E-cigarette Use: Models and Data

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FDA: Public health standard

“Public health standard” calls for the review of the scientific evidence regarding

1. Risks and benefits of the tobacco product standard to the population as a whole, including both triers and non-triers of tobacco products;

2. Whether there is an increased or decreased likelihood that those who do not currently use tobacco products, most notably youth, will start to use tobacco products; and

3. Whether there is an increased or decreased likelihood that existing triers of tobacco products will stop using such products

Focus on Risks and Potential Gains from Switching to E-cigarettes

- **Considered two hypothetical scenarios involving rates of switching from cigarettes to e-cigarettes over a ten year period to the residual cigarette prevalence**
- **Projected from 2016 to 2100 by age and gender for US**
- **Model calculates cigarette and e-cigarette attributable deaths and life year lost**

Levy et al. 2017, Tobacco Control

The Two Scenarios

ASSUMPTIONS

OPTIMISTIC

1. Excess mortality risk of e-cigarettes at 5% that of cigarettes
2. Cessation from cigarettes and e-cigarettes at the 100% the rate of cigarette cessation pre-strategy
3. Initiation at the 100% the rate of cigarette initiation pre-strategy
4. Residual cigarette prevalence of 5% after 10 years

PESSIMISTIC

1. Excess mortality risk of e-cigarettes at 40% that of cigarettes
2. Cessation from cigarettes and e-cigarettes at the 50% the rate cigarette cessation pre-strategy
3. Initiation at the 150% the rate of cigarette initiation pre-strategy
4. Residual cigarette prevalence of 10% after 10 years

Status Quo and E-Cigarette Substitution, Premature Deaths and Life Years Lost For All US Cohorts, Males and Females Combined

OUTCOME	Year 2016	2026	2060	2080	2100	Cumulative (2016-2100)	Deaths Prevented/ Life Years Gained*	% Change relative to status quo
Status Quo Scenario								
Premature Deaths	461,588	470,743	316,556	167,037	2,905	26,065,448		
Life Years Lost	5,689,458	5,625,286	2,626,503	685,593	1,852	248,639,532		
Optimistic Scenario								
Premature Deaths	461,588	380,832	233,243	56,399	459	19,484,289	**6,581,159**	**-25.2%**
Life Years Lost	5,689,458	3,839,765	1,345,385	183,297	294	161,905,579	**86,733,953**	**-34.9%**
Pessimistic Scenario								
Premature Deaths	461,588	456,297	298,689	127,706	2,188	24,432,065	**1,633,383**	**-6.3%**
Life Years Lost	5,689,458	5,261,398	2,319,388	528,926	1,396	227,835,203	**20,804,329**	**-8.4%**

*** Life Years gained = Life years lost in Status Quo - Life years lost in E-cigarette Substitution Scenario**

Results and Implications

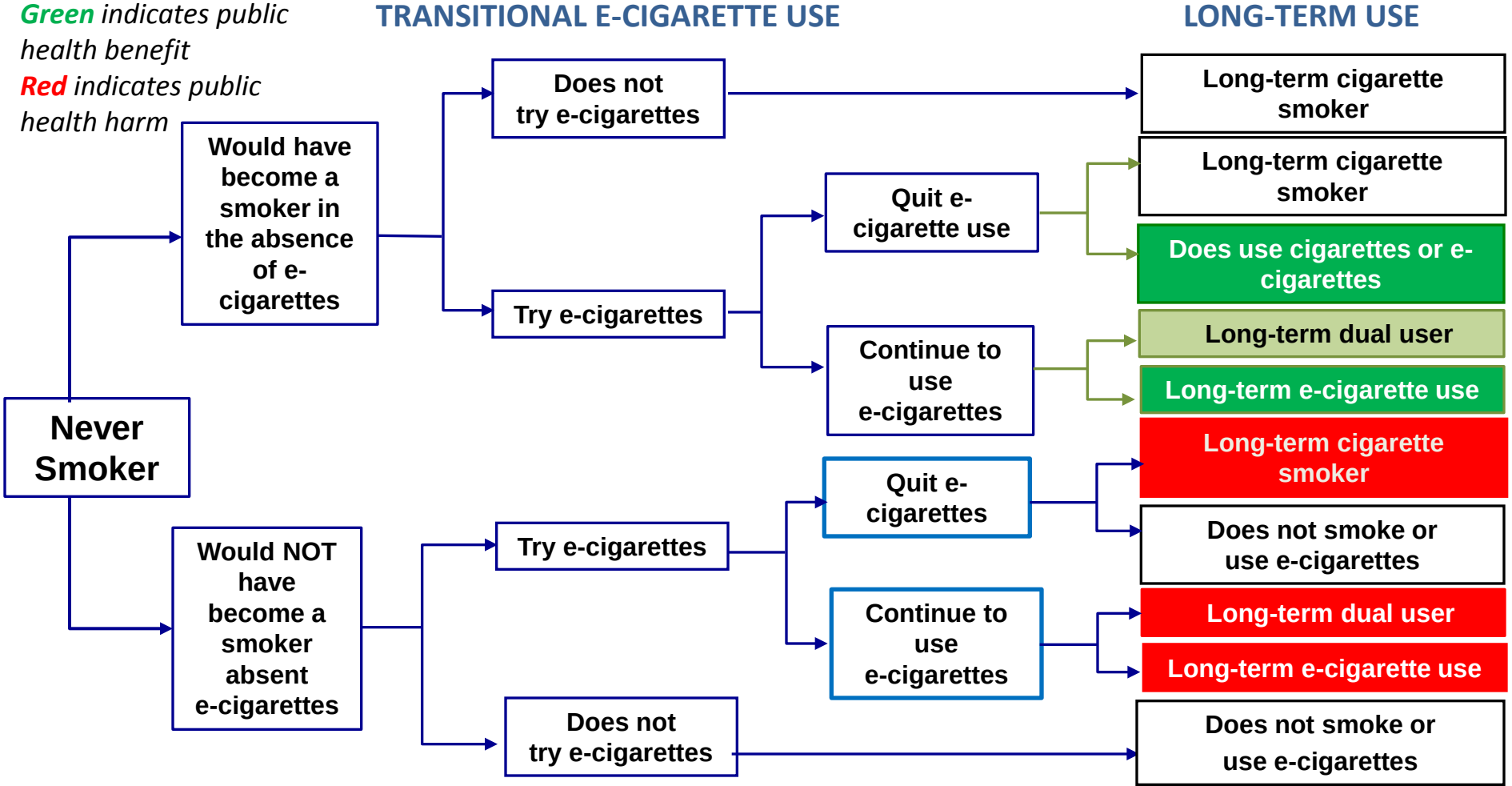
- Even under pessimistic (worst case scenario), there are gains from a strategy of encouraging switching from cigarettes to e-cigarettes
- Potential for major gains in optimistic scenario due primarily to the reduced risks of e-cigarettes relative to cigarettes

