COMMENT ON THE INAPPROPRIATE APPLICATION OF A CONSUMER SURPLUS DISCOUNT IN THE FDA'S REGULATORY IMPACT ANALYSIS

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Like the cost-benefit analysis that the FDA conducted for its graphic warning label regulation,[1] the Preliminary Regulatory Impact Analysis (RIA) for the proposed rule deeming tobacco products to be subject to FDA jurisdiction,{Economics Staff, April 2014 #186, p. 52} the FDA estimated the benefits due to reduced tobacco-induced illness and premature death, and then cut these estimated benefits of these warning labels by 70 percent[*] to account for the cost of lost "welfare" smokers incurred as a result of quitting (and lost welfare would-be smokers would never experience) because of the effects of changes proposed in the new rule.

The RIA presents no empirical justification for this large discount, which, without explanation, was increased from the 50 percent discount in the warning label rule. Indeed, as discussed in detail below, the RIA ignores extensive evidence, presented in the proposed rule itself,{Food and Drug Administration, 2014 #187, p. 23146 and p. 23159} that the underlying economic concept of consumer surplus upon which this discount is based is not appropriate for analysis of behavior involving tobacco because tobacco use and the associated nicotine addiction almost always begin during adolescence (well before the age of reason) and that nicotine changes the way the brain processes information, and thus, rendering "rational" decision-making models inapplicable.

For these reasons, expanded below, the FDA should drop any such discount from the RIA for this rule and all subsequent rules related to the use of tobacco products.

Inappropriate Application of Consumer Surplus to Tobacco Products

[*] This 70 percent discount is presented differently in the RIA as the remaining 30% welfare gain ratio (rather than the corresponding 70 percent discount), on page 52 of the RIA.

The FDA quantified the cost of this lost welfare ("pleasure of tobacco use" in common language) using the economic concept of "consumer surplus," which is the difference between what a utility maximizing individual would be willing to pay and the actual price.[2-5, 6] To the extent that people would be willing to pay more for tobacco products than their monetary cost, this willingness to pay more is an indication that users obtain a surplus benefit of tobacco consumption beyond the cost of the product (cigarettes, cigars, e-cigarettes, etc.)

Consumer surplus based on willingness to pay is a well-established concept in classical economics and is grounded in rational choice theory, a normative model of human decision-making.[7] Rational choice theory represents human decision making at its most logical, when decisions are the result of careful cost-benefit analysis with people choosing the option that maximizes the utility of the choice after subtracting perceived costs.[8-10] Applied to tobacco use, this theory posits that users (and potential users) consume tobacco products because the current and future benefits of the pleasures of smoking *outweigh* the present value of future financial, social and medical costs of smoking.[11-13] These benefits might include the both physiological responses and emotional/social advantages (either real or imagined) that smoking provides. In contrast, a large body of empirical evidence from cognitive behavioral sciences demonstrates that tobacco users (and would-be users) do so because they are addicted and overestimate their ability to quit in the future.[14]

Rational choice theory (and the adjustments that have been proposed to deal with addictive behaviors) assumes stable preferences, foresight, knowledge, and adequate cognitive abilities to make the decision to start or continue smoking. Conversely, empirical evidence demonstrates that these assumptions are seriously violated by smoking and other tobacco use behavior that almost always begins during adolescence[15, p. 179] and continues in adulthood through addictive consumption. In addition, there is no empirical literature that suggests adults who start smoking and other tobacco use engage in deliberate decision-making process in which they evaluate risks against benefits. The empirical literature suggests the contrary: even adults, who presumably are better equipped to consider the risks and benefits of smoking and other tobacco use do not anticipate regret or understand addiction.[16-18] Applying a significant loss in (real or potential) consumer surplus when measuring the value of anti-tobacco initiatives has important implications for policy, including reducing the benefits of proposed health regulations. This reduction in the estimated benefits of the policy results in weakened regulations and that are harder to defend when challenged in court.[19, 20] In using consumer surplus, a measure grounded in rational choice theory, to estimate a theoretical "cost" of not smoking, the FDA is ignoring the strong empirical evidence against the validity of applying rational choice to smoking decisions, leading the FDA to seriously overestimate the costs of reducing smoking and, in turn, underestimate the net benefits.

