BEHAVIORAL INTENTIONS ASSESSMENT OF A DISPOSABLE E-CIGARETTE AMONG ADULT CURRENT, FORMER, AND NON-SMOKERS IN THE UNITED STATES

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DISCLOSURE



Funding for the study described in this presentation was provided to RBRC by Bidi Vapor, LLC via McKinney RSA, LLC.

Bidi Vapor, LLC also provided information about the BIDI® Stick ENDS and images of the BIDI® Stick ENDS, labels, labeling, and marketing materials for use in the study questionnaire.

Bidi Vapor, LLC had no other input to or control over the study design, questionnaire development, sample recruitment, data analysis, interpretation, or reporting of findings.

I alone am responsible for the content of this presentation.

WEIGHING RISKS AND BENEFITS



Potential of ENDS to simultaneously benefit some, harm others in the population.

Switching from cigarettes to ENDS can substantially reduce health risks.

ENDS use likely to carry some excess health risks to tobacco non-users.

Likelihood that a new ENDS will promote cigarette switching and initiation.

STUDY PUBLICATION





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SPECIAL ISSUE - RESEARCH ARTICLE

WILEY

Behavioral intentions assessment of a disposable e-cigarette among adult current, former, and non-smokers in the United States

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Abstract

Modeling the public health effects of e-cigarettes requires estimates of the likelihood that different individuals and population subgroups will start using e-cigarettes and subsequently transition to and from combustible cigarette use. To begin to generate input values for modeling efforts, this study assessed adults' behavioral intentions in relation to a disposable e-cigarette, "BIDI® Stick." An online questionnaire assessed intentions to try and use a BIDI® Stick regularly in 11 flavor variants among United States (U.S.) nationally representative samples of adult (21+ years) non-





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²McKinney Regulatory Science Advisors, LLC, Henrico, Virginia, USA

³whatIF? Consulting Ltd, Harwell, UK

BIDI® STICK ENDS







BIDI® Stick Flavor Name	Flavors
Arctic	Menthol
Classic	Tobacco leaf
Dawn	Mint, Ginger, Lemon
Gold	Mango
Marigold	Mango, Menthol
Regal	Dragon fruit, Strawberry
Solar	Strawberry, Blueberry
Summer	Blueberry, Pomegranate
Tropic	Mango, Apple, Orange
Winter	Watermelon, Melon, Menthol
Zest	Melon, Pineapple, Banana

BIDI® STICK ENDS – 11 FLAVOR VARIANTS



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WARNING:

THIS PRODUCT

CONTAINS NICOTINE

NICOTINE IS

AN ADDICTIVE

CHEMICAL.



















RESULTS



Main Study Sample (N = 6916):

- \circ Non-Smokers (n = 2284)
- \circ Current Smokers (n = 2391)
- \circ Former Smokers (n = 2241)

Oversample Group:

Young Adult Non-Smokers (n = 1140)