Predictive: Levy et al. Initiation Model (2017, Nicotine & Tob Res)

- Applies a decision-theoretic framework (Levy et al. 2017, Addiction) grounded in a public health approach to examine the effect of transitions to final states of established use. Unlike other models, focuses on a representative single cohort: age 15 in 2012
- Distinguishes trial use from established e-cigarette use
- With trial use, individuals may transition to: 1) exclusive e-cigarette use, 2) dual (cig and e-cig) use, 3) exclusive cigarette use, or 4) no use (e-cigarettes as transition to quitting both).
- Public health implications depend on the counterfactual of what would have happened in the absence of e-cigarette use

The Public Health Impact of E-cigarette Use Among Never Smokers

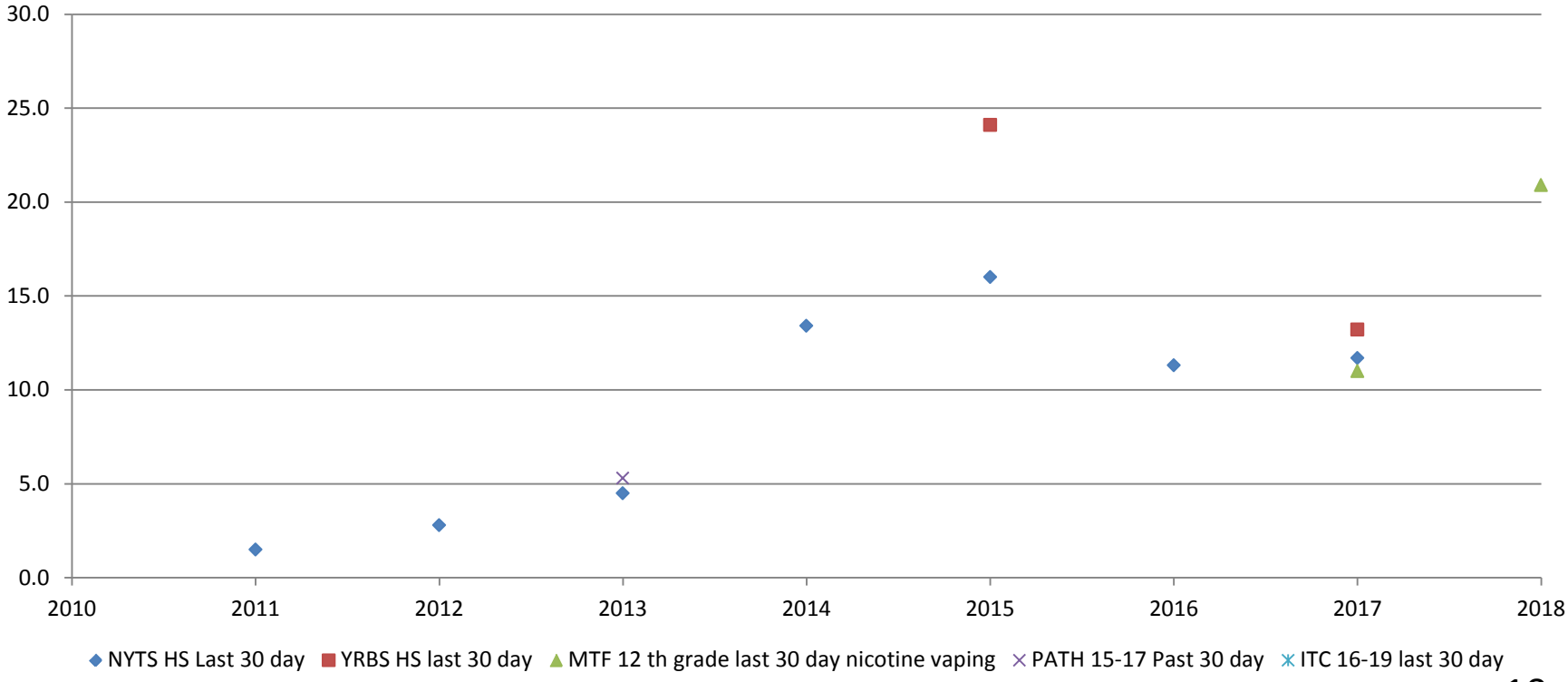
Green indicates public health benefit
Red indicates public health harm



