STPOST63

Challenges and Opportunities in Cigar Science

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Abstract

An independent Cigar Working Group was formed by interested cigar stakeholders (e.g. manufacturers and testing laboratories) to explore opportunities for engagement with the Food and Drug Administration (FDA) on issues relating to the manufacturing, analysis and testing of cigars. Recent deeming by the FDA places the burden on cigar manufacturers to obtain authorization for new products not on the market as of February 15, 2007 through one of three regulatory pathways. However, scientific research necessary to support regulatory submissions for cigars is limited and some of what exists, due to a lack of standardization in the field, is lacking in rigor. Though cigars and cigarettes are both combustible tobacco products, cigars, unlike cigarettes, have not been the subject of widespread scientific study. A Cigar Science sub-group was formed within the Cigar Working Group to explore the challenges and opportunities within the cigar science space. The group has identified the following as areas where research and development is warranted:

- Quantity and breadth of scientific literature on cigars
- Cigar use patterns and smoking topography
- Cigar reference products
- Standardized, validated analytical methods for chemical constituents

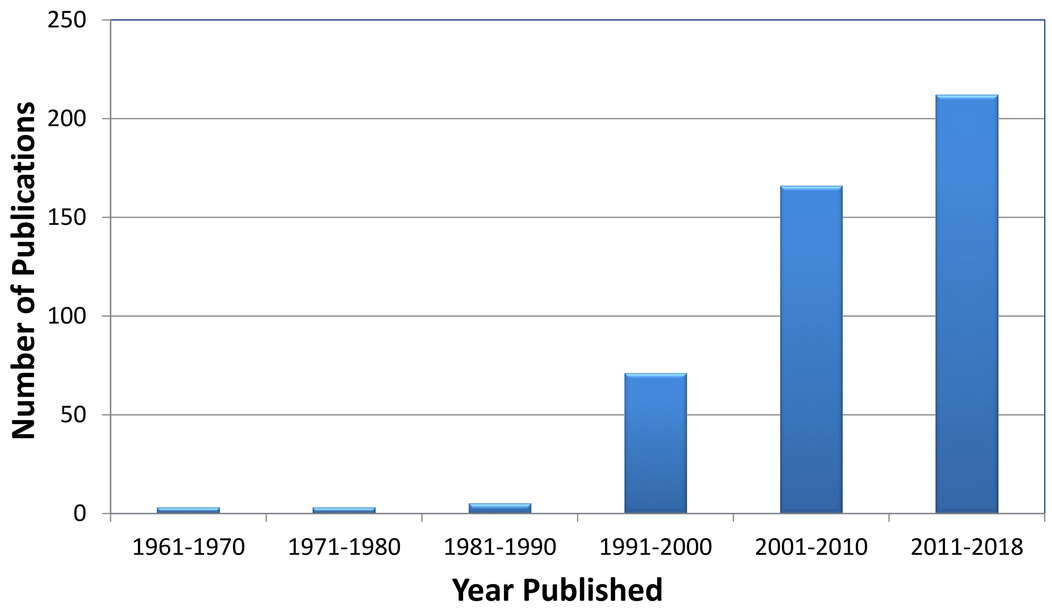
Differences Between Cigarettes and Cigars[1]

	Cigarettes	Cigars
Analytical	• Extensive testing experience • Standardized methods • Proficiency testing • Reference products • Uniform product category	• Limited testing experience • Few standardized methods • Limited proficiency testing • No reference products • Diverse product category
Manufacturing Process	• More sophisticated equipment • Typically blend over multiple crop years • Wrapped in paper	• Less sophisticated equipment • Typically blend from single crop • Wrapped in tobacco

Specific challenges of cigar regulation
- Testing experience / methods
- Product variability
- Category diversity