1. What is the likelihood of use of the BIDI® Stick ENDS in the U.S. adult population aged 21 years and older?

NON-INST. U.S. POPULATION AGED ≥21 YEARS



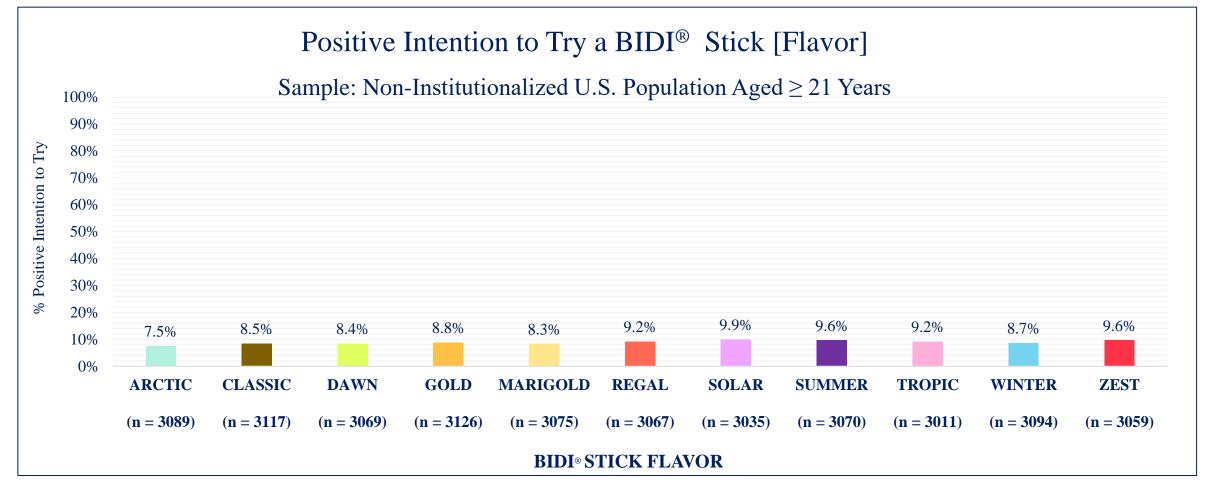


Figure 1. Positive intention to try each BIDI[®] Stick flavor among the non-institutionalized U.S. general population aged ≥ 21 years.



- 1. What is the likelihood of use of the BIDI® Stick ENDS in the U.S. adult population aged 21 years and older?
- 2. What is the likelihood that current tobacco users will use the BIDI® Stick ENDS?

CURRENT SMOKERS



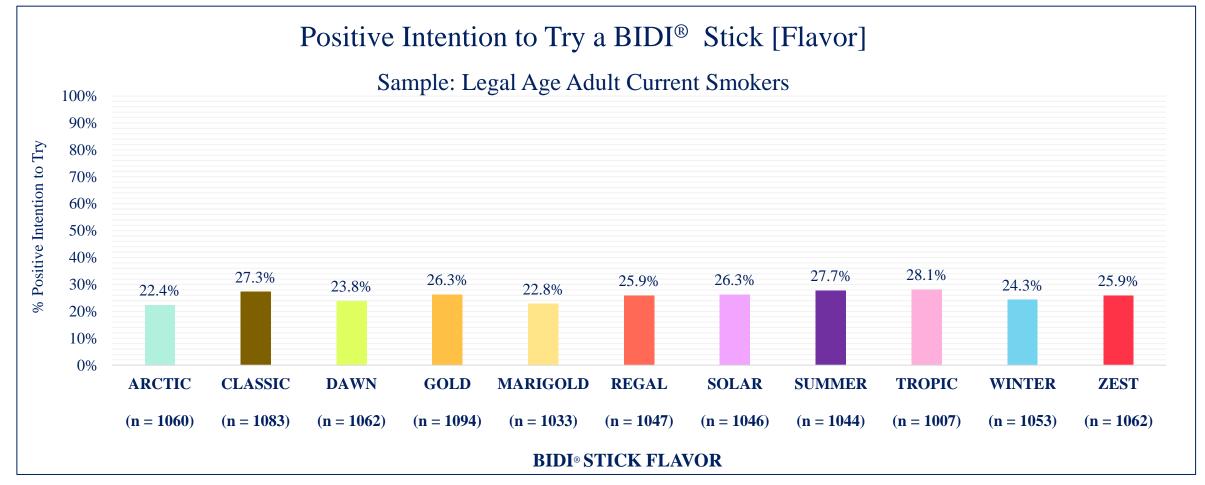


Figure 2. Positive intention to try each BIDI® Stick flavor among Current Smokers.

APPH QUESTIONS



- 1. What is the likelihood of use of the BIDI® Stick ENDS in the U.S. adult population aged 21 years and older?
- 2. What is the likelihood that current tobacco users will use the BIDI® Stick ENDS?
- 3. What is the likelihood that non-users of tobacco products, including youth and young adults, will initiate tobacco use through use of a BIDI® Stick ENDS?