Results: US Males for 1997 cohort

Scenario	Measure	Age	15	25	45	65	85	Cumulative Ages 15-85	Difference from Status Quo
Status quo	**Prevalence**	**Smoker**	4.6%	20.4%	12.7%	5.6%	1.1%		
	SADs		-	-	581	2,116	2,816	79,322	
	LYL		-	-	23,573	46,335	16,706	1,539,242	
Best	**Prevalence**	**Smoker**	2.8%	12.4%	7.7%	3.4%	0.6%		
		E-cigarette	1.3%	5.9%	3.7%	1.6%	0.3%		
		Dual	1.3%	5.9%	3.7%	1.6%	0.3%		
Low Risk	**SADs**		-	-	442	1,522	1,879	56,213	23,109
	LYL		-	-	17,921	33,313	11,147	1,112,151	427,091
Low-mid Estimate	**SADs**		-	-	480	1,653	2,041	61,058	18,264
	LYL		-	-	19,465	36,184	12,108	1,208,000	331,242
Medium Risk	**SADs**		-	-	514	1,769	2,185	65,365	13,958
	LYL		-	-	20,838	38,736	12,962	1,293,200	246,042
High risk	**SADs**		-	-	565	1,944	2,401	71,824	7,498
	LYL		-	-	22,898	42,564	14,243	1,421,000	118,242