Breadth of Scientific Literature for Cigars

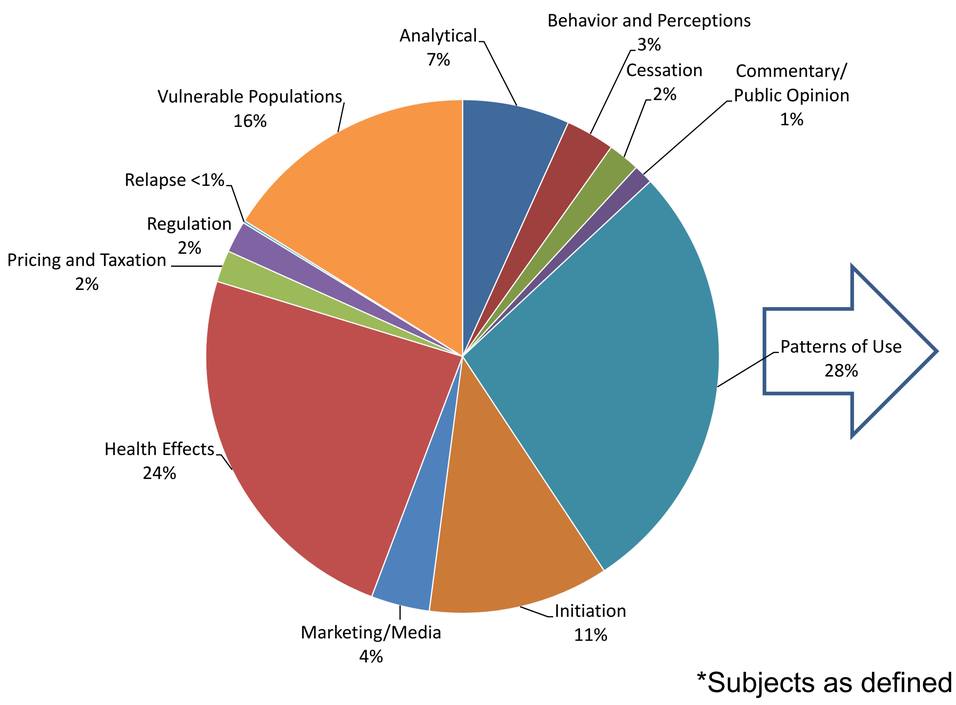
Cigar Publications Over Time



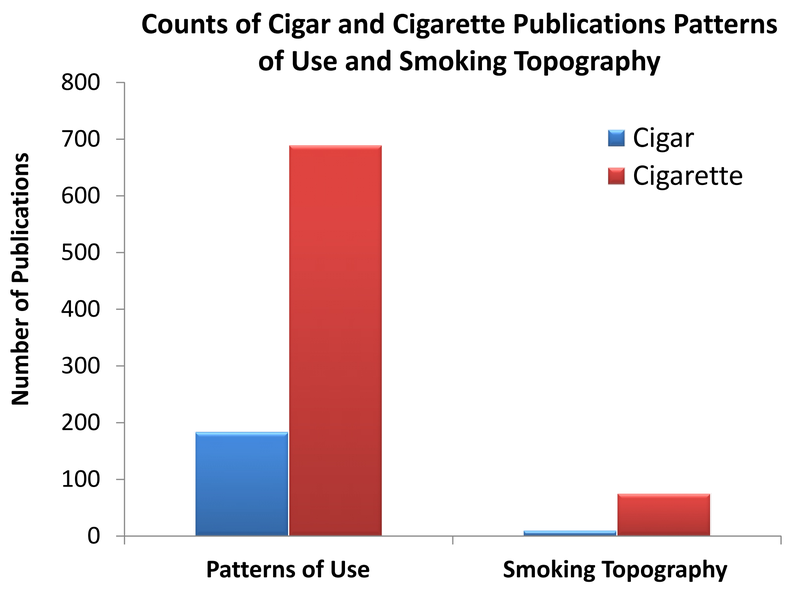
For every 1 cigar journal article, there are ~100 cigarette articles**

Cigars Are a Diverse Product Category

Cigar Publications by Subject* (1961-2018)



