FDA is on Fire:

FDA Fast Tracks More Than 1,500 New Cigarettes and 11,000 Other Smoking Products: 2019 - 2023

Vapor Technology Association

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vaportechnology.org

Last year, the Vapor Technology Association (VTA) conducted a detailed analysis of FDA's tobacco product database which tracks product authorizations across categories. Our report detailed the alarming rate at which the agency was approving new *combustible* tobacco products. The problem has only gotten worse.

In light of FDA Commissioner Robert Califf's testimony before the House Oversight and Accountability Committee on April 11, 2024, during which he said he was uninformed about our findings that FDA had authorized 900 new cigarettes in the last five years (2018-2022), VTA updated our analysis based on the new FDA database (FDA Searchable Tobacco Products Database) which FDA only recently made publicly available.

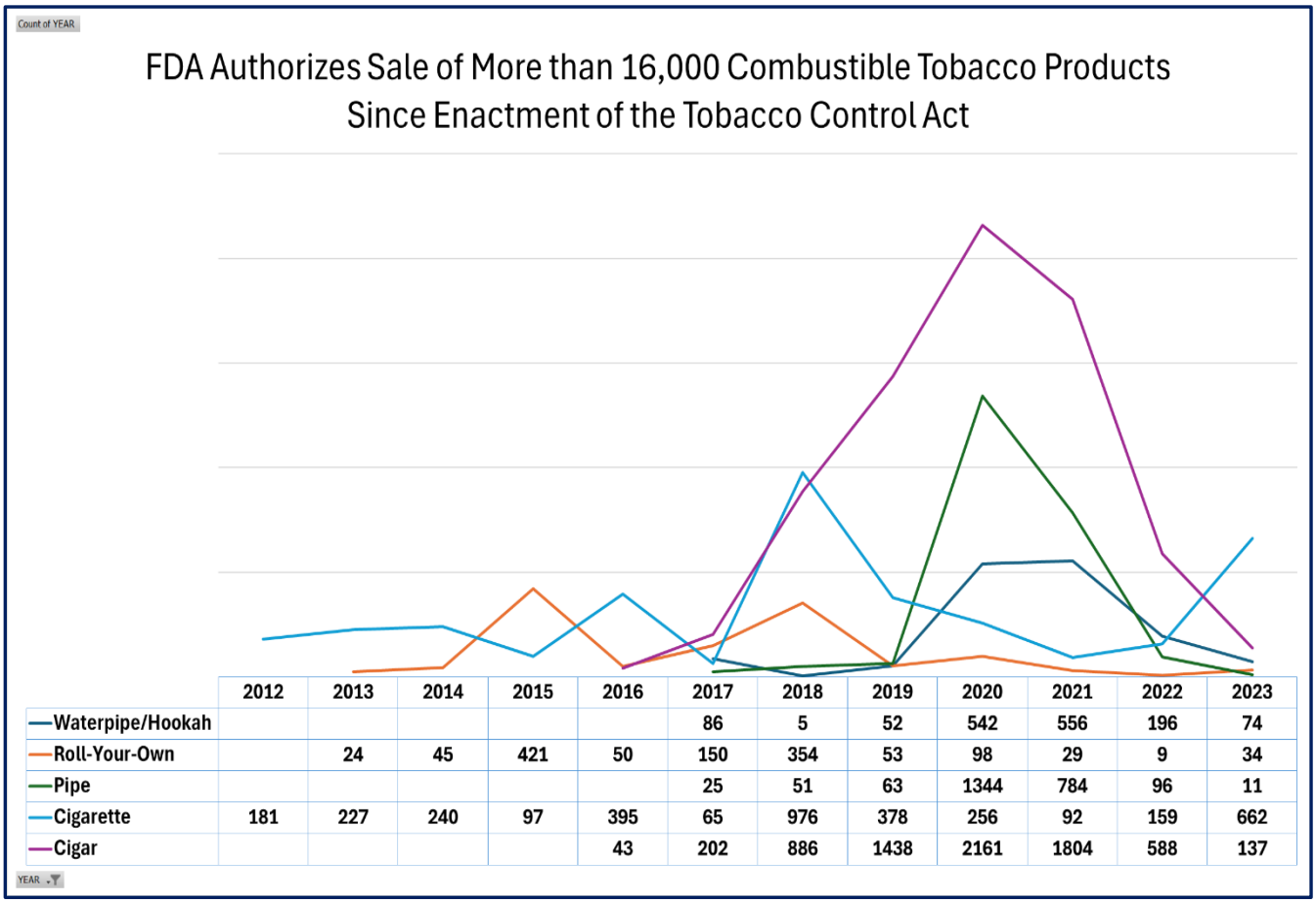
What we found: the FDA is on fire, quite literally, authorizing new combustible tobacco products at a stunning rate and, therefore, failing in its mission to end smoking. Only by cowing to international cigarette conglomerates demanding more cigarettes, on the one hand, and politically bent "public health" groups, on the other hand, could the FDA rapidly accelerate to market more than 16,000 new combustible tobacco products but merely a handful of dramatically less harmful alternatives to smoking