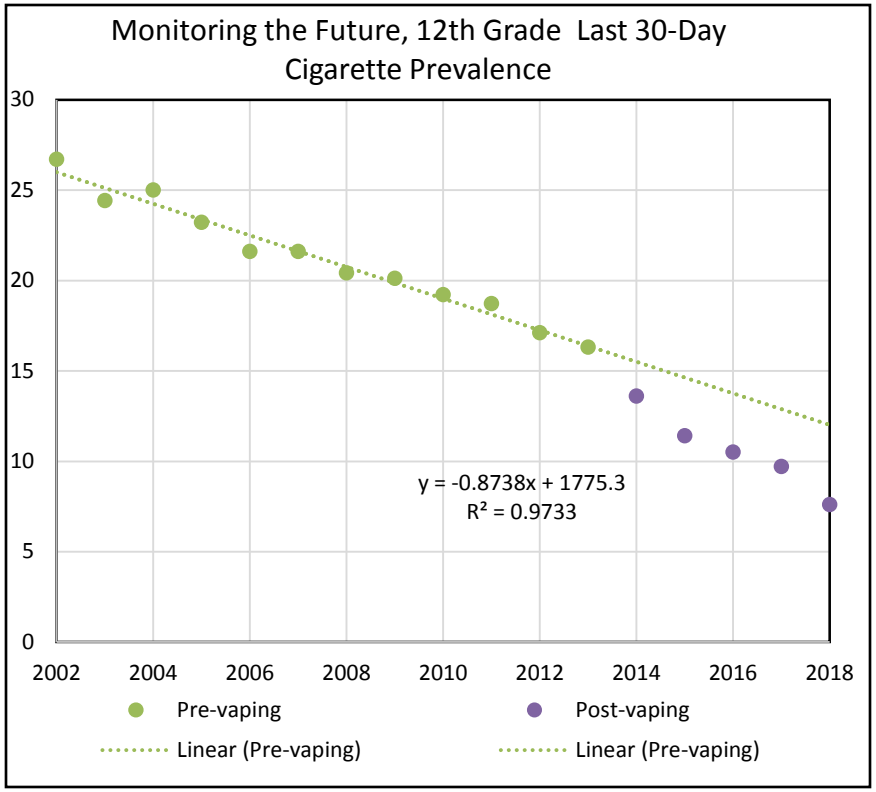
Youth Last 30 day E-cigarette Use- US

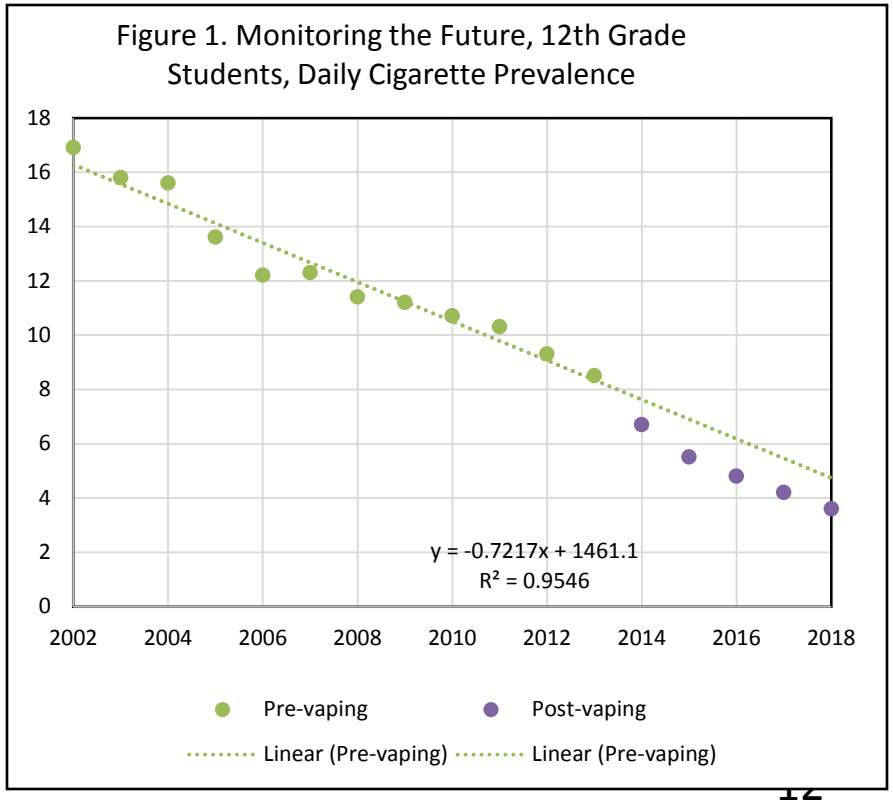


In Examining Past Behavior, Need to Focus on Useful Measures

- **Need to determine useful measures of experimental and long-term use**
  - **NYTS 2017 only 17.4% of past 30 day use 20+ day, (Jamal et al. MMWR 2018), YRBS (MMWR 2018) 25% of past 30 day users use 20+ days, earlier studies by Warner et al (AJPM 2015), Farsolinos (AJPM 2017) and Villanti et al. (NTR 2017) indicate even lower rates of regular use**
  - **Rates are much higher among current than never smokers**
  - **Hair et al. (NTR, 2018) indicate unstable transitions over time for young adults**
- **Use will vary over time**
  - **Awareness and perceived risk**
  - **Previous experience with products with differing appeal, ability to satisfy cravings, E.g., Juul => cohort is important**
  - **Differing policies, especially price of e-cigs relative to cigarettes**

Trends in Smoking (2014-2017 vaping period)