NEVER SMOKED + NEVER VAPED



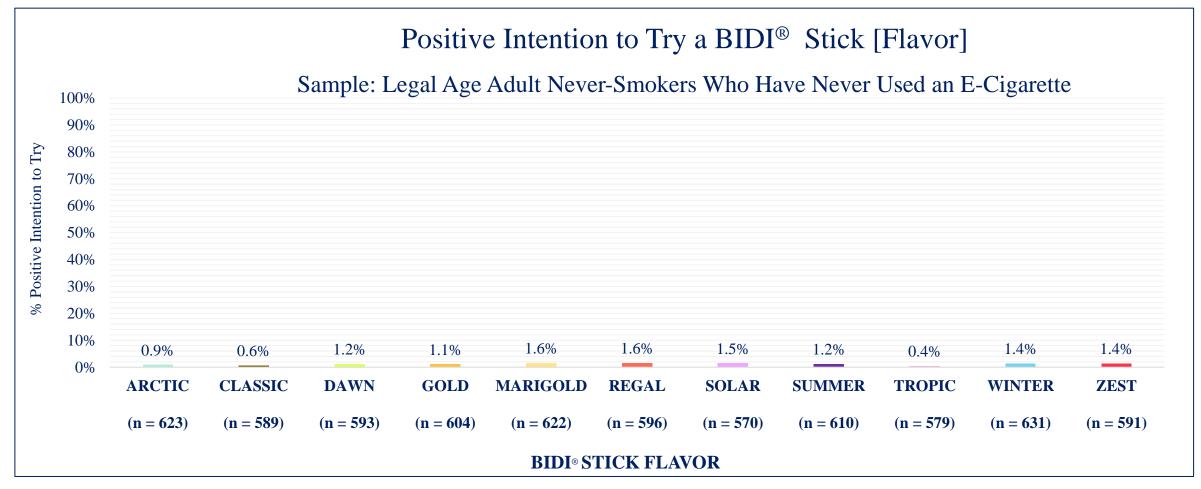


Figure 3. Positive intention to try each BIDI® Stick flavor among Never-Smokers who have never used an e-cigarette.

NON-SMOKERS + NEVER VAPED



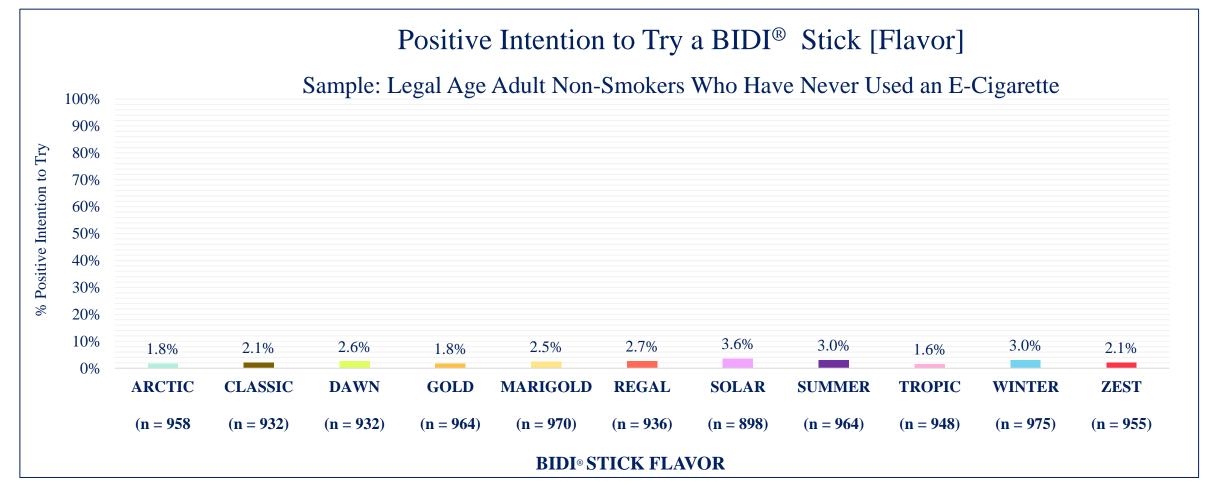


Figure 4. Positive intention to try each BIDI® Stick flavor among Non-Smokers who have never used an e-cigarette.