FDA's Tawdry History with Smoking

VTA has accessed and analyzed FDA's Searchable Tobacco Products database. Our analysis reveals the upside-down world in which FDA and the Center for Tobacco Products (CTP) live and their complete abandonment of what was once their mission to end smoking in the U.S.

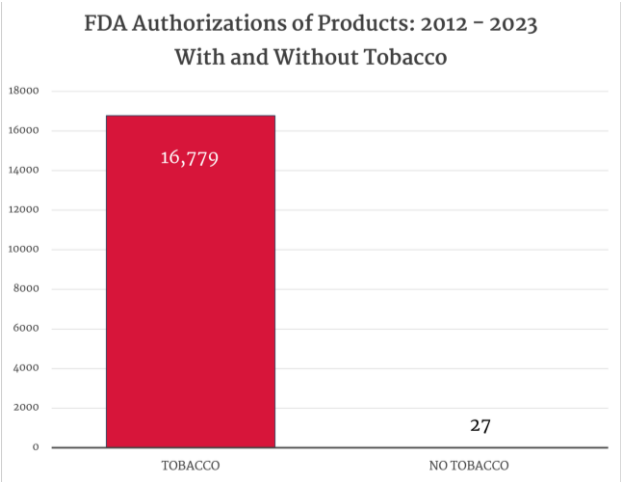
One of the fundamental purposes of the 2009 Tobacco Control Act (TCA) was to end smoking in the U.S. by permitting the marketing of less harmful nicotine products. However, since 2009, the FDA instead has used its power to authorize the sale of more than 16,800 tobacco products.[1] All this while FDA and CDC repeatedly state that smoking kills nearly half a million Americans every single year.

[1] The numbers reflected in this report taken from the FDA Searchable Tobacco Products database undercount the actual number of combustible products that the FDA has authorized for two reasons: (1) FDA states that the number of products allowed on the market as "pre-existing tobacco products" are underreported, and (2) the FDA only released data starting in 2012, rather than 2009 when the Tobacco Control Act took effect.



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Waterpipe/Hookah						86	5	52	542	556	196	74
Roll-Your-Own		24	45	421	50	150	354	53	98	29	9	34
Pipe						25	51	63	1344	784	96	11
Cigarette	181	227	240	97	395	65	976	378	256	92	159	662
Cigar					43	202	886	1438	2161	1804	588	137