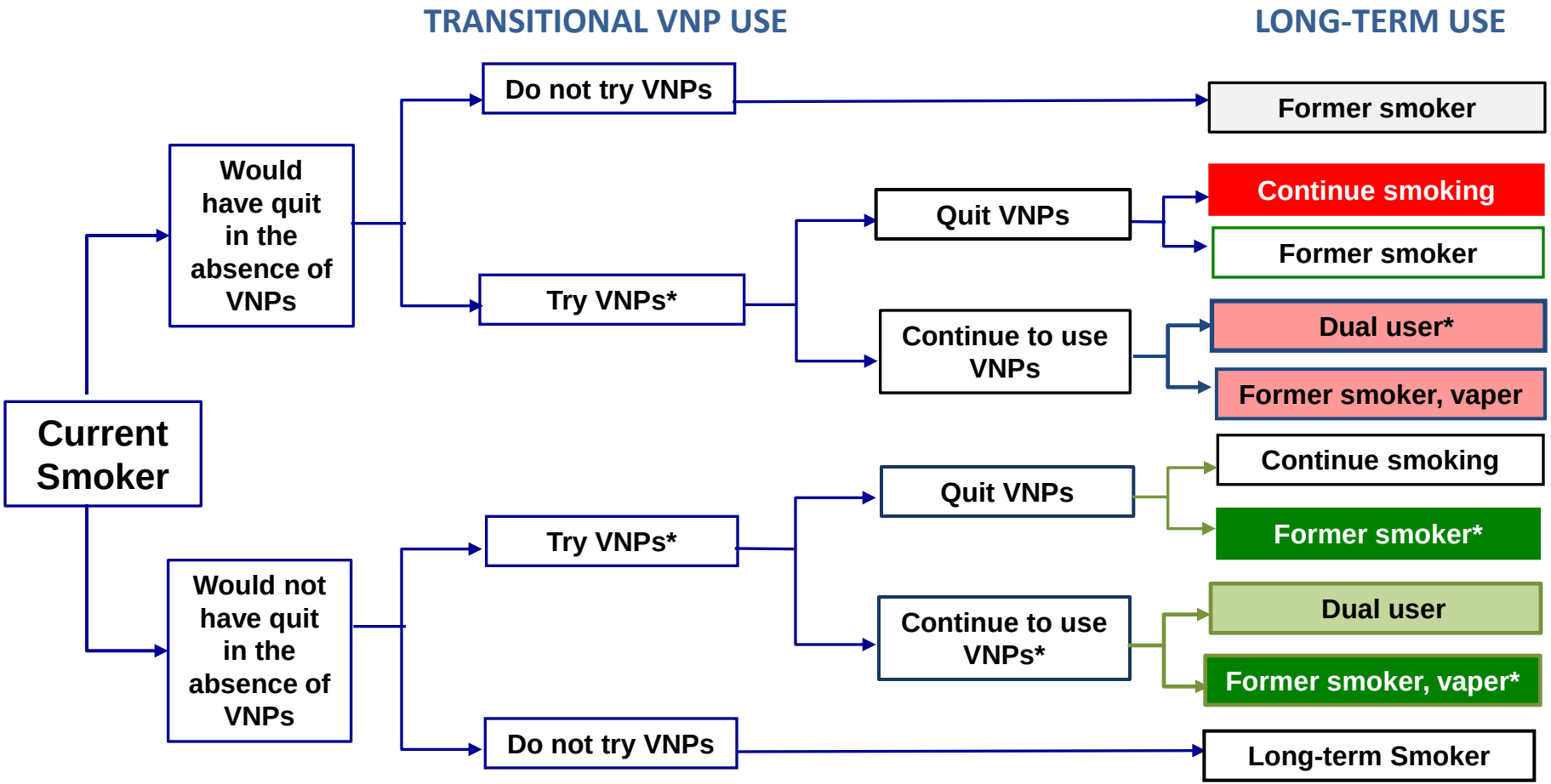




Trend Line Analysis of Smoking Rates with Deviations from Long-Term Trend with Vaping(Levy et al, Tob Control (2018)

Survey	Measure	Years	Long-term trend	P-value	Vaping trend	P-value	Durbin Watson	Adj. R-squared
			Last 30-day Use					
MTF	10th-grade, M & F*	2004-2017	-0.058	<0.001	-0.14	.0002	1.27*	0.954
MTF	12th-grade, M & F*	2004-2017	-0.046	<0.001	-0.095	<0.001	1.14*	0.985
NYTS	High School, M&F	2010-2017	-0.082	0.005	-0.22	0.02	3.01*	0.980
YRBS	High School, M&F	2003-2017	-0.062	0.04	-0.52	0.004	3.18*	0.969
MTF	Ages 18-21, M & F	2004-2016	-0.048	<0.001	-0.091	<0.001	2.23	0.973
MTF	Ages 22-24, M & F	2004-2016	-0.047	<0.001	-0.041	0.01	2.92*	0.979
NSDUH	Last 30 day Ages 18-25, M & F	2004-2016	-0.027	<.0002	-0.092	<0.001	2.20	0.988
			Established Smoking					
MTF	Daily, 10th-grade, M & F	2004-2017	-0.070	<0.001	-0.15	0.0002	2.23	0.959
