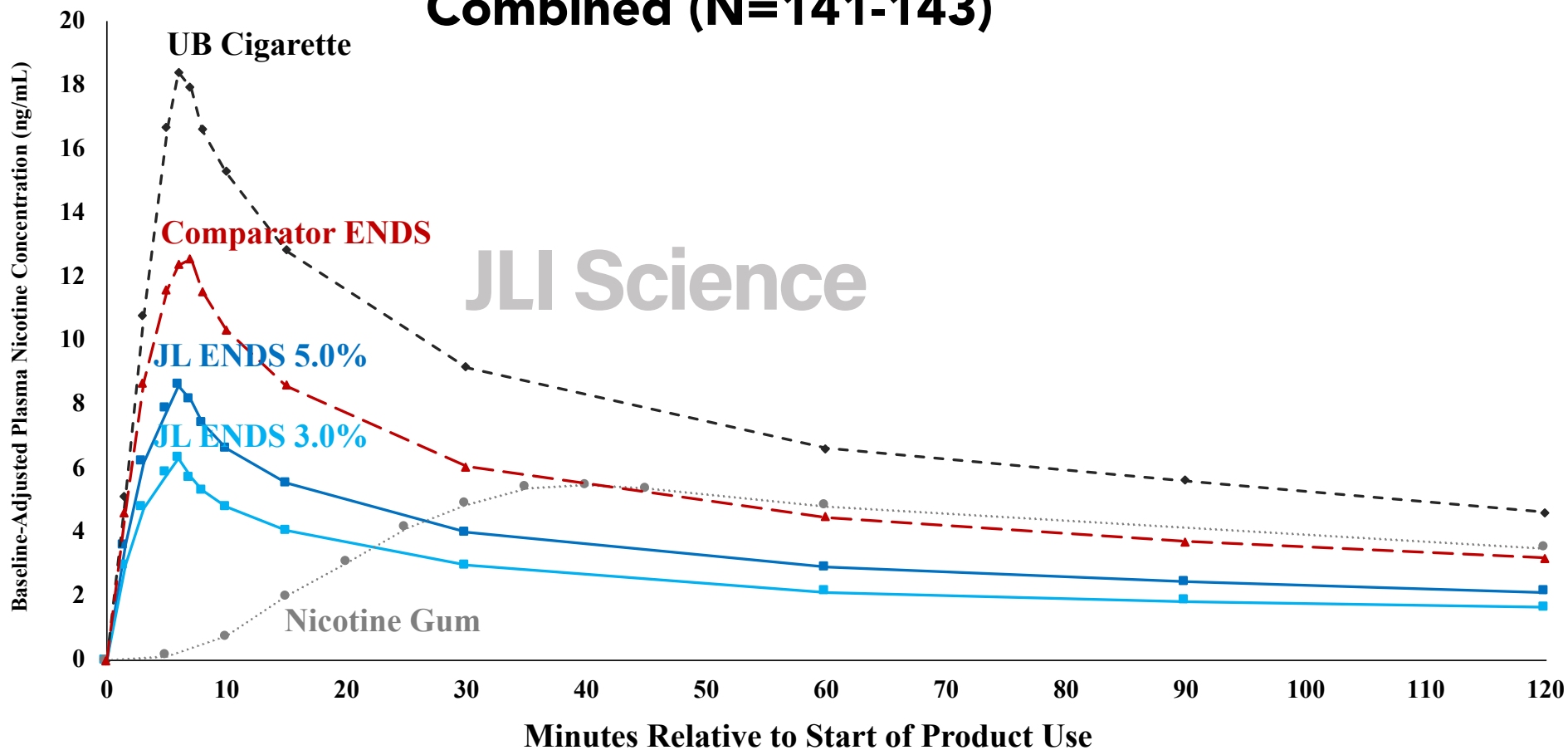**PK Parameters and Subjective Measures Presented Today:**