Source: FDA Searchable Tobacco Products Database, last accessed April 30, 2024

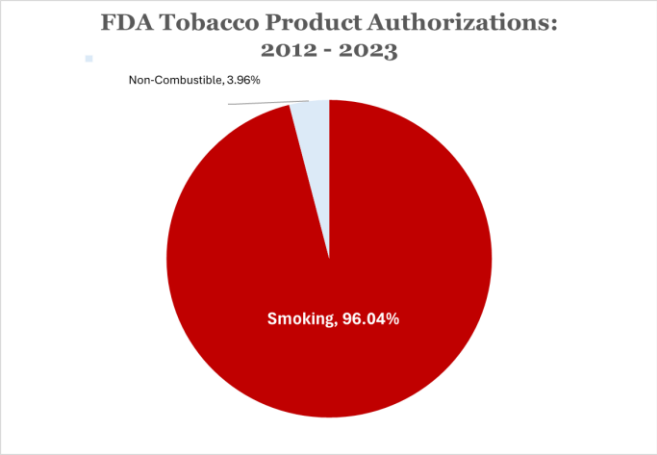


Tobacco v. Non-Tobacco

FDA has all but ignored the next generation of products that *do not contain tobacco* which, the agency knows, do not contain carcinogens and other dangerous substances inherent in tobacco. Of all the "tobacco products" authorized by FDA, a remarkable 16,779 contain tobacco (99.83%) and only 27 do not contain tobacco; a ratio of 621:1.

Smoking v. Non-Combustible

FDA has long acknowledged that it is the *smoking* (i.e., burning or combustion) of tobacco -- and the thousands of chemicals and carcinogens imbued in or created by smoking cigarettes and other tobacco products -- that maims and kills Americans. And yet, more than 96% of the 16,808 products authorized by the FDA are *combustible* tobacco products, while less than 4% are non-combustible products.

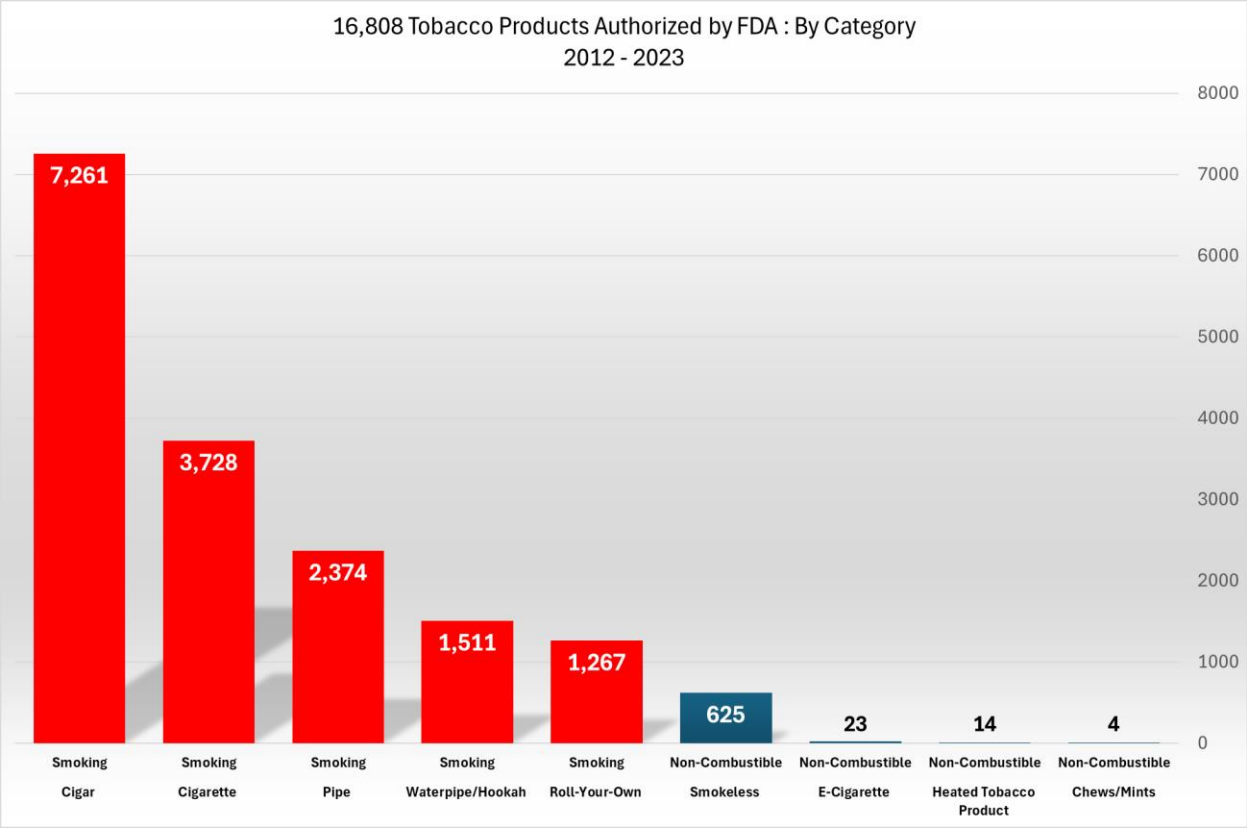


In stark contrast to the more than 16,800 combustible products that FDA has authorized since passage of the TCA, the FDA has seen fit to authorize a paltry 45 next generation tobacco products. By category, FDA's 45 authorizations include:

- 2 new combustible *cigarettes* (low nicotine, but still *combustible*);
- 4 oral tobacco mints and chews;
- 8 smokeless tobacco products (snus);
- 8 heat-not-burn products (the IQOS device and assorted Marlboro HeatSticks);
- 23* electronic nicotine delivery systems (out of more than 20M PMTAs).

*Since facts do matter, it is important to note that the often cited list of "23" authorized e-cigarettes, only includes 8 unique e-cigarette devices (some of which are no longer available on the market). The remainder of the list of 23 "e-cigarettes" are either replacement pods, accessories, or other products not traditionally identified as e-cigarettes.

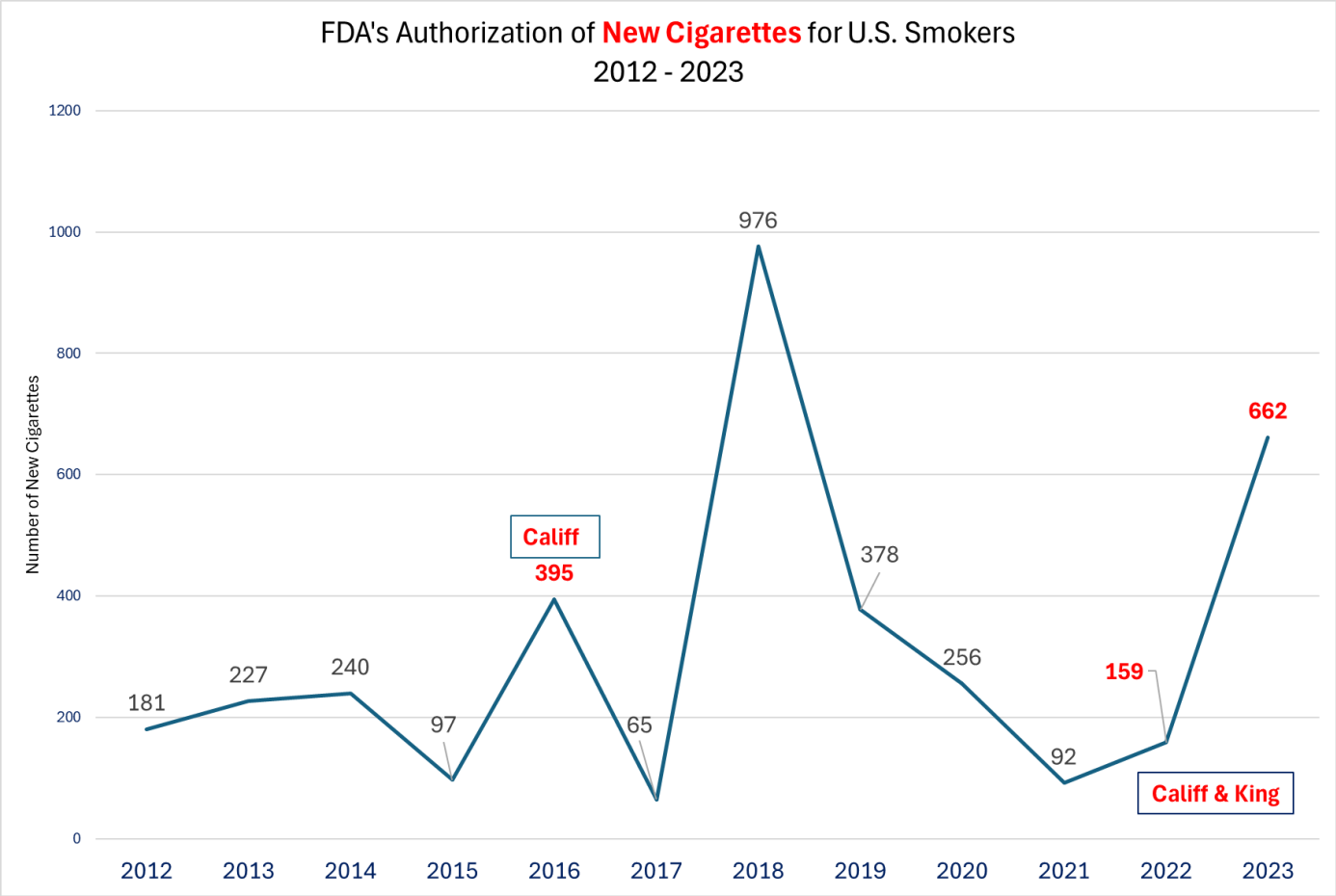
A breakdown of FDA's tawdry record of authorizing smoking products over non-combustible products is apparent for all to see.



