MITCH ZELLER
Head Of the Center For Tobacco Products

THE FDA ATTEMPTS TO KILL THE HOPE OF VAPE

By **TONY ABBOUD**
National Legislative Director, Vapor Technology Association (VTA)

On May 10, 2016, the FDA issued its long-awaited Deeming Regulation ushering in a brand new era of backwards thinking on technology and public health. The FDA simply ignored all of our industry's comments on their proposed regulations, giving little consideration to the advances in vapor technology, the industry's survival as a whole, or the broader objective of advancing public health.

Instead, with great fanfare, the FDA appeared from behind the curtain, stood before the cameras and declared that after more than two years of contemplation, they were proud to announce their "new" rules. Let's be clear: there is nothing "new" about the FDA's antiquated regulations which perpetuate in the worst way the notion that "we regulate because we can."In all likelihood, the FDA knows that its "new" rules could very well jeopardize public health. All you need to do is read the public statements about the potential positive impact that vapor products could have on the individual and the population that are made by FDA leadership.In fact, the FDA's own Mitch Zeller, a life-long anti-smoking advocate, appeared before a Senate Health, Education, Labor and Pensions Committee and testified, "If we could get all those people [who smoke] to completely switch all of their cigarettes to noncombustible cigarettes, it would be good for public health."

So, let's ask a few basic questions: Why now? What were they thinking? And, what are WE going to do about it.

WHY NOW?

Why after two-plus years did the FDA act on May 5, 2016? Well, frankly, the FDA couldn't handle yet another major medical group's pronouncement that, based on an extensive review of all the available scientific, peer-reviewed literature,the risk profile of vapor products is no more than 5%, and probably substantially less than 5% when compared to the risk profile of tobacco cigarettes. And, the FDA couldn't risk another report from Public Health England – Great Britain's equivalent of our Department of Health and Human

Services –proclaiming for a third year in a row that, based on their independent scientific review of all the research, that we should be promoting rather than quashing the hope of vapor products. Knowing that more and more public health voices would continue to undercut their planned adverse action against the entire vapor industry, the FDA had to act.

Less than one month after the Royal College of Physician's latest declaration that vapor products are, by all accepted standards, safe enough to be relied upon by millions of addicted smokers, the FDA stood before the cameras to announce their "new" rules. Remarkably, they did not lead with the proclamation that today was a great day for public health. Rather, they used the oldest play in the book claiming that their rules will protect the children.

In some of the very first words uttered at their press conference, the FDA proclaimed that they were going to protect youth by banning the sale of vapor products to minors. But, the FDA failed to mention that virtually every state already bans sales to minors. In the same breath, the FDA proclaimed that its"new" rules will protect children by implementing in Augustchild resistant packaging requirements. But, once again, the FDA failed to mention that, with the help of the vapor industry, Congress already made child resistant packaging the law of the land effective July 1 of this year. Given the real negative impact that the Deeming could have on public health, it is obvious why the FDA took credit for protecting youth in ways that they already are protected, especially when you consider the Royal College's conclusion that vapor products are NOT a gateway to traditional tobacco.

WHAT WERE THEY THINKING?

Instead, the FDA has targeted for extinction the overwhelming majority of companies that manufacture or supply vapor products to millions of adult smokers. At best, the FDA's "new" rules demonstrate callousness to the millions of adult consumers of cigarettes by eradicating consumer choice. At worst, the FDA's "new" rules directly threaten the health and well-being of millions of Americans by first wiping out a decade of technological innovation and then forcing consumers who rely on these products to choose between returning to traditional tobacco cigarettes or living off of what could become a robust black market.Not only is the FDA's recent action a dereliction of its duty to the public, the "new" rules reflect just how ill-equipped FDA is to regulate microchips, electronic circuits, and batteries. Truly, given all that went into the Deeming, FDA has demonstrated a significant lack of vision for how to regulate a revolutionary technology, much less some of the most innovative companies in the world that are driving that technology forward. You see, FDA's rules work for cigarettes because, for more than four decades, the only "innovation" in that segment has been the introduction of a filter.

To say that the FDA is ill-equipped to handle the very regulations it has chosen to implement is an understatement. The FDA is sitting on 3,500 provisional substantial equivalence applications that have been filed and for tobacco products that are currently on the market. These applications, which have not been ruled on by FDA, have been pending for up to 5 years. To make matters worse, through FY2015, an additional 2,000 new substantial equivalence applications have been languishing at the FDA awaiting a decision. Now, if the FDA gets its wish, vapor companies will be submitting tens (perhaps hundreds) of thousands of substantial equivalence and premarket tobacco product applications (PMTAs) for FDA review. Putting aside the fact that these applications create an unprecedented paperwork burden on small businesses, they will create an avalanche of requests the FDA will simply be unable to process, especially in the mere 12 months that the FDA has given itself to do so. Remember, only recently was the FDA able to rule on its first PMTA for products which were already well-known and for which there was already extensive population-based research, in a product category familiar to the agency.

SO, WHAT DO WE DO NOW?

Without changing the predicate date, the vapor industry as we know it will move from deemed to doomed. Literally, thousands upon thousands of small businesses, a/k/a job creators, will be forced to shut their doors. Fortunately, we already have the Cole-Bishop Amendment, which cleared its first major hurdle in Congress on April 19, 2016. During a mark-up of the Agriculture, Rural Development, Food and Drug Administration bill, Representatives Tom Cole (R-OK) and Sanford Bishop (D-GA) offered a bipartisan approach that would accomplish the goal of protecting small businesses and preserving the industry, while setting the stage for commonsense regulations that will protect youth and ensure the safety of consumers. This is exactly the type of legislative solution that we need. Unlike the FDA's one-size-fits-all approach, the Cole-Bishop approach seeks to regulate vapor products as the new technology they are, not as the tobacco products that they are not.

As of this writing, the Cole-Bishop Amendment is the only immediate vehicle that can change the predicate date to save the vapor industry. The Cole-Bishop Amendment brings the predicate date forward to 2016, thereby enabling everyone to continue to sell and buy existing products on the market. This is why we have consistently been calling for all to support Rep. Cole and Rep. Bishop's bipartisan amendment with the loudest voice our collective vapor community can muster.

This is and has always been the first phase of saving vapor and protecting consumers. If passed as part of the Agricultural Appropriations bill, the Cole-Bishop Amendment will literally keep everyone in business and immediately implement common-sense regulations that will protect consumers and youth. Our living, breathing industry, even if curtailed somewhat by the spectre of a suffocating Deeming, still will be vibrant and empowered to carry on the fight. Then, as the FDA continues to try to slam the proverbial square peg into the round hole, we will embark on something as innovative as our products: crafting and passing a rational regulatory regime that promotes innovation and technology and that protects adult consumers and youth alike. At the same time, we will expose the remarkably unfair status quo in which our new game-changing technologies are treated farworse thanall forms of combustible tobacco products.

We are built for this battle. We are up to the task. Join us in this fight!

VTA

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