PK parameters
- Plasma nicotine concentration time course
- Peak nicotine levels (C_{max-BL})
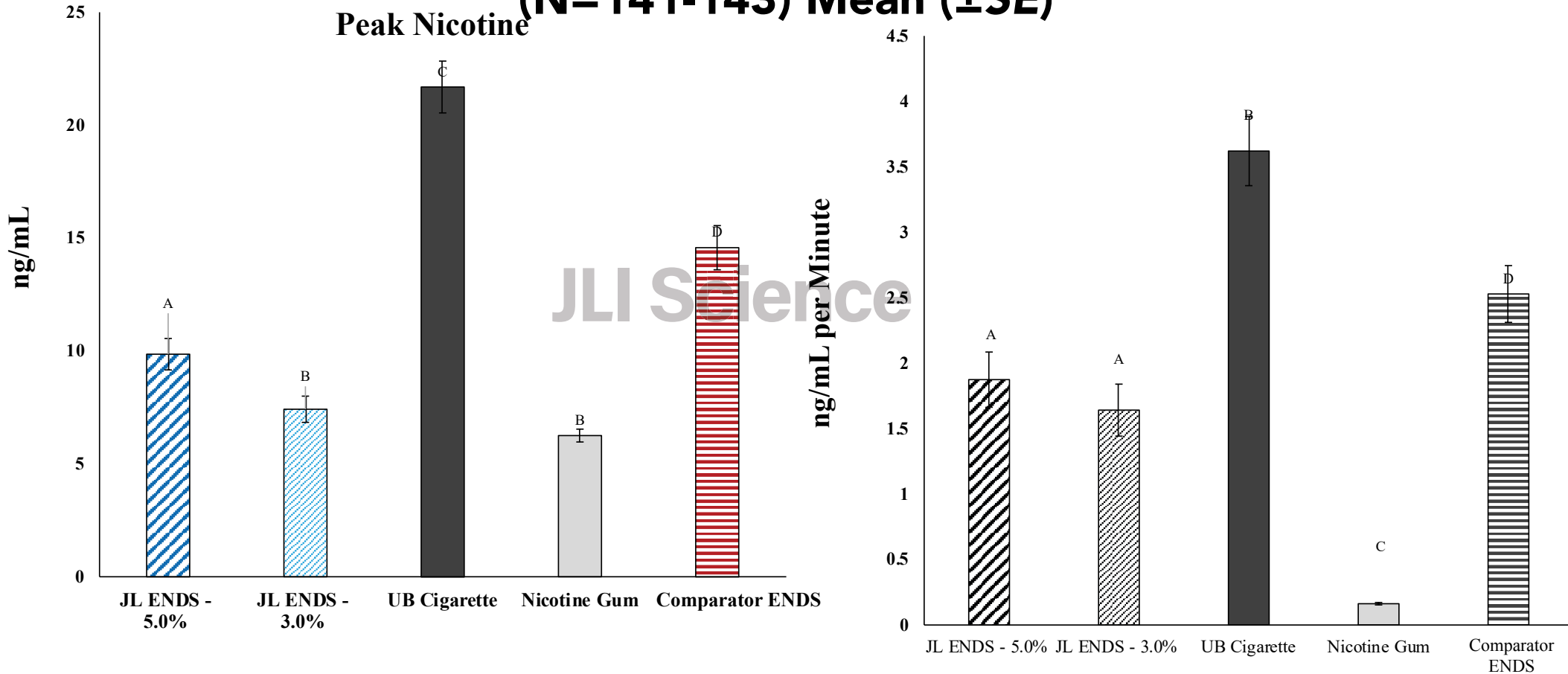- Rate of plasma nicotine rise (C_{max-BL}/T_{max})

Subjective measures – 100 mm visual analog scales
- Product Liking
- Urge to Smoke

