# Equity Research

# Good For the Goose, Less For the Gander

New Rules of Engagement Set To Benefit MO and RAI

- The August 8th "Freeze Date" Has Arrived! E-Cig/Vapor Industry Chafes At The New Rules of Engagement That Stifle Innovation -MO/RAI Actively "Engage" With the FDA Supporting Hope for Potential Industry-Friendly Changes - While the final deeming e-cig regulation brings much needed structure and oversight to the e-cig/vapor category, there is little doubt that the cost and complexity of compliance overwhelmingly favor big tobacco (the goose) at the expense of smaller, less wellfunded players (the gander). MO and RAI are, as expected, ahead of the game with RAI having launched "numerous" VUSE formats ahead of today's Aug 8 deadline - the date after which no new products can be sold without FDA authorization, and MO persuading the FDA to not enforce a descriptor ban on its Black & Mild cigar brand, demonstrating its command of the issues and legal acumen. As industry leaders, MO & RAI are actively engaged with the FDA on a number of critical issues that could have longstanding effects on innovation, the promotion of healthy competition, and ultimately consumer choice. Bottom line Both MO & RAI appear well prepared to comply with the FDA's deeming regs, if not benefit from potential category consolidation. That said, the companies are rightfully taking the longer view as they actively work with the FDA to ensure a rich environment for innovation and healthy competition. As such, we reiterate our Overweight sector rating and Outperform ratings on RAI given its strong VUSE positioning, and MO given its opportunity with iQOS.
- FDA "Open" to Hearing Top Industry Concerns Stifles Innovation, Restrictive Predicate Date, Disregards 'Continuum of Risk' Principle – In addition to multiple lawsuits and legislative action pending, we believe MO & RAI lend considerable weight to current stakeholder discussions with the FDA to rethink some of the more strident areas of the regulation. We were pleased to hear <u>both companies reporting that the FDA is "open to listening," "not immune,"</u> and "more straightforward" than it would appear. As such, we are increasingly optimistic that the ultimate outcome won't be as deleterious to the category or as burdensome as we originally feared.
- Further Implications of Deeming Regs: (1) We expect to see a continued shift in consumption of e-cigs/vapor back to combustible cigs as e-cig choices become more limited -- a net 'win' for big tobacco. This has continued to baffle us given the FDA's public health priorities. (2) We expect further e-cig/vapor consolidation and, as a result, manufacturers' pricing power and retail leverage to increase with MO and RAI best positioned given their scale and capabilities. (3) We expect increased, but manageable, timing risk for MO to be able to commercialize iQOS by late FY17/early FY18 assuming its premarket tobacco application (PMTA) is approved given PM & MO's active dialogue with the FDA.
- As Is, Deeming Regs Are A Clear 'Win' For Big Tobacco, Not Necessarily Public Health – Our main concern remains that the final deeming e-cig regs will realistically stifle innovation, which could dramatically slow industry growth by dis-incentivizing consumer conversion from combustible cigs to e-cigs. This ultimately has a net negative impact on public health, which is clearly in direct opposition to the FDA's goal. However, we have reason to be more optimistic given actions being taken by both MO & RAI to soften the current limitations of the deeming regs on innovation.

#### Please see page 7 for rating definitions, important disclosures and required analyst certifications All estimates/forecasts are as of 08/08/16 unless otherwise stated.

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### Together we'll go far



### **New Rules of Engagement**

Since the FDA issued in May its final deeming rule to extend regulatory oversight to all tobacco products, tobacco manufacturers have been under enormous pressure to: (1) get new products out the door into market or test market ahead of today's **August 8** effective date -- the date after which no new products can be sold without FDA authorization, and (2) get started on preparing either Substantial Equivalence (SE) exemption requests or Premarket Tobacco Applications (PMTA), which start to become due in 2018, to keep products in the market (see our Deeming Regs application timeline chart below). Given the Aug 8 effective date has arrived and that MO and RAI have both reported Q2 results, we thought an update was in order on where the industry and MO and RAI, in particular, stand with regard to the FDA's new "rules of engagement."

First off, we believe the sweep of the new regulation has been a real blow to the broader vapor industry, particularly smaller, less well-funded players, and innovation more broadly, given the costly and time consuming requirements and because innovation will likely be stifled. While perhaps not hugely evident yet, we believe many small industry players will be forced out of business as a result which has been foreshadowed by several announced leadership departures at many companies and industry/trade groups. Those left standing, may seek "white knights" or consolidation in an attempt to build a stronger, more survivable competitive platform. Large, well-funded manufacturers such as MO (MO, 1, \$66.22) and RAI (RAI, 1, \$49.22), however, are doing well (no surprise). Their key vapor brands (RAI's VUSE, MO's MarkTen XL) continue to receive critical investment and marketing/distribution support and are among the few vapor brands thriving, which is evident in recent Nielsen measured channel data and feedback in our "Tobacco Talk" retailer survey (see charts below).