The FDA itself summarizes this evidence in the proposed deeming rule on page 23146:

> First, the available data on the addictiveness of nicotine suggests the adolescent brain is more vulnerable to developing nicotine dependence than the adult brain, that exposure to substances such as nicotine can disrupt brain development and have long-term consequences on executive cognitive function and on the risk of developing a substance abuse disorder and various mental health problems as an

adult (Ref. 1), and this exposure to nicotine can also have long-term results on decreasing attention performance and increasing impulsivity which could promote the maintenance of nicotine use behavior (id.).{Food and Drug Administration, 2014 #187, p. 2316}

The FDA expands the evidence supporting this assertion on page 23159 of the proposed deeming rule:

> Non-clinical research has shown that: (1) Alterations to the brain caused y nicotine may have a lasting effect on the developing brain (Ref. 55 at 668–676); (2) the rewarding effects of low and moderate doses of nicotine were enhanced in adolescent animals as compared to adult animals, while the aversion to high doses of nicotine normally seen in adult animals were reduced (Ref. 60 at 658–663); (3) these affects are long lasting, as exposure to nicotine during adolescence reduced aversion to high doses of nicotine when the animals were tested as adults; (4) the adolescent brain is differentially sensitive to both the acute and repeated effects of nicotine relative to the adult brain (Ref. 76 at 2295); and (5) there are significant differences in nicotine sensitivity between early and late phases of adolescence (Ref. 60 and 76).
>
> Brain processes that lead to rational decision making continue to mature through adolescence (Ref. 122 at 69–70). Acquisition of a fully coordinated and controlled set of executive functions occurs relatively later in development. As a result, several researchers have found that young people may not have the ability to rationally consider the risks and benefits involved with smoking and its long-term effects (Ref. 123 at 259–266). Young people also wrongly perceive that they are personally at less risk than others who smoke, and youth underestimate antismoking attitudes of their peers (id.). ‘‘The belief pattern that emerges from this study and other research is one in which many young smokers perceive themselves to be at little or no risk from each cigarette smoked because they expect to stop smoking before any damage to their health occurs. In reality, a high percentage of young smokers continue to smoke over a long period of time and are certainly placed at risk by their habit’’ (id.). Because they lack fully capable executive function, youth seriously underestimate the future costs associated with an addiction to nicotine (Ref. 55 at 4). Researchers believe that youth underestimate the risks of smoking because they are unable to appreciate the nature, severity, and probabilities of consequences associated with smoking. Youth also fail to understand the cumulative nature of the risk (Ref. 123 at 259s–266). The proportion of students seeing a great risk associated with being a smoker leveled off during the past several years, according to recent research results, as has the proportion of teens saying that they disapprove of smoking or attach negative connotations to it (Ref. 83). Similarly, the ‘‘Monitoring the Future’’ survey identified a ‘‘rebound’’ in the rate of smokeless tobacco product use by high school students, which previously had declined from the mid-1990s to the early 2000s (id.). Researchers attributed the ‘‘rebound’’ to leveling off perceptions of harm caused by smokeless tobacco products, increased advertising

> of these products, and a proliferation of new types of smoke-free tobacco products (id.). In addition to systematically misunderstanding their risks of harm from various tobacco products, youth and young people also systematically underestimate their vulnerability to becoming addicted to nicotine and the use of tobacco products, and overestimate their ability to stop using tobacco products when they choose. See section VII.C.{Food and Drug Administration, 2014 #187, p. 23159}

This accurate summary of the evidence that actual human behavior is inconsistent with the assumptions that underlie a consumer surplus calculation. There is, as discussed below, a large body of empirical evidence to support the FDA's analysis in the main deeming rule. This discussion is an expanded version of our peer reviewed paper, "When health policy and empirical evidence collide: the case of cigarette package warning labels and economic consumer surplus,"{Song, 2014 #185} which is cited in the deeming rule (but not the RIA) as reference 140).