*Subjects as defined by the FDA



****Search Methodology**
To determine the order of magnitude of difference between cigarette and cigar publications currently on PubMed as of 8/2/2018, we:

- First identified search terms to cover 'cigar' including both singular and plural forms of the noun. The word 'cigarillo' was also included in both singular and plural forms as cigarillo is a term outlined in many publications. The same was done for cigarettes: ("cigar" OR "cigars" OR "cigarillo" OR "cigarillos"), ("cigarette" OR "cigarettes")
- Second, 'AND' logic was used between both search terms to identify all publications covering both topics: ("cigar" OR "cigars" OR "cigarillo" OR "cigarillos") AND ("cigarette" OR "cigarettes") = 900
- Lastly, 'NOT' logic was used between both search terms to identify only cigar or only cigarette publications: ("cigar" OR "cigars" OR "cigarillo" OR "cigarillos") NOT ("cigarette" OR "cigarettes") = 559
- ("cigarette" OR "cigarettes") NOT ("cigar" OR "cigars" OR "cigarillo" OR "cigarillos") = 63502
- To calculate the order of magnitude of cigar to cigarette publications the following calculation was performed: (900 + 559) / (900 + 63,502) = 0.0226 or ~10^{-2}

Testing Methodology and Reference Products

Table 1. Abbreviated List of Harmful and Potentially Harmful Constituents

HPHCs in Cigarette Smoke	HPHCs in Smokeless Tobacco	HPHCs in Roll-your-own Tobacco and Cigarette Filler[6]
Acetaldehyde	Acetaldehyde	Ammonia ✓
Acrolein	Arsenic	Arsenic
Acrylonitrile	Benzo[a]pyrene	Cadmium
4-Aminobiphenyl	Cadmium	Nicotine (total)
1-Aminonaphthalene	Crotonaldehyde	NNK* ✓
2-Aminonaphthalene	Formaldehyde	NNN** ✓
Ammonia	Nicotine (total and free)	
Benzene	NNK*	
Benzo[a]pyrene	NNN**	
1,3-Butadiene		
Carbon monoxide ✓		
Crotonaldehyde		
Formaldehyde		
Isoprene		
Nicotine (total) ✓		
NNK*		
NNN**		
Toluene		

*4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone
**N-nitrosonornicotine
✓ Represents an available standardized method for cigars[3]

- Standardized methods are needed to generate useful, scientifically valid, and reliable information to the FDA
- 2 standardized smoke methods and 3 standardized filler methods exist for cigar
- Reference products exist for cigar filler, but do not exist for cigars
- Limits method development
- Limits proficiency / collaborative studies

Conclusions

On August 8, 2016, the FDA finalized a rule that extended its regulatory authority to all tobacco products, including e-cigarettes, cigars, and hookah and pipe tobacco (Deemed Products), as part of its goal to improve public health. This decision greatly expanded the scope of tobacco products being regulated by the FDA and introduced significant challenges that needed to be addressed to ensure accurate, reliable data can be generated for the Deemed Products, particularly cigar products, and provided to FDA to allow appropriate regulatory decisions to be made. Here we have outlined some of the most important challenges.

- Scientific research necessary to support regulatory submissions for cigars is limited when compared to cigarettes
- The cigar category is diverse and fundamentally different from cigarettes
- Standardized analytical methods do not exist for cigars
- Cigar reference products are needed to develop, standardize and validate analytical methods

References

1. Wagner, K.A.; Blake, T.L., Melvin, M.S.; Morton, M.J.; Smith, J.H., 2017. An evaluation of the variability of HPHCs in cigars as compared to cigarettes. Presented at CORESTA Meeting, Smoke Science/Product Technology, 2017, Kitzbühel, ST 02 (also presented at TSRC 2017)
2. https://www.fda.gov/downloads/tobaccoproducts/labeling/rulesregulationsguidance/ucm297828.pdf
3. http://coresta.org (CORESTA Recommended Methods Nos. 64, 65, 66, 68, 72 and 79)

This poster may be accessed at www.altria.com/ALCS-Science