MTF	Daily, 12th-grade, M & F	2004-2017	-0.061	<0.001	-0.13	<0.001	1.19*	0.986
MTF	Daily, Ages 18-21, M & F	2004-2016	-0.063	<0.001	-0.15	<0.001	2.09	0.977
MTF	Daily, Ages 22-24, M & F	2004-2016	-0.062	<0.001	-0.050	0.01	2.65*	0.982
NSDUH	Daily, Ages 18-25, M & F	2004-2016	-0.044	<0.001	-0.083	<0.001	2.36	0.992
MTF	Half pack per day, 10th grade, M & F	2004-2017	-0.088	<0.001	-0.200	0.002	2.06	0.948
MTF	Half pack per day,12th grade, M & F	2004-2017	-0.086	<0.001	-0.150	<0.001	1.97	0.989
MTF	Half pack per day, Ages 18-25, M & F	2004-2016	-0.073	<0.001	-0.041	0.029	2.76*	0.986
NHIS	Current Smoker, Ages 18-24, M	2004-2016	-0.033	0.002	-0.10	0.01	1.54	0.864
NHIS	Current Smoker, Ages 18-24, F	2004-2016	-0.04	<0.001	-0.059	0.06	2.99*	0.889

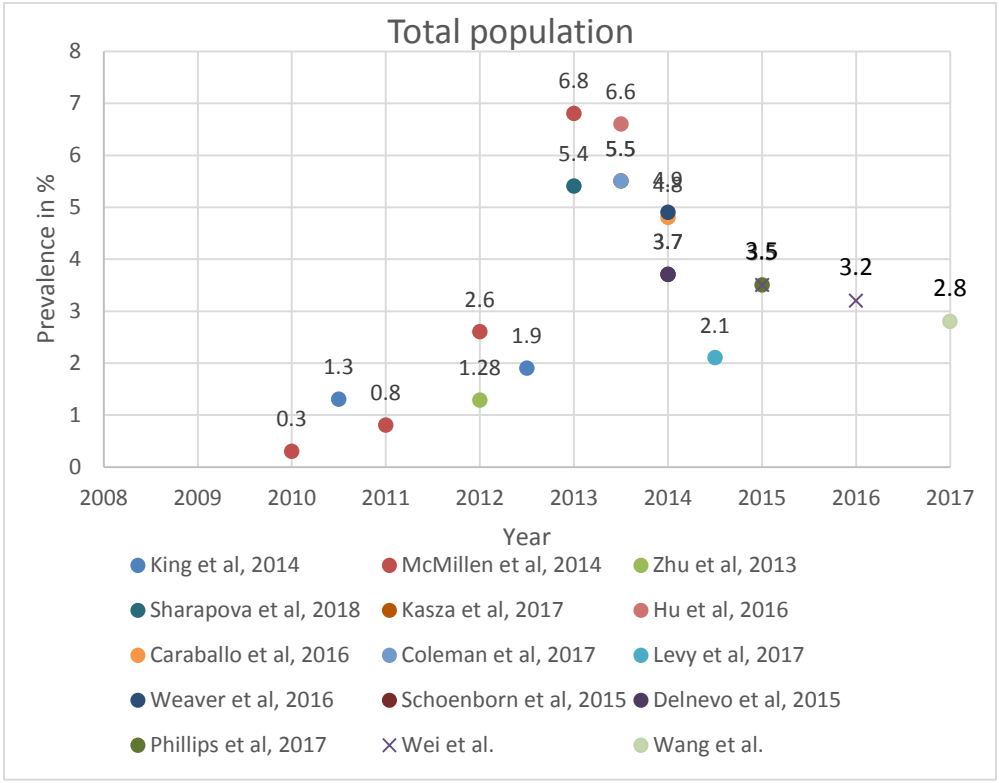
The public health impact of VNP use among smokers (Cessation)