The RIA needs to be revised to be consistent with the body of the draft rule as well as the large empirical evidence base that supports the statements in the draft rule.

Rational Choice and Rational Addiction

Rational choice theory has been an important and useful tool to understand large-scale market trends or population-level consumption of many products.[8, 21] The assumption of rationality also works very well for many individual behaviors, particularly simple situations in which costs and benefits can be easily represented as a numeric metric, such as money. For example, rational choice can be used to explain an individual consumer's purchasing behavior in situations like buying earthquake insurance for one's home. The costs are calculable (e.g., cost of insurance versus costs of earthquake damage given the probability of an earthquake) and the benefits are known (e.g., insurance coverage). The potential consequences associated with behavioral choices are limited to four potential outcomes: insurance coverage with an occurrence of an earthquake, insurance coverage without an earthquake, no coverage with an earthquake, and no coverage and no earthquake. When the situations involve very clear-cut, money-based utilities, descriptions of decision-making processes and subsequent behaviors based on rational choice reasonably approximate actual human behavior. In these cases consumer surplus calculations, which are based on the nature of the demand curve, are appropriate.

However, in other situations, including smoking and other tobacco use, the application of rational choice theory (and, so, the calculation of consumer surplus) is problematic because empirical data have consistently shown that the decision-making process behind smoking and other tobacco use decisions significantly deviates from the assumptions that underlie rational choice theory.[22, 23] Rational choice theory assumes that the human decision maker is *homo economicus*, a human with stable preferences, accurate foresight, adequate knowledge, and cognitive efficiency[24] who consistently acts to maximize pleasure and benefits.[8, 21, 24-26] In contrast, in some situations – including smoking and other tobacco use – human decision preferences are unstable, foresight is flawed, knowledge is imperfect, and cognitive abilities are limited.[9, 24, 27] This realization has lead researchers to look for alternatives to standard rational

choice in order to understand decision making. For instance, the field of "evonomics" is predicated on the assumption that economic behavior follows evolutionary principles and that the rational choice assumption of a self-interested homo economicus is contrary to the realities of a complex homo sapiens who evolved within a physical and social environment.[28-30] In cases where the decision and the consequences of behaviors are multi-dimensional, rational choice theory often fails to accurately characterize individual decisions.[24]

Economists have attempted to adapt rational choice to predict and describe human behavior relaxing some of the core underlying assumptions,[3] including introducing factors such as bounded rationality,[21] hyperbolic discounting,[31] differences in risk taking,[32] and reduced expectations of future earnings.[33] Examples of assumption relaxation to deal with addiction include intertemporal decision-making,[11, 34-36] "projection bias" models where future preferences are assumed to be similar to current preferences[37, 38] or current preferences supersede future considerations.[39] In particular, in Becker and Murphy's rational addiction model consumption decisions are based on past consumption and predictions about future consumption and future costs.[11, 40] Chaloupka tested the rational addiction model against actual smoking behavior and showed that the predictions from the rational addiction model provided a reasonable fit to observed behavior.[40] Others have expanded the model to demonstrate that in the short-term (over a few months), mature adults do exhibit forward-looking behavior as it pertains to one dimension of cost-benefit measurement, monetary price.[3] Alamar and Glantz,[41] however, showed that it was possible to fit the rational addiction model to a synthetic data set that was generated from a model that had no forward looking behavior at all. This result means that the empirical test of the rational addiction model for smoking[40] provided necessary, but not sufficient, evidence that the rational addiction model accurately embodied smoking behavior.