FDA Commissioner Califf and CTP Director Brian King's Record of Authorizing Combustible Products: Bad and Worse

During his two tours as FDA Commissioner,[2] Dr. Robert Califf authorized 2,736 combustible tobacco products, of which 1,179 (43%) were *new cigarettes*. Of these, a remarkable 821 new cigarettes were authorized in 2022 and 2023 alone. All told, 17% of all the combustible tobacco products FDA has ever authorized were ushered to the market under Dr. Califf's leadership.

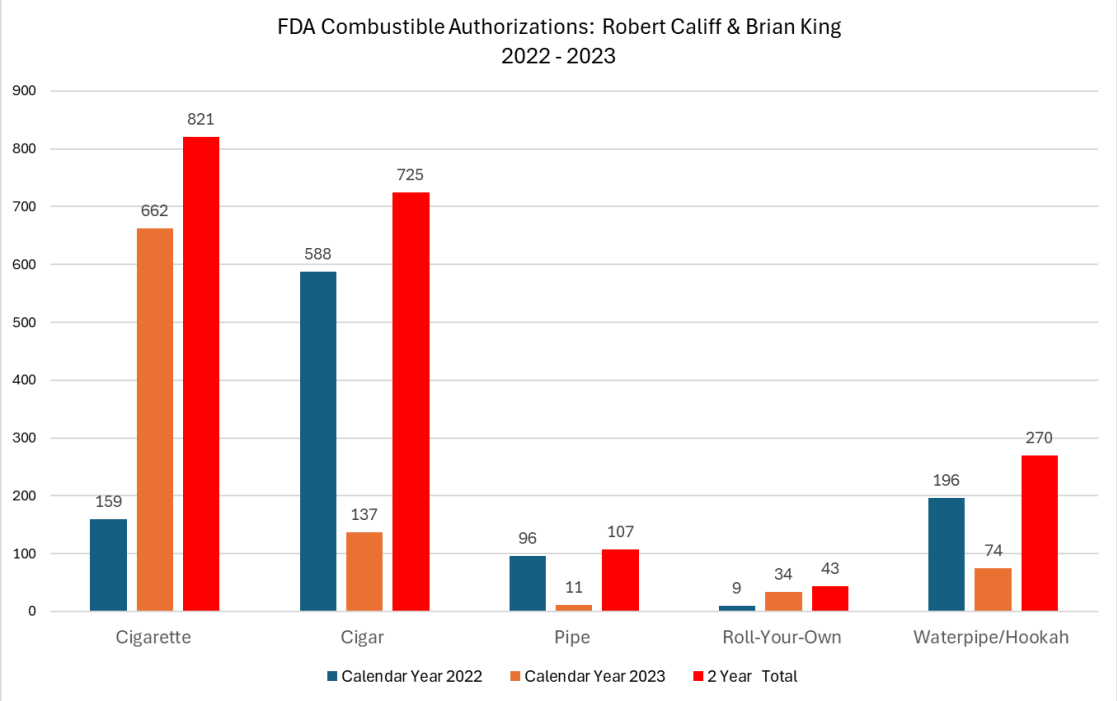
[2] Robert Califf served as FDA Commissioner from February 22, 2016 – January 20, 2017 and from February 17, 2022 – present.



