



THE IMPORTANCE OF COLE-BISHOP & CHANGING THE PREDICATE DATE

WHY CHANGE THE PREDICATE DATE?

1. The vapor industry is at a critical juncture where manufacturing companies will be forced to spend tens of millions of dollars on PMTAs just to keep pre-8/8/16 products on the market.
2. Right now, vapor has NO grandfathered products since there were no vapor products on the market on February 15, 2007 (the current grandfather date).
3. Cole-Bishop would change the February 15, 2007 grandfather date (aka "predicate date") to August 8, 2016, thereby allowing all pre-8/8 products to be grandfathered in and serve as "predicate products" going forward.

Why is this important? Once we've established all those pre-8/8/16 products as *predicate products*, your company will save millions of dollars because they will be able to take advantage of the Substantial Equivalence (SE) pathway, rather than the Pre-Market Tobacco Application pathway (PMTA) to get NEW products approved.

Unlike PMTA, the SE pathway is much less expensive and is legally available to all companies with predicate products. The standard for SE is that the new product must have the same characteristics as a predicate product or has *different* characteristics but does not raise different questions of public health. This standard is considered to be significantly less burdensome than the PMTA standard, i.e., that the product in question is *appropriate* for the public health.

So, rather than spending millions on highly subjective PMTAs – which few companies (big or small, tobacco or vapor) may get approved by the FDA – manufacturers could spend their dollars investing in new product innovation and substantial equivalence applications.

Bottom-line Questions for Company Leaders and Financial Backers

- Do you want to lock in cash flow generated by all your pre-8/8 products by grandfathering?
- Do you want to your company to keep millions of dollars in your pocket?
- Wouldn't you prefer to spend your money on innovating *new products*, not PMTAs?
- Do you want to have a chance to compete by bringing innovative products to market by proving them to be substantially equivalent to your pre-8/8 products?
- Do you want to continue building on success in Washington, D.C.?

Frequently Asked Questions

What if We Don't Support Cole-Bishop Now? Abandoning Cole-Bishop now would be a direct affront to the powerful Members of Congress who have stepped up to champion our issue. Blindsiding these champions or "walking away" will only make them less likely to want to help our industry going forward. In addition, it would make the vapor industry appear confused, fractured, and immature.

Cole-Bishop FAQ (continued)



Doesn't the FDA's Deadline Delay Solve This Problem? No. Anyone who thinks the delay is the answer is wrong. The delay only allows FDA time to come up with its foundational rules, aka regulations, for the various pathways to market, which may provide clarity but may not mitigate the burdens on manufacturers. Securing this change now will provide insurance against other potential negative changes that may come.

Is Cole-Bishop Likely to Eliminate Flavors? No. This is a red herring. Cole-Bishop says NOTHING about banning flavors. On December 11, 2017, FDA sent to the Office of Management and Budget its Advanced Notice of Proposed Rule Making (ANPRM) regarding flavors. Cole-Bishop only tells FDA to do what FDA already has decided to do: conduct a regulatory process on flavors. The language sets out a timeline; however, agencies tend to operate under their own timelines when promulgating rules.

Will Cole-Bishop "speed up" the flavor regulation? No. It is extremely unlikely that FDA's rulemaking process will be completed by 2020 whether Congress dictates that or not. The science which they are required to develop takes time. Again, FDA just initiated its ANPRM on flavors which means they have elected to take the longest potential regulatory path on the issue. This first step is simply an information-gathering process, during which we as stakeholders must weigh in about the importance of flavors. There are plenty of "deadlines" set by Congress which FDA in its discretion does not meet.

Won't Congress Just "Mark Up" Cole-Bishop to Ban Flavors Before Passage? Again, no. Congress doesn't "mark-up" the Appropriations package. Fact: the House Appropriations bill already went through mark up and our industry's language predicate date language was included. Fact: the Senate Appropriations bill already has been "marked up" and does not include this language. House and Senate conferees will negotiate whether to include the predicate date section or not, and there is no reason to believe that negotiators would insert a flavor ban. FDA already is working on a rulemaking on this issue and Congress generally will not step in front of an agency in this way.

Don't We Have to Choose to Support HR 2194 Instead of Cole-Bishop? No. These two pieces of legislation are NOT mutually exclusive so why choose one over the other? Also, why tear down one strategy that the entire vapor industry has been working on for 3 years, and which is moving forward with support from powerful members of Congress, just to try something different? The biggest difference between HR 1136/Cole-Bishop and HR 2194 is their path. Cole-Bishop has been passed by the full House of Representatives via the House FY2018 Agriculture Appropriations bill. Cole-Bishop is currently in the mix for the must-pass spending package. HR 2194 has not been scheduled for a hearing and, unless a bill has the force of something like tax reform, there are not enough days on the Congressional calendar to pass a stand-alone bill in 2018.

Shouldn't We Be Aiming Higher than Changing the Predicate Date? You can aim anywhere you want, but strong beliefs alone won't achieve anything. There must be a viable industry strategy to hit any target. Changing the predicate date is an important first step in a longer-range plan to provide for sensible regulation of the vapor industry. Frankly, it is unlikely (at best) that a complete overhaul of the Tobacco Control Act will occur in a timeframe that will be helpful absent a predicate date change.

Will Cole-Bishop Devastate the Industry? No. If that were the case, why would all of the major vapor industry and consumer associations, including AVA, CASAA and SFATA, be supporting it?

Can't Cole-Bishop Be Easily Changed in Other Appropriations Bills? No. Cole-Bishop's language says: "None of the funds appropriated or otherwise made available by this Act or any other Act with respect to any fiscal year..." Regardless, nothing that happens in Congress is easy.