Ashley, Nardinelli, and Lavatay's attempt to quantify intrapersonal costs and benefits of health policies (including tobacco control) using market equilibrium models is predicated on the belief that behavioral scientists are opposed to including market demand in cost-benefit analyses. They write, "noneconomist authors read in the economics literature that regular demand curves cannot be used to estimate benefits in the presence of addiction or other intrapersonal market failures, they conclude that market demand should not be considered at all. Economists need to recognize—and seek to overcome—this disconnect between disciplines."{Ashley, 2014 #188} After making this observation, Ashley, et al proceed to do just what they advise against and conclude that the economic literature suggests at least a 2/3 reduction in policy effectiveness due to consumer surplus, which, while uncited, appears to be the origin of the 70% consumer surplus discount in the RIA. The problem is not the inclusion of market demand in cost-benefit analyses of health policies; the problem is basing these models on assumptions on human decision-making discussed earlier in this comment that are contradicted by the wealth of empirical evidence about actual decision making reviewed in this comment (and elsewhere{Song, 2014 #185}). For these reasons, FDA should not rely on the Ashley, et al analysis (or any such similar analysis) in the final RIA.

Another important limitation of the economic literature attempting to modify the rational model in order to apply it to smoking behavior is that this literature almost exclusively deals with addicted adult consumers. In contrast, the mean age of smoking initiation is 15.9, with 88.2% of smokers starting smoking before age 18 and 65.1% smoking daily by then,[15, p. 179] well before

they reach the age of reason.[42]

Issues of Dimensionality of Determinants of Choice

The underlying foundation of rational choice is that people are motivated to maximize utility. Maximization requires that choices be ordered so that if choice A is preferred over B, and B over C, then A must always be preferred over C. This mathematical ordering is only possible if the scale is one-dimensional (i.e., it is not possible to order a two-dimensional – or higher – vector space[43]). From a behavioral point of view, this means that the determinants of the behavior be (or be close to be) one dimensional, so the preference ordering is invariant across context. That is, if A is preferred over B in one situation, this ranking should hold regardless of how the situation is presented. These assumptions are easily upheld if units of analyses are limited to one dimension, such as money, or when the different measurements of behavior are highly correlated so that, while measured by multiple factors, the behavior is essentially one dimensional. (From a statistical point of view, this would mean that the measures of behavior exhibit one highly dominant principal component.) However, based on the evidence discussed below, this situation likely does not hold for smoking and other tobacco use behavior: the monetary cost of cigarettes measures one dimension of the effects of tobacco use, while the morbidity effects, mortality, and social consequences represent other orthogonal dimensions.

The classic example of how dimensionality issues impact decision-making is a long-standing cognitive phenomenon called preference reversal.[44-46] Given the option of a low-risk, high probability of small gains scenario versus a high-risk, low probability of high gains, people prefer the low-risk scenario. However, when asked to assign a monetary value to each scenario, people value the high-risk scenario more than the low-risk scenario. If a person was an expected (monetary) value decision maker, the problem would be reduced to a single dimension and transitivity would be maintained. The preference inconsistency arises from the fact that risk represents a second independent dimension, which could include emotions, thereby precluding simply multiplying the probabilities times the money value and adding things up. Presence of a second dimension precludes a transitive ordering of all the possibilities[43] and gives rise to the observed preference reversal.[45, 46]

The preference reversal phenomenon has been empirically demonstrated in health-related research as well.[47] Given the choice between a health-related item (e.g., preventive treatment to avoid cancer) and a leisure commodity (e.g., 1 day vacation in Bermuda), people valued health-items higher than commodities when the dimension of evaluation was life expectancy, measured in days. However, when the person was asked to place a monetary value on the health item and the commodity, the commodity was valued higher than the health item. In this case the two independent dimensions are health status and the leisure commodity. Thus, in a multidimensional behavior such as smoking and other tobacco use where it is impossible to order all possible outcomes, one cannot compute the utility optimization that lies at the core of idea of consumer surplus.