Even more concerning is that, after Dr. Califf hired Brian King as CTP Director, the pace of combustible tobacco authorizations, particularly new cigarettes, dramatically accelerated. Under King's short reign at CTP (July 2022 - present), FDA has authorized 1,213 new combustible tobacco products and, of those, an incredible 61% were *new cigarettes* (736 in total) with King's CTP authorizing 662 new cigarettes for the U.S. market in 2023 alone.

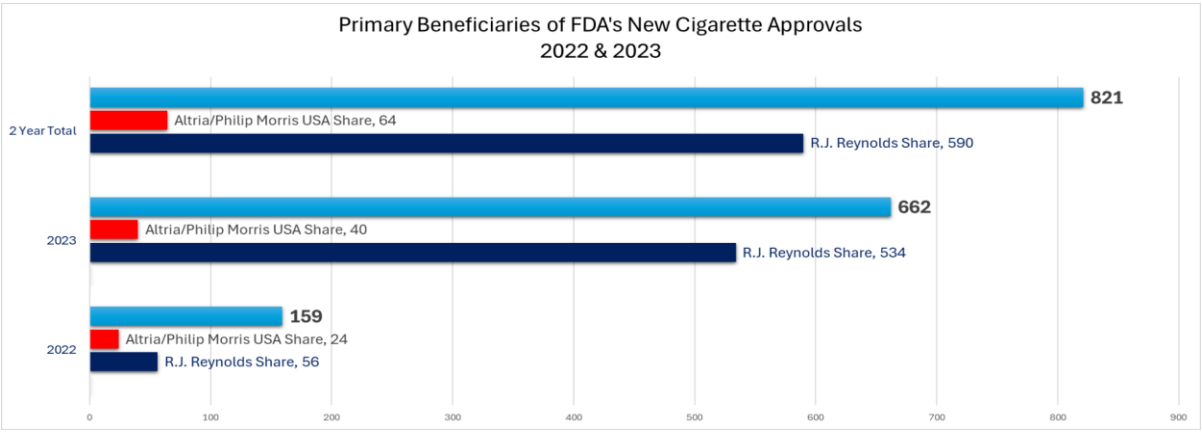
CTP Director Brian King has authorized the sale of 736 new cigarettes in the U.S. - 662 new cigarettes in 2023 alone!

The following shows the breakdown of all combustible tobacco products authorized in the last two years by Dr. Califf and Brian King.