### RAI Appears Well Prepared; We Expect VUSE To Be A Primary Beneficiary of Deeming Regs

RAI continues to invest behind its VUSE platform and has reportedly launched "numerous" formats ahead of today's Aug 8 deadline to ensure that it will "have choices to work with the [FDA] on potentially rolling those out" in compliance with the final deeming regulations. In the meantime, VUSE continues to grow with volume "significantly up." Suffice it to say, RAI is "very pleased" with the brand and we see no reason it won't continue to succeed in the new regulatory environment, if not benefit from it.

### MO Equally Prepared, Working on FDA Compliance, Proceeding with "Financial Discipline"

MarkTen XL continues to show "encouraging" progress with retailers reporting a second round of "heavy" couponing helping to build trial awareness and sales. Nu Mark's distribution of the brand at retail now represents ~50% of e-vapor category volume with "very good marketplace response," according to MO. While feedback from our "Tobacco Talk" retailer contacts and Nielsen data corroborate the brand's strong relative performance (see charts below), it is still early days for the XL line extension, which is driving recent gains, and we expect MO to maintain financial discipline as it stages its rollout. On the FDA front, MO likewise reports itself to be "well-prepared" to meet requirements under the new regulations. Both Nu Mark and Middleton (MO's cigar business) are working on compliance and are actively engaging with FDA regulators and "other stakeholders" to advocate for changes to the regs.

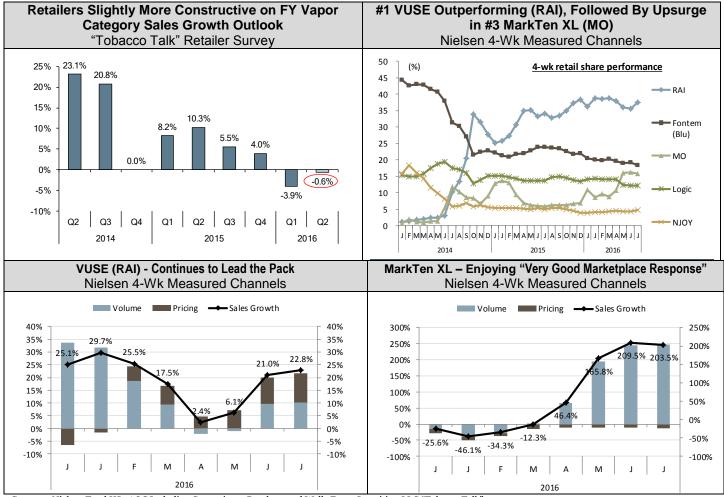
### MO/RAI Remain Actively "Engaged" With the FDA; Suggests Change Could Be Afoot

Both MO & RAI report active engagement with the FDA on a number of fronts, including: (1) clarification of the process, (2) preventing the new regs from stifling innovation, (3) amending the 2007 predicate date given that most vapor products currently sold "basically came into the marketplace after 2007," and (4) ensuring that the regs stay true to the underlying 'continuum of risk' principle espoused by FDA Tobacco Director Mitch Zeller: "Anyone who would ponder the endgame must acknowledge that the continuum of risk exists and pursue strategies that are designed to drive consumers from the most deadly and dangerous to the least harmful forms of nicotine delivery."

Short of lawsuits (the FDA is reportedly already facing many) and legislative action (namely, the Cole-Bishop Amendment) prevailing, we believe <u>MO & RAI lend considerable weight to current stakeholder discussions</u> with the FDA to rethink some of the more strident areas of the regulation. MO says it has found the FDA to be "open to listening to reasonable arguments" and "not immune from listening to different points of view and coming to some reasoned judgment." On a positive note, RAI reports "a lot of signaling" that suggests the FDA process will be "more straightforward" than previously feared. MO, for its part, has successfully persuaded the FDA to not enforce a descriptor ban on its Black & Mild cigar brand (The FDA had purported that deeming regs' ban on cigarettes from using the terms "mild," "light" and "low" on product labels extended to cigars). We believe the implications will be far-reaching in that the matter demonstrated MO's clear command of the issues, influence and legal acumen relative to the FDA. Given MO & RAI's interest in growing the industry, we expect they will play an active role in any regulatory reshaping that occurs.