Empirical Evidence of Unstable Tobacco-Related Preferences

Tobacco use-related preferences do not remain stable over time.[3] If preferences were

stable, tobacco users would continue to choose behaviors that support their tobacco use. Moreover, smokers and other tobacco users would not feel regret in the future because their decisions are based on preferences that are stable (and they base their decisions using foresight about the future). However, many smokers engage in self-control devices to undermine their own decision to keep smoking or using other tobacco products such as by announcing intentions to quit or making pacts to quit in groups with other smokers.[48-50] By publicly announcing his or her decision to quit or making pacts with other smokers to quit as a group, the smoker is attempting to add an additional obstacle to continued smoking (i.e., self-induced social pressure). Smokers who engage in self-control devices are self-sabotaging their own decision to smoke by making it harder to smoke without incurring others' negative opinions for failing to quit. Moreover, as discussed below, most smokers report feeling regret over their decisions to smoke.[16, 17, 51] It is reasonable to apply these same conclusions to all tobacco products.

In addition to smokers' self-sabotaging behavior, the empirical literature suggests that people are "cognitive misers" who have limited cognitive resources and employ cognitive short-cuts called heuristics to help them make decisions.[52] In particular, people tend to base decisions on information that is readily accessible, vivid, or familiar to them (availability heuristic).[52, 53] In the case of smoking, at least two other factors that explain why preferences are unstable: framing effects and emotions.

Framing Effects

The earliest empirical evidence to contradict rational choice theory came from Kahneman and Tversky's studies illustrating framing effects on decision-making,[9, 10, 44, 54, 55] which demonstrated that people's preferences, and thus choices, varied according to how information was presented, even when the substance of the information remained constant. They found that people are more likely to accept risk when results are presented as potential losses than when results are presented as potential gains.[55] In their classic experiment, participants were told to imagine they were given $1000, but had to choose between A) a 50% chance of gaining another $1000 or B) a 100% chance of gaining $500. Alternatively, other participants were told they were given $2000, but had to choose between C) a 50% chance of losing $1000 or D) a 100% chance of losing $500. Options A and C yield the same result (50% probability of having $2000, 50% probability of having $1000), while options B and D yield the same outcome (100% probability of having $1500). However, most people choose B over A, but C over D, demonstrating that people tend to accept uncertainty to avoid losses.

This principle, which is embodied in Prospect Theory, has also been reported in the willingness-to-pay literature, which observed that people value potential benefits differently depending on whether they are giving something up or keeping something they already have.[56, 57] People are willing to pay far less to keep what they possess, but demand significantly more if they are to be compensated for losing the good[56-60] (also called "willingness to accept"). For example, law students were asked how much they much money they would want if they were selling their textbook, with notes and underlining. These same law students were asked how much they would pay to get the same textbook back if they lost it and wanted to retrieve it. In this example, law students demanded more money to sell their textbook (willingness to accept), compared to paying to retrieve (keep) the same textbook.[61] Despite efforts to explain this

disparity by varying the type of item or good in question,[58, 62] the difference between values measured in the willingness to pay and the willingness to accept scenarios demonstrates how consumer surplus is largely dependent on how the situation is framed, something that would not affect the decisions of a completely rational decision maker. Smoking situations can be framed in a variety of ways, including a loss frame (e.g., a potential smoker considering the loss of social standing if they do not smoke) to compensation for a lost right or benefit (e.g., the tobacco industry argument against smokefree policies). It is unclear whether the FDA cost-benefit analysis considers preference variation due to framing effects. Even so, analyses that are predicated on the assumption that preferences are stable are inappropriate in the context of tobacco control policy.

Emotions and Preferences

In addition to framing effects, preferences fluctuate according to the emotional state of the person at the time the decision is made. When explaining what people currently perceive as bad choices made in the past, people point to the strong influence of emotional states at the time the decision was made as the cause of illogical actions. Emotions not only interfere with human abilities to engage in rational cost-benefit analyses, but also change people's preferences by altering their perceptions, goals, and evaluations of options, and thus, behavior.[63-66]

Emotions play a large role in human decision-making because calculations that weigh costs and benefits are often complex and cognitively difficult. Emotions provide an alternative to cost-benefit analyses for shaping preferences, particularly when the decision is complex.[67, 68] Rather than engaging in a challenging cognitive processes to a) identify preferences and b) use identified preferences to compute utilities (as specified in rational choice theory), people rely on emotions related to objects and ideas to help them make faster, easier decisions about whether some behavior would be positive or negative to the decision-maker. For example, people are less likely to perceive risks for things and activities they like (and feel positive emotions towards), compared to things and events they dislike. The more they like something, the lower the perceived risk and higher the perceived benefit. The opposite is true for things people dislike. This reliance on emotions as cues to inform judgment is the affect heuristic,[68] which is a type of cognitive shortcut that allows people to make decisions without engaging in time-consuming, cognitively burdensome cost-benefit calculations.