YOUNG ADULT NON-SMOKERS + NEVER VAPED



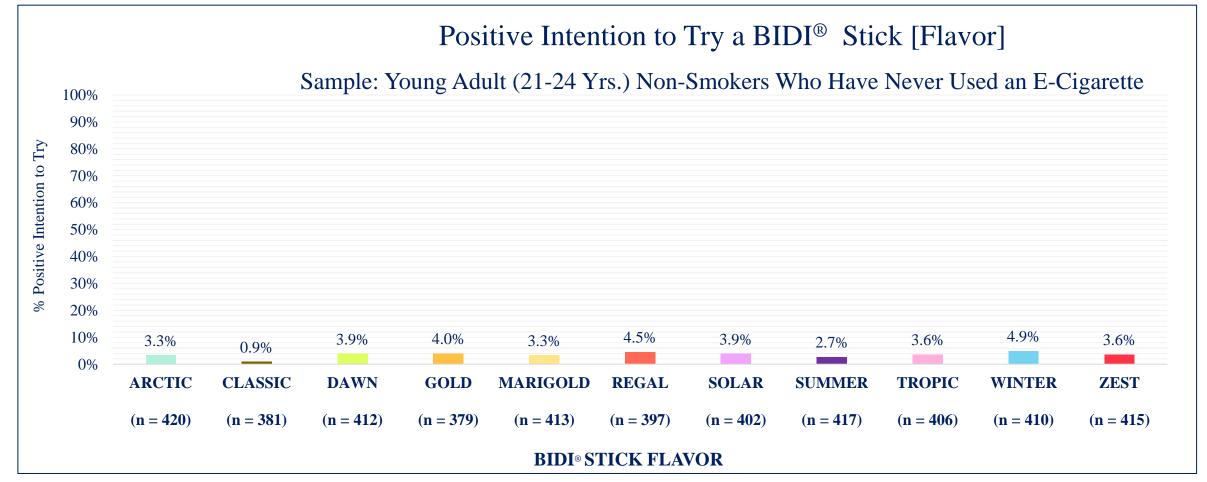


Figure 5. Positive intention to try each BIDI® Stick flavor among Young Adult Non-Smokers who have never used an e-cigarette.

APPH QUESTIONS



- 1. What is the likelihood of use of the BIDI® Stick ENDS in the U.S. adult population aged 21 years and older?
- 2. What is the likelihood that current tobacco users will use the BIDI® Stick ENDS?
- 3. What is the likelihood that non-users of tobacco products, including youth and young adults, will initiate tobacco use through use of a BIDI® Stick ENDS?
- 4. What is the likelihood that former users of tobacco products will re-initiate tobacco use through use of a BIDI® Stick ENDS?

FORMER SMOKERS + NEVER VAPED



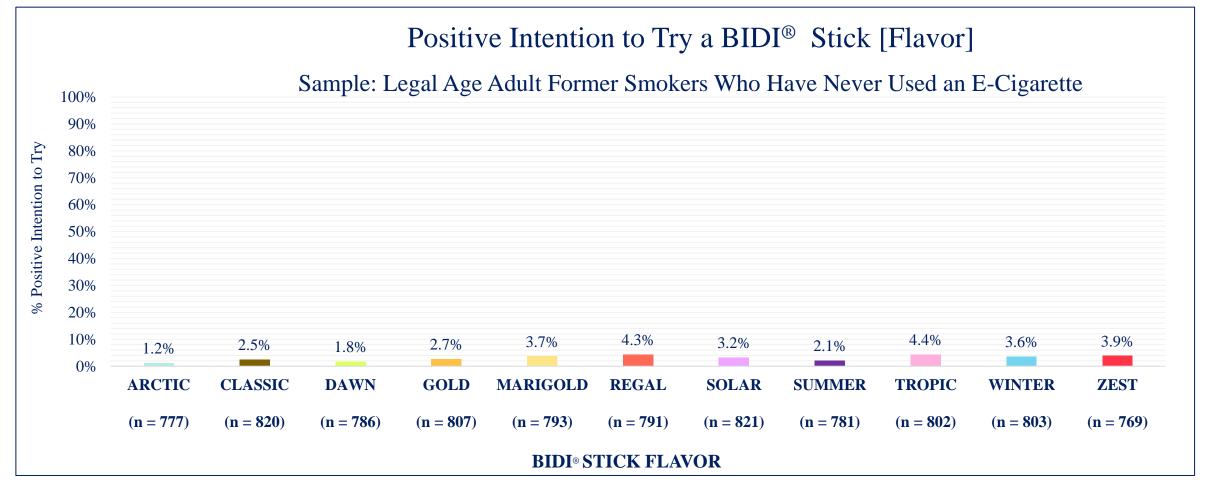


Figure 6. Positive intention to try each BIDI® Stick flavor among Former Smokers who have never used an e-cigarette.