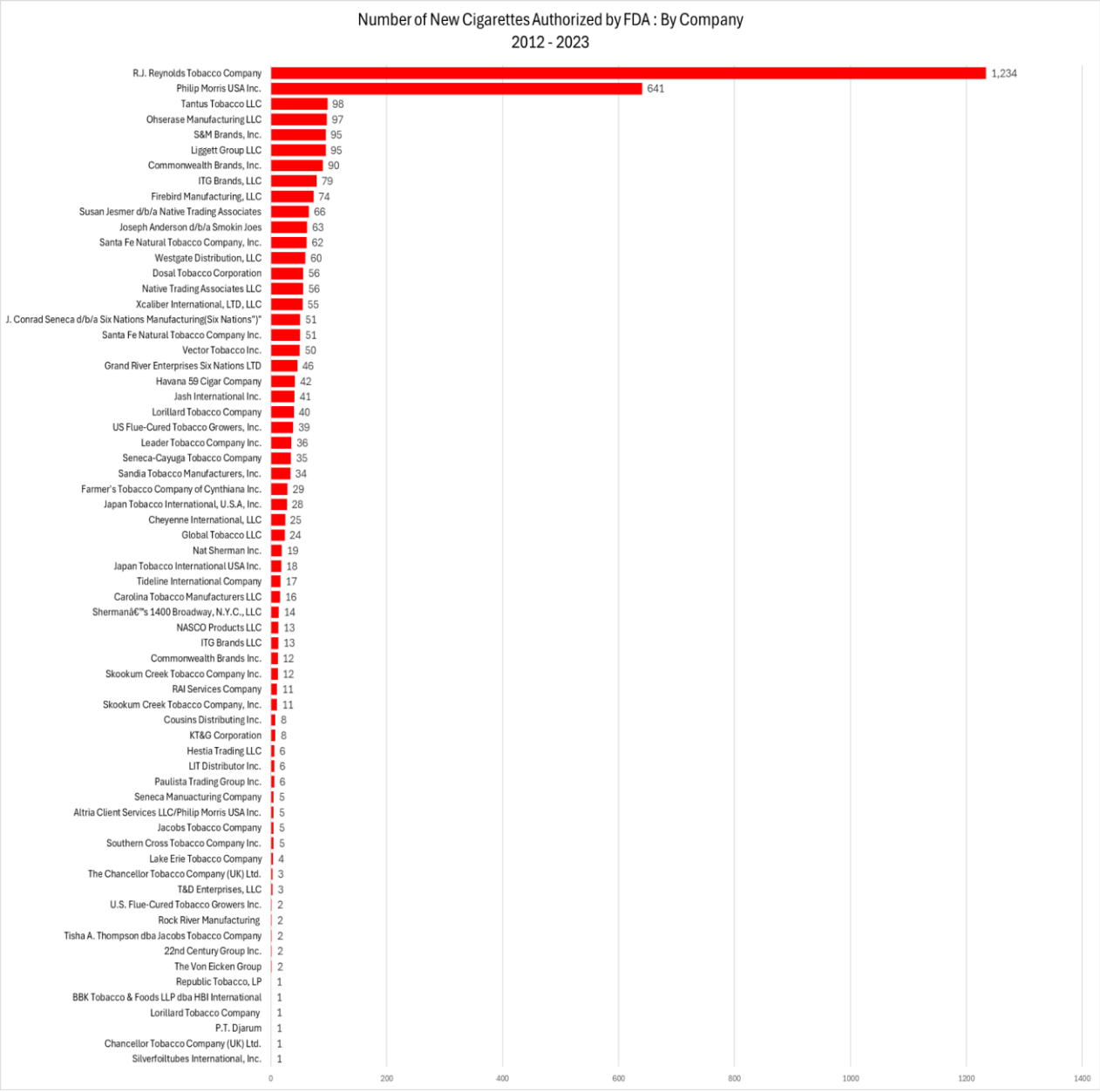


And the Winner is…Big Tobacco

In 2022 and 2023, Califf and King have satisfied the insatiable thirst for more and more new cigarettes by some of the biggest tobacco companies in the world. For example, of the remarkable 821 new cigarettes authorized for sale to U.S. consumers, R.J. Reynolds Tobacco Company, owned by international tobacco conglomerate British American Tobacco, has secured the lion's share - an incredible 590 new cigarettes representing 72% of the new cigarette approvals granted by Dr. Califf and Brian King.



Here is the breakdown of the number of new cigarettes that FDA has allowed by each company between 2012 and 2023.