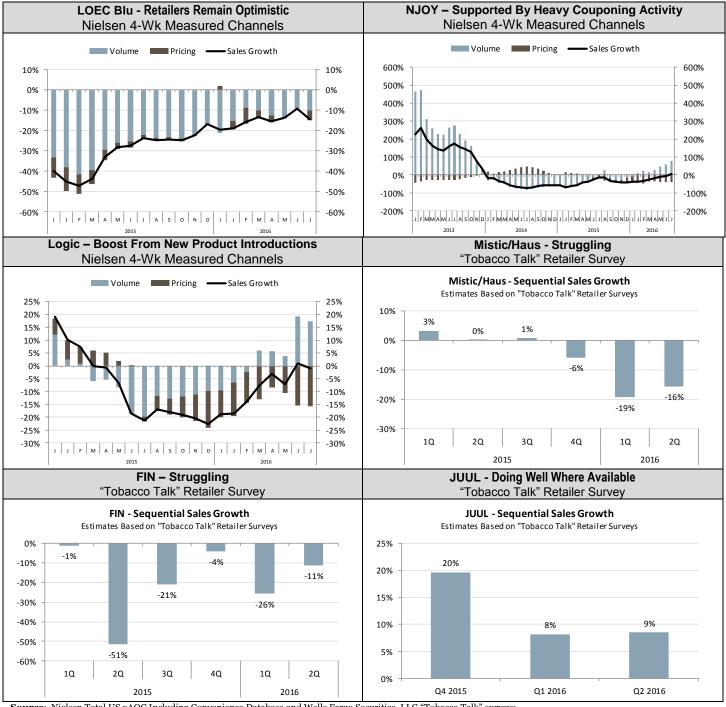
### No Sign of Speedbumps for iQOS Commercialization

We were pleased to hear from MO that plans are on track for PM (PM, 1, \$99.14) to submit its FDA applications for pre-market authorization (PMTA) and a modified-risk tobacco product (MRTP) designation for iQOS by year end with "excellent progress" being made on commercialization strategies. As such, we continue to expect iQOS to hit store shelves as early as late 2017/early 2018 without a health claim assuming the application is filed in late 3Q16/early 4Q16. As such, we continue to expect iQOS to add \$10/shr to MO, which we believe is not entirely captured in MO's current share price. To briefly reiterate our conclusions from our March 9, 2016 note, "PM – Changing the World One Smoker at a Time," we believe: (1) iQOS will accelerate MO's operating profits by 260bps to a 9% CAGR and MO's EPS by 250bps to a 10% CAGR in the next decade; (2) iQOS could displace up to 30% of the U.S. combustible cig industry by 2025, increase smoking prevalence and accelerate the premiumization of the overall market; and (3) iQOS could add incremental value of \$10 per share for MO, which we believe is being underestimated.



Source: Nielsen Total US xAOC Including Convenience Database and Wells Fargo Securities, LLC "Tobacco Talk" surveys





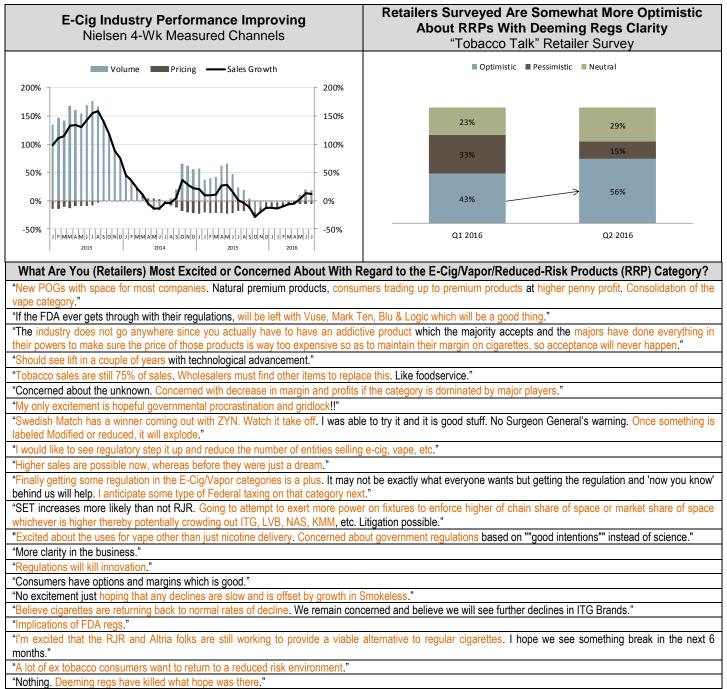
Source: Nielsen Total US xAOC Including Convenience Database and Wells Fargo Securities, LLC "Tobacco Talk" surveys

### **Retailers** Increasingly Optimistic About Reduced-Risk Products (RRPs)

In the meantime, retailer sentiment on the vapor category and the future of RRPs continues to improve. In general, retailers see deeming regs leading to further consolidation within the industry which should weed out non-viable players and aid category management. They also see the regs putting more 'power' in the hands of the few (i.e., well-funded, big tobacco), which could leave retailers at a disadvantage in terms of contract negotiation and, ultimately, margin/profits.