SUMMARY



	Positive Intention to Try a BIDI Stick ENDS	
Population Subgroup	Low % – High %	Low Flavor – High Flavor
Non-Inst. U.S. Population ≥ 21 Yrs.	7.5 - 9.9	ARCTIC – SOLAR
Current Smokers	22.4 - 28.1	ARCTIC – TROPIC
Never-Smokers + Never EC Users	0.4 - 1.6	TROPIC – REGAL
Non-Smokers + Never EC Users	1.6 - 3.6	TROPIC – SOLAR
Young Adult Non-Smokers + Never EC Users	0.9 - 4.9	CLASSIC – WINTER
Former Smokers + Never EC Users	1.2 - 4.4	ARCTIC – TROPIC

CONCLUSIONS



Exposure to the BIDI[®] Stick ENDS generated high levels of positive intention to try a BIDI[®] Stick ENDS among legal age adults who are Current Smokers and/or current users of e-cigarettes – the intended users of the BIDI[®] Stick ENDS.

Exposure to the BIDI® Stick ENDS simultaneously generated low levels of positive intention to try a BIDI® Stick ENDS among legal age adults who have:

- A. Never smoked.
- B. Never smoked regularly.
- C. Do not currently smoke cigarettes and/or use e-cigarettes.

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CONCLUSIONS



If granted marketing authorization, each of the 11 BIDI® Stick ENDS flavors would likely appeal to a moderate-high proportion of the intended user populations to use on at least a trial basis.

The likelihood that legal age adults who have never used, have never regularly used, or have formerly used cigarettes and/or e-cigarettes would initiate, or re-initiate tobacco use through use of a BIDI® Stick ENDS is estimated to be low.

5. What is the likelihood that adult smokers will use the BIDI® Stick ENDS for cigarette switching or reduction?

USE FOR CIGARETTE SWITCHING OR REDUCTION



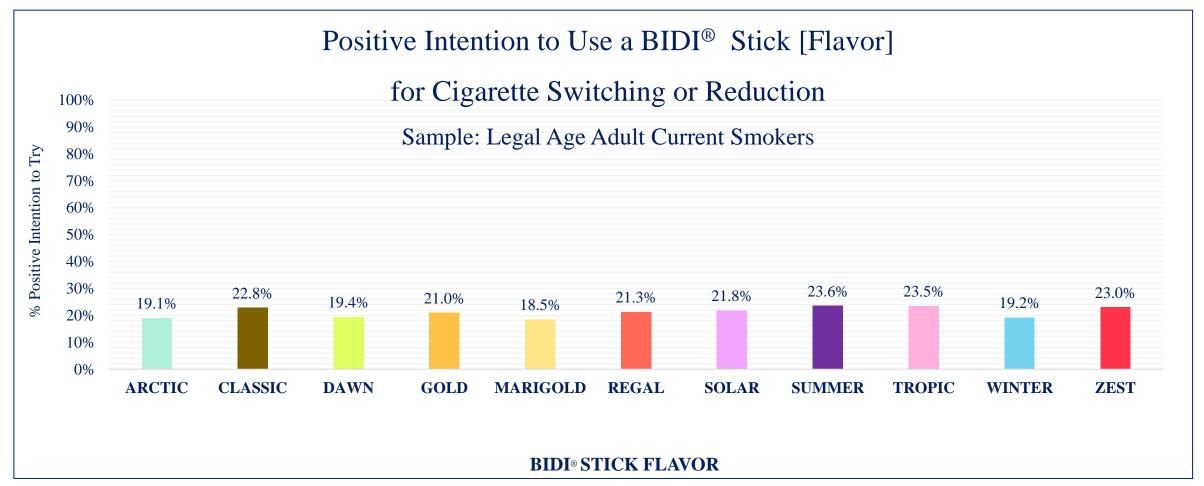


Figure 7. Positive intention to use each BIDI® Stick flavor to facilitate cigarette switching or reduction.