Baseline-Adjusted Plasma Nicotine Concentration Profiles of Test Products 120-Minutes Post-*Ad Libitum* Product Use, All Cohorts Combined (N=141-143)
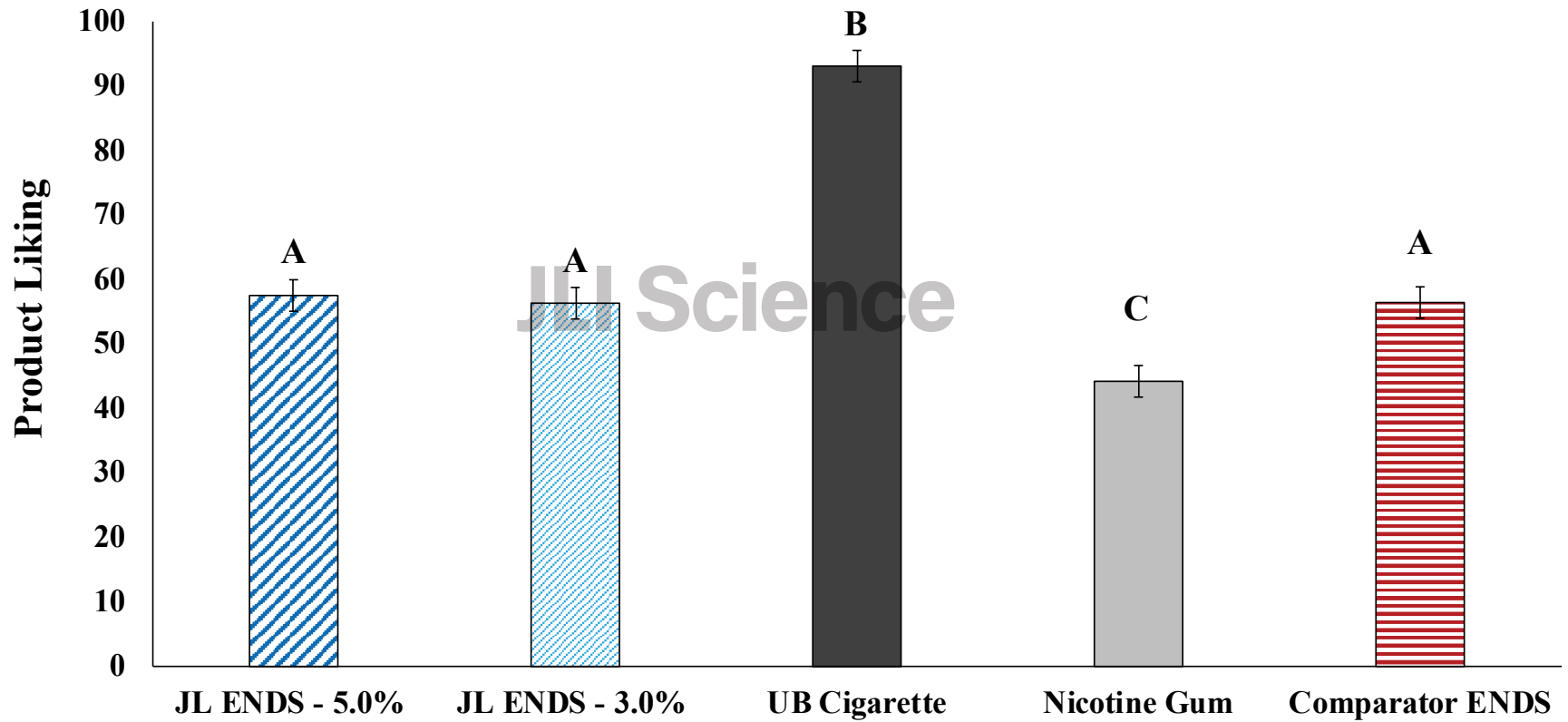
PK Parameters of Test Products, All Cohorts Combined (N=141-143) Mean (±*SE*)
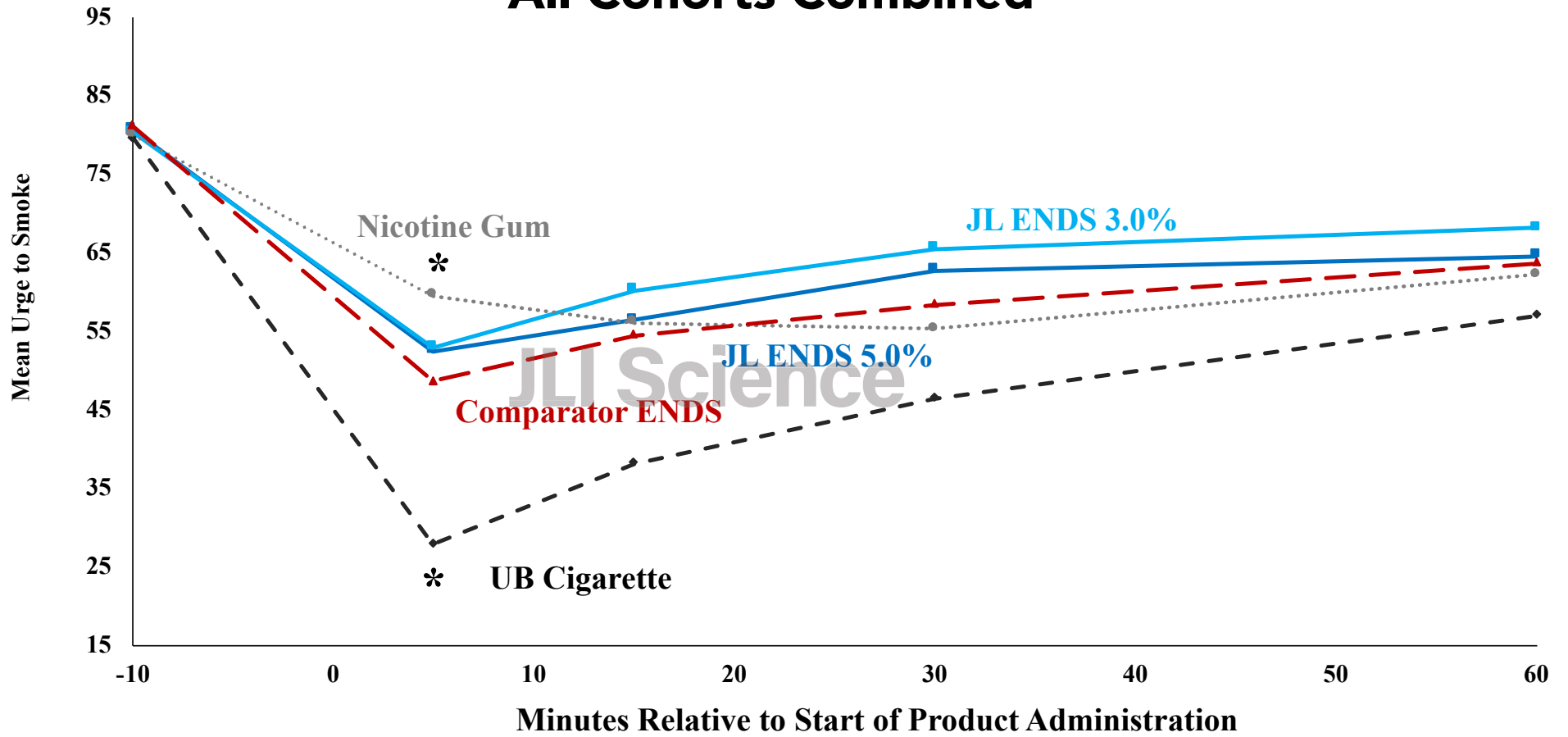
Peak Nicotine

Note. Test products that do not share the same letter significantly differ.

Product Liking Ratings of Test Products, All Cohorts Combined (N= 141-143) Mean (±*SE*)

Note. Test products that do not share the same letter significantly differ.

Time Course of Mean Urge to Smoke Ratings, All Cohorts Combined

Note: N=141-143. *Significantly different from other test products (*p*<0.05).

Conclusions

- Use of the JL ENDS among a sample of adult smokers resulted in nicotine delivery and product appeal that were less than that of combustible cigarettes but were generally greater than nicotine gum

- The pharmacokinetic and pharmacodynamic profiles suggest that the abuse liability of both the 5.0% and 3.0% JL ENDS is:
  1. Lower than the UB cigarette
  2. Somewhat lower than the comparator ENDS (VUSE Alto)
  3. Higher than nicotine gum

- The abuse liability of the JL ENDS 5.0% is somewhat higher than 3.0%

- Findings are generally consistent with other JL ENDS abuse liability studies
  - E.g., Dr. Buchhalter et al. poster at this CPDD meeting
  - Dr. Goldenson et al. poster at SRNT, March 2020