While MO holds the advantage, we believe, on RRPs with PM in its corner, **the challenge**, we think, for RAI is to articulate where it sees itself on the spectrum of broader RRP development and how it's positioning itself to

be able to fully participate in light of strong science-backed advances by PM (iQOS) and the eventual commercialization of iQOS in the U.S. by MO.



Source: Wells Fargo Securities, LLC "Tobacco Talk" Retailer Surveys

**Clarity on Timing & Review of Applications to the FDA -** In terms of timing and process, there are three essential 'pathways' to obtain FDA approval with the official 'clock' starting today, the effective date – the first two being not terribly viable options. Manufacturers can file for: (1) a substantial equivalence (SE) exemption, (2) an SE determination, or (3) a Premarket Tobacco Application (PMTA). The first two are the least burdensome pathways, but are for all intents and purposes not viable for most companies as they require new products to be based on a "predicate" product that is substantially equivalent to the new product having been on the market before February 15, 2007 (the "predicate date" or "grandfather" date). The problem is that there were very few e-cig/vapor products on the market before February 15, 2007. We count only a handful,

including RAI's original heat-not-burn *Eclipse* product (launched in the 1990s), Brown & Williamson's *Advance Lights* (test marketed in 2001), and Vector Tobacco's *Omni* brand (launched in the early 2000's). Furthermore, we find it interesting that February 15, 2007 was set as the predicate date as it was originally set as the predicate date for the Tobacco Control Act of 2009. **Bottom line – Whether intended to or not, we believe the FDA has effectively (even if inadvertently) engaged in a form of protectionism that favors big tobacco/combustible cigs, shielding the top players from incursions by smaller players and thereby stifling much-needed competition.** 

Key Deeming Reg Compliance Dates						
Month	Inductor Doodlings*	Event/Filing Bathway	Meaning	Ultimate Deadline For FDA Decision	Our Comment	
0	August 8, 2016		Introducing new Companies are prohibited from <b>(1)</b> introducing new products into the market and <b>(2)</b> making changes to existing products without formal FDA approval		Largely viewed to be an arbitrary date. But after this date, not even small changes to products will be allowed. Fo example, not even a battery upgrade that would improve the safety of the product would be allowed	
12	August 8, 2017	(SE) <u>exemption</u> filing deadline	Companies may request to be exempt from the FDA process if they had a "predicate" product on the market prior to <b>Feb 15, 2007</b> (the "predicate date" or "grandfather" date) that is <u>for all intents and purposes the same</u> ("substantially equivalent") as the product under consideration	August 8, 2018	One of two "least burdensome pathways" to FDA approval, but won't apply to the vast majority of manufacturers as there were very few vapor products in existence in 2007.	
18	February 8, 2018	(SE) application filing	Companies filing for this determination would need to show that their new products are <u>similar</u> to a predicate product on the market in 2007	February 8, 2019	Also a least burdensome pathway, but again very few companies will meet thi threshold We can think of just a handful, including <b>(1)</b> RAI's original hear not-burn <i>Eclipse</i> product (marketed in the 1990s), <b>(2)</b> Brown & Williamson's <i>Advance Lights</i> , and <b>(3)</b> Vector Tobacco's <i>Omni</i> brand	
24	August 8, 2018	Premarket Tobacco Application (PMTA) application filing deadline	Full, new product application	August 8, 2019	Expected to be prohibitively expensive for all but the most deep-pocketed manufacturers, i.e., big tobacco	