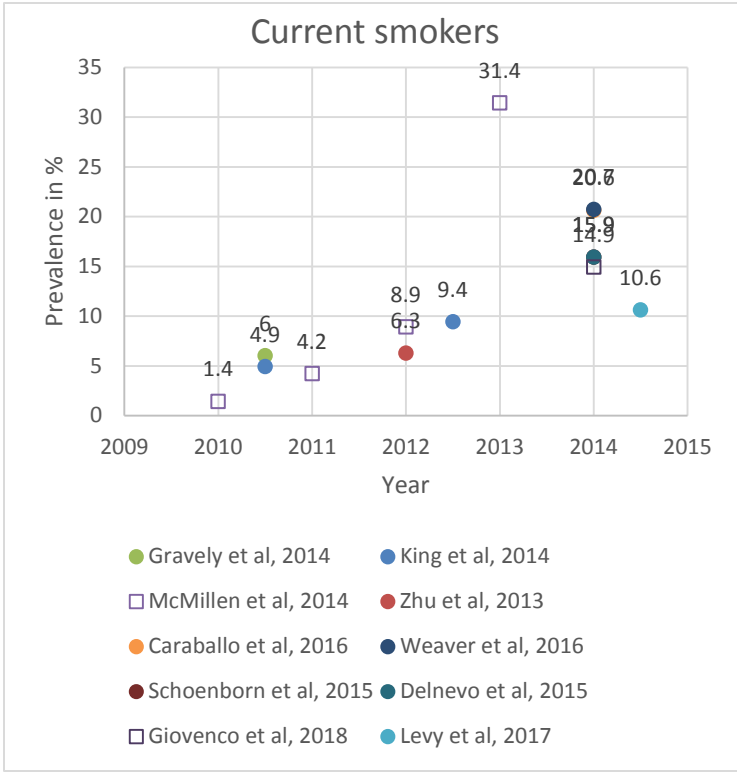


Effects through Cessation

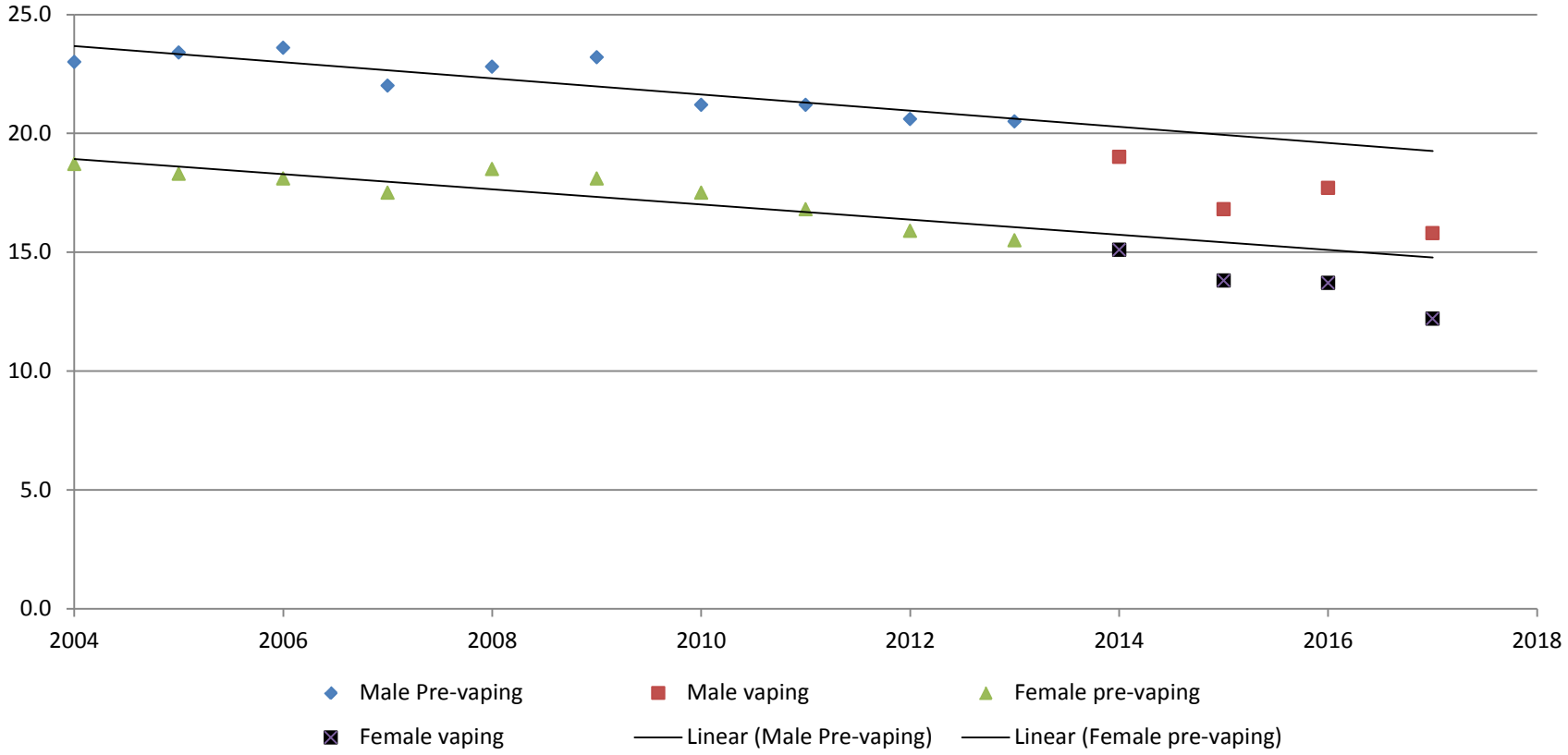
Scenario		Age	26	35	45	65	85	Cumulative Ages 26-85	Life Years Gained vs. No-VNP scenario
No-VNP scenario	Prevalence	Smoker	29.4%	25.5%	19.1%	8.2%	1.1%		
	SADs		-	-	975	3,398	3,928	128,403	
	LYL		-	-	38,035	70,288	21,004	2,366,736	
VNP Best Estimate Risk	Prevalence	Smoker	29.4%	19.9%	14.5%	6.3%	0.9%		
		FS-VNP	0%	1.7%	1.9%	1.6%	0.7%		
		Dual	0%	4.0%	3.8%	2.3%	0.6%		
	SADs		-	-	880	3,318	4,007	126,038	-2,365 (-1.8%)
	LYL		-	-	34,350	68,617	21,425	2,281,140	-85,596 (-3.6%)
Variation in Levels of VNP and Dual Risks									
Low Risk	SADs		-	-	840	3,194	3,959	122,127	-6,276 (-4.9%)
	LYL		-	-	32,759	66,071	21,168	2,198,503	-168,233 (-7.1%)
Medium Risk	SADs		-	-	914	3,416	4,040	129,132	729 (0.6%)
	LYL		-	-	35,657	70,661	21,601	2,347,513	-19,223 (-0.8%)
High risk	SADs		-	-	957	3,545	4,085	133,167	4,765 (3.7%)
	LYL		-	-	37,334	73,319	21,841	2,433,631	66,895 (2.8%)
Changes in Cessation Rate with Best Estimate Risks									
Dual Rate at 100% of Smoker only	SADs		-	-	857	3,192	3,927	122,014	-6,388 (-5.0%)
	LYL		-	-	33,454	66,024	20,997	2,205,661	-161,075 (-6.8%)
Added 2% VNP initiation From Age 36 to 85									
Cessation at	SADs		-	-	863	3,237	4,019	124,067	-4,335 (-3.4%)
100% of smokers	LYL		-	-	33,665	66,951	21,489	2,235,525	-131,211 (-5.5%)