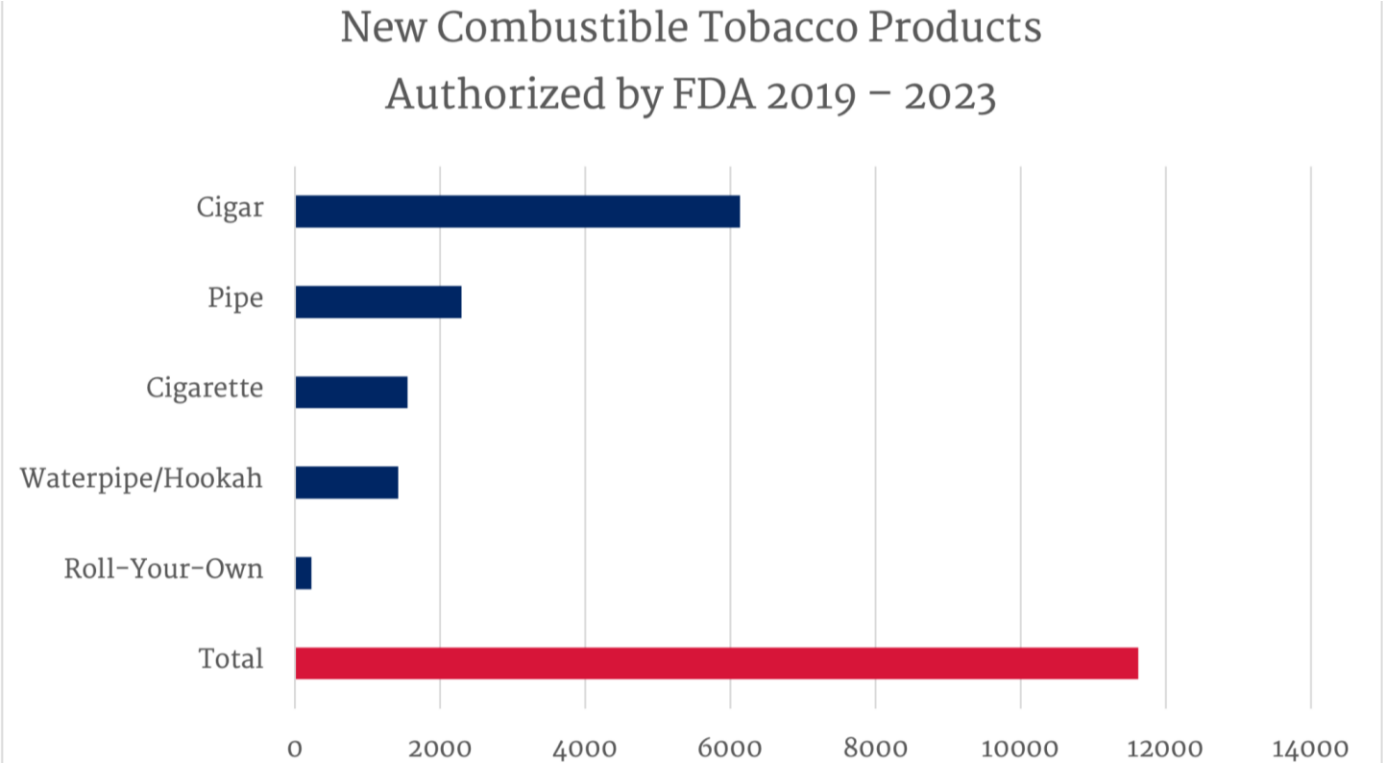
And the losers are….

Americans trying to quit smoking, American companies offering less harmful nicotine products, and everyone that believes in harm reduction. Under Dr. Califf and CTP Director Brian King, the FDA has refused to authorize a single premarket tobacco application for electronic nicotine delivery systems (ENDS) out of

millions of products for which PMTAs were submitted or a single modern oral nicotine product. These are products that are known to be dramatically less harmful than smoking cigarettes.

The Califf and King team has only seen fit to authorize three tobacco Marlboro HeatSticks to be used in a heat-not-burn product that predates their appointments. Other than that, this FDA has steadfastly failed to authorize a single other less harmful non-combustible product, regardless of the risk profile, regardless of the delivery mechanism, and regardless of the flavor.

All told, in just the last five years (2019 – 2023), FDA has fast tracked to market more than 11,600 combustible tobacco products. Of these, 1,547 were new cigarettes, 6,128 were new cigars, and 1,420 were new hookah tobacco products, so many of which were flavored.



The question is two-fold: Why is FDA still aggressively allowing new cigarettes to be brought to market today 16 years after the TCA took effect and why isn't the FDA filling the market with a plethora of new, less harmful flavored e-cigarettes and modern oral nicotine pouches that Americans are demanding?

About VTA

The Vapor Technology Association is the U.S. industry trade association whose members are dedicated to innovating and selling high-quality vapor and modern oral nicotine products that provide adult smokers with a better alternative to combustible cigarettes. VTA represents the industry-leading manufacturers of vapor devices, e-liquids, and flavorings, as well as the distributors and retailers, including hardworking American mom-and-pop brick-and-mortar retail store owners.

Sign up for the monthly VTA Insider and stay informed of critical issues impacting the vaping industry and nicotine products.