Source: FDA, Wells Fargo Securities, LLC

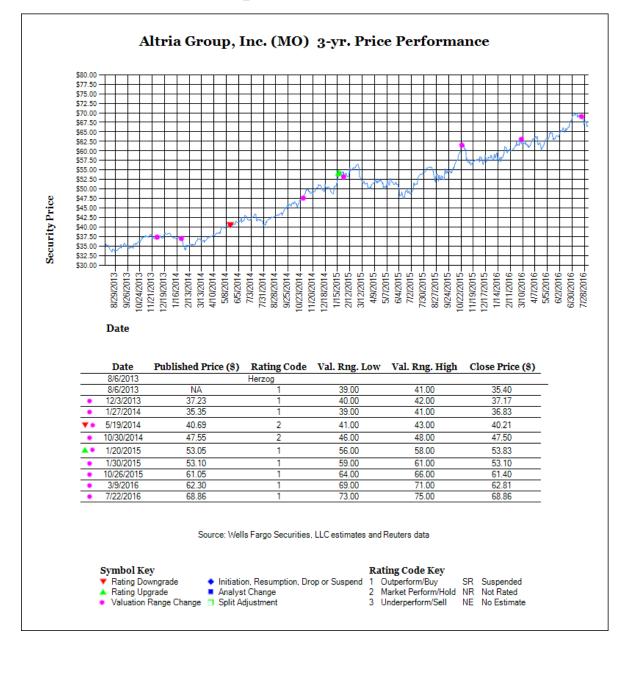
### **Rating Basis Information:**

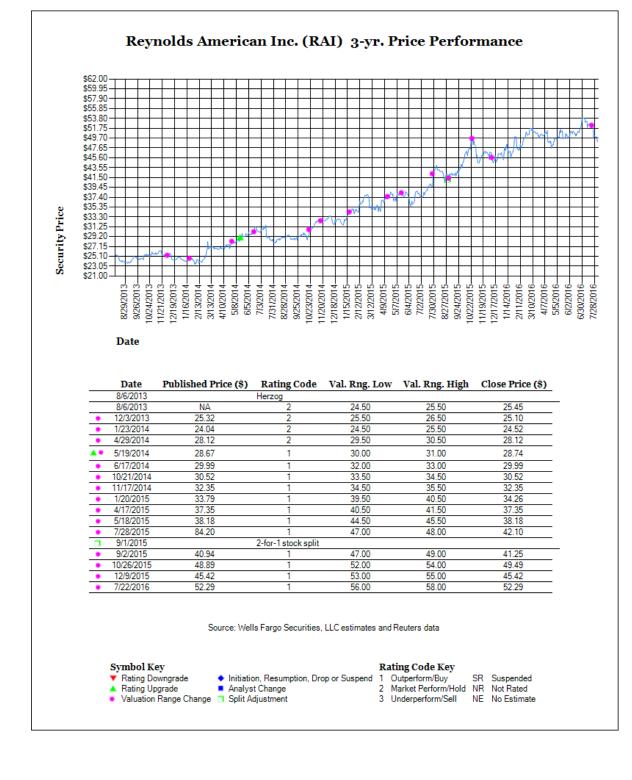
**MO Thesis:** We believe Altria is achieving a better balance between stabilizing Marlboro market share and growing profitably. We see further upside from strong pricing trends and potential of vapor that isn't currently reflected in the stock.

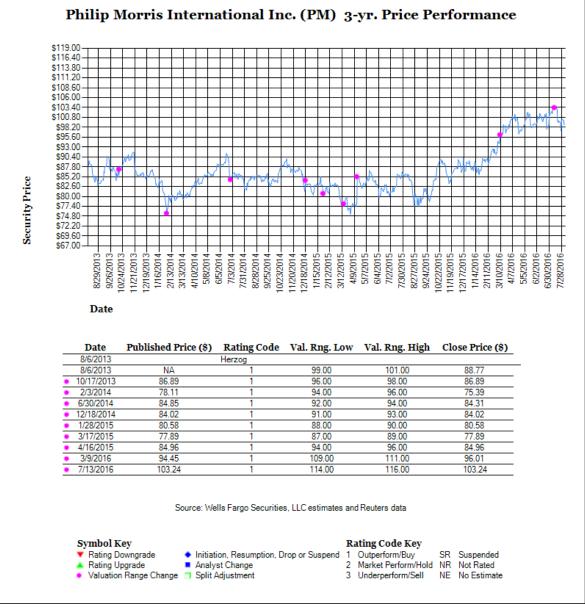
**PM Thesis:** We expect PM to outperform over the long term given its (1) superior and re-invigorated Marlboro brand franchise, (2) its industry-leading, diverse brand portfolio, and (3) its impressive ROIC and improving economic profit. PM has emerged in a class of its own and we believe it is poised for further growth.

**RAI Thesis:** We believe RAI has transformed itself into a more focused, total tobacco company, driven by innovation and a methodical approach to driving sustainable growth. We believe the stock has further upside potential given several growth drivers.

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**MO:** Risks include increased price competition and increased downtrading by consumers.

**PM:** Risks to our valuation range include currency fluctuations and a broad-based pullback in consumer spending.

RAI: Risks to our valuation include increased competitive pressure within the category and a pullback in consumer spending.

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