- 5. What is the likelihood that adult smokers will use the BIDI® Stick ENDS for cigarette switching or reduction?
- 6. What is the likelihood that adult smokers with no intention to quit smoking will completely switch to using a BIDI® Stick ENDS?

USE FOR CIGARETTE SWITCHING OR REDUCTION



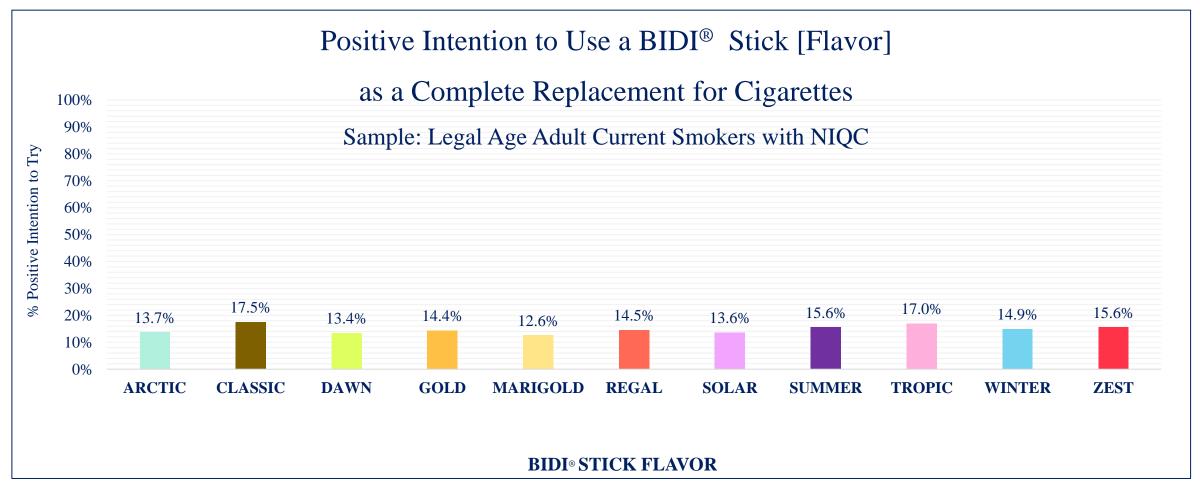


Figure 8. Positive intention to use each BIDI® Stick flavor as a complete replacement for cigarettes among CS-NIQC.

SUMMARY



	Positive Intention to Use a BIDI Stick ENDS For	
Population Subgroup	Low % – High %	Low Flavor – High Flavor
Cigarette Switching or Reduction	18.5 – 23.6	MARIGOLD - SUMMER
Cigarette Reduction	17.5 – 22.3	MARIGOLD – TROPIC
Cigarette Switching	14.1 – 19.8	MARIGOLD – TROPIC

CONCLUSIONS



The BIDI® Stick ENDS is likely to be acceptable to a moderate-high proportion of adult smokers as a partial or complete replacement for combustible cigarettes.

Marketing of the BIDI® Stick ENDS in the current range of flavors may be effective for stimulating thoughts about switching or reducing cigarette consumption among adult smokers who were not planning to quit smoking in the near future.

OVERALL CONCLUSION



Together with other data and information on the BIDI® Stick ENDS, the results of this study can inform the FDA's evaluation of the effects that permitting each flavor of BIDI® Stick ENDS to be marketed may have on overall tobacco-related morbidity and mortality in the United States.

In turn, results can inform FDA's evaluation of whether issuing marketing granted orders for the BIDI® Stick ENDS in each flavor would be appropriate for the protection of the public health under Section 910 of the FD&C Act (21 U.S.C. 387j).



Thank You for Listening

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