Adult E-cigarette Use

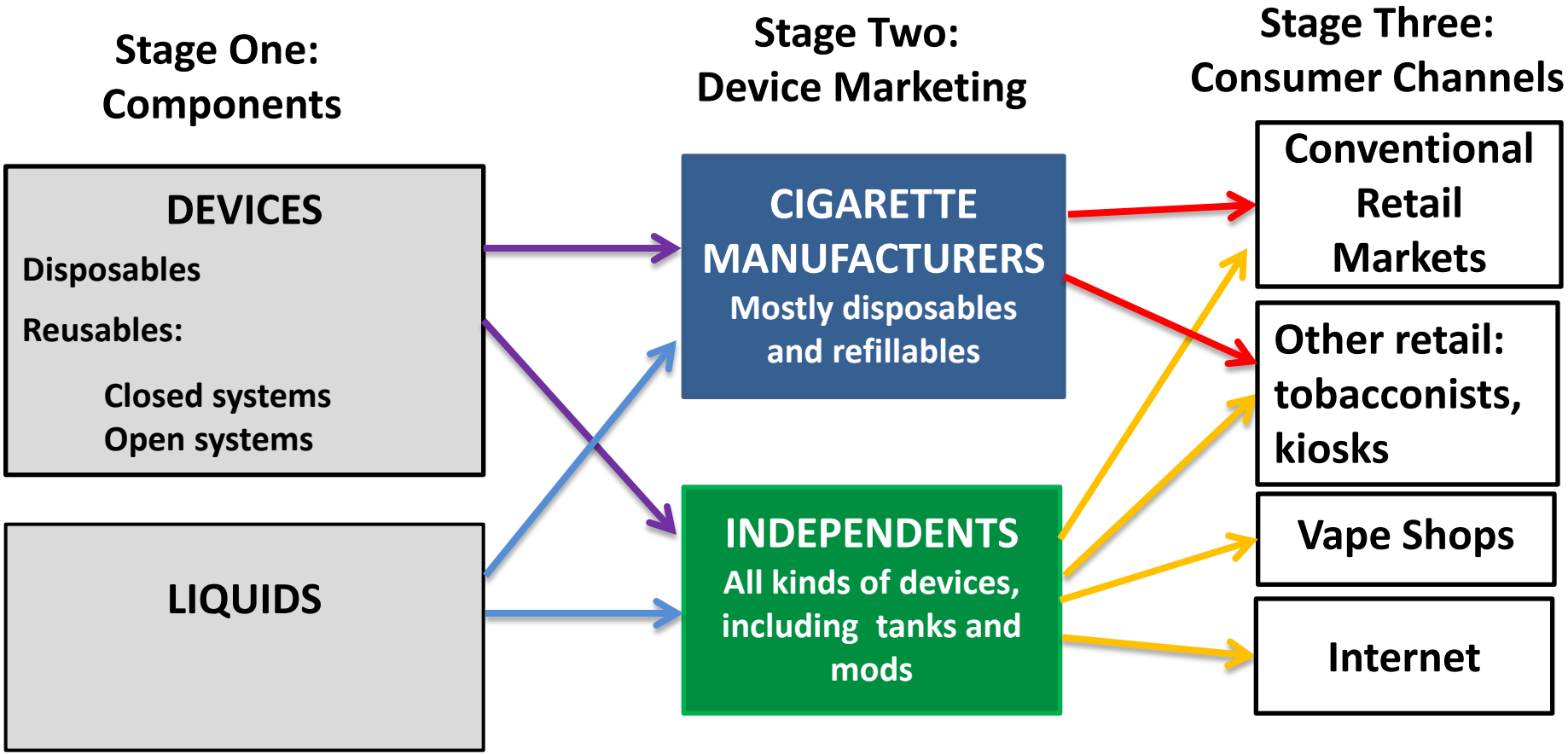




NHIS US smoking prevalence



Structure of the E-Cigarette Industry



Market Segments and Industry Shares (in millions)

	2014	2015	MARKET SHARES 2015	2016	2017	MARKET SHARES 2017	2018	MARKET SHARES 2017
E-cigarettes (Disposables and Closed system)	1,000	1,400	**42.4%**	1,600	1,400	**31.8%**	2,080	**36.4%**
Mass Market Retail (convenience store, Food, Drug stores)	600	600	18.2%	700	700	15.9%	1,100	20.0%
Online	200	400	12.1%	500	400	9.1%	500	9.1%
Other Retail (including tobacconists and kiosks)	200	400	12.1%	400	300	6.8%	400	7.3%
Vapors/Tanks/Mods & Personal Vaporizers (Open System)	1,500	1,900	**57.6%**	2,500	3,000	**68.2%**	3,500	**63.6%**
Mass Market Retail (convenience store, Food, Drug stores)	300	300	9.1%	500	500	11.4%	650	11.8%
Online and other retail outlets	300	400	12.1%	600	700	15.9%	850	15.5%
Vape Shops	900	1,200	36.4%	1,400	1,800	40.9%	2,080	37.8%
Total	2,500	3,300	**100.0%**	4,100	4,400	**100.0%**	5,500	**100.0%**

Type: Open Systems 68%, Closed Systems and Disposables 32% in 2017

Purchase channels: Mass market retail 27%, Other retail 7%-20%, Online 15-20%, Vape shops 41% in 2017

Source: Wells Fargo Securities

Most growth in vape shops and online through 2017, then major growth in retail e-cigarettes in 2018

Conventional Retail Shares of Firms*

- The conventional retail market for VNPs was concentrated, initially dominated by independents (21st Century, NJOY, Mistic, Logic), but less concentrated by mid-2012.[3] The large cigarette companies entered the market in 2012-2014.
- While the large cigarette companies controlled 72% of conventional retail **by 2015,** that sector accounted for 27% [(900)/3300] of all purchase channels (see previous slide). With minimal sales at vape shops or via the Internet, **the share in all purchase channels by cigarette companies via conventional retail was less than 20% (72% x 27%).** Shares of individual independent firms were all less than 5% of conventional retail, but they remained viable with a combined 25% share.
- An independent, Pax Labs entered the market with **Juul** in June 2015 and replaced Vuse for top position by the end of 2017, with **projected conventional retail sales reaching a 55% share in dollar sales and a 36% in unit sales by March 2018 (roughly 17.5% in $ sales and 11% in unit sales of all purchase channels). By 2018, projected conventional retail sales of the four cigarette companies' plummeted to 41% and 56% of unit sales -- or roughly 13% of $ sales and 18% of unit sales from all purchase channels. Concentration just in conventional retail is not high!!**
- ***Based on Nielsen data as found in 2016 SGR and in Wells Fargo Reports, but these data only cover conventional retail***

US Market Conduct

- Competitive: With minimal concentration and low entry barriers (subject to government regulation)
- Prices of specific products have been falling over time
- New products through innovation: recent growth in sales of Juul
- Demand may to have flattened for some products, but growth in others (e.g., Juul)
- Future growth likely to depend on regulations, information dissemination about risks and new products, smoke-free air laws and taxes

The market structure and conduct of firms in this industry is very different from the prior (pre-2005) experience in the cigarette market

Conclusions

- E-cigarette use appears to have beneficial public health impact over a wide range of plausible values, but there is considerable uncertainty
- To gauge effects:
  - Cohort analysis is central, will need to examine age patterns over time by cohort
  - Will need better measures of use, especially established use (exclusive and dual)
  - Much will depend on products available (esp HNB)
- Government regulation and industry structure are likely to play an important role