The affect heuristic plays a role in smoking-related decisions because smoking behavior is tied emotionally to smoking-related images. Positive emotions often follow repeated exposure to smoking advertisements.[15] Among adolescents, exposure to cigarette brands increased positive emotions associated with those brands, and consequently, increased preferences towards smoking.[69] Likewise, negative emotions elicited by graphic warning labels on cigarette packages reduce smokers' preferences to smoke and increase preferences to quit.[70] The effects of positive emotions from cigarette brand exposure, as well as negative emotions from graphic warning labels work because people do not always make decisions based on stable preferences. Instead, preferences can change according to emotions that are mutable. Although the rational choice theorists may adjust consumer surplus calculations to account for small variations in preferences at the population level, as the empirical literature on framing and emotions shows, these changes can be significant even within individuals, thus violating an important tenant of rational choice

theory and, so, the calculation of consumer surplus.

Empirical Evidence of Flawed Smoking-Related Foresight

Rational choice theory assumes that people make *accurate* predictions about decision outcomes, including the effects of decisions on their future states. However, there is strong empirical evidence of smoker's optimism bias: that despite knowing the potential health risks of smoking, smokers believe they are less susceptible to health effects compared to the average smoker.[71-75] This trend is demonstrated in youth[73, 74, 76, 77] as well as adults.[72, 75] For example, in one study,[75] 61.2% of smokers estimated that the average smoker had 5-10 times the risk of lung cancer compared to nonsmokers. In contrast, 23.1% of adult smokers estimated they had 2 times the risk of lung cancer compared to nonsmokers, with an additional 31.8% estimating no elevated risk or slightly higher risk compared to nonsmokers. In reality, smokers have 25 times the lung cancer risk as nonsmokers.[78, 79] The study also reported very weak or no relationship between the amount of cigarettes smoked and beliefs about personal smoking-related consequences. Moreover, a majority of smokers incorrectly believed that they could negate the effects of smoking by engaging in healthy behaviors, such as exercising.

Smoking and other tobacco use decisions are particularly prone to violating the foresight assumption because risks and benefits tend to accrue at very different times. Although there is some evidence that adolescents recognize smoking's short-term health risks, most frame health risks as long-term while framing benefits as short-term.[77] These potential benefits are related to social norms and peer acceptance, which can be highly susceptible to tobacco industry marketing and promotion (creating a social benefit to smoking) and tobacco control measures (creating a social stigma towards smoking). Moreover, people tend to discount future consequences and heavily weight present-day consequences,[80] making future smoking-related risks less salient compared than immediate social and physical benefits despite the fact that future regret may counter-balance these short-term benefits.

Economists attempt to account for temporal changes in preferences by applying hyperbolic discounting. Behavioral sciences and psychology show that people who are characteristically impulsive, including smokers and drug addicts, more heavily discount future consequences.[81-85] In one study participants were asked to choose between an immediate monetary reward (decreasing from $1000 to $1) versus $1000 delivered in the future (increasing from one week to 25 years). Smokers strongly favored immediate rewards, compared to nonsmokers and ex-smokers who were less likely to discount future rewards.[81] (As a result, some researchers have concluded that unhealthy behaviors resulting from hyperbolic or delayed discounting can be muted by targeted interventions[85]including graphic warning labels.) Although the tendency to discount future events in favor of immediate rewards may be a relatively stable personality trait with smokers and nonsmokers using different discount rates, their degrees of discounting can vary in response to the social environment.[86] Taken together, these findings suggest that revising the rational choice model to provide a more accurate description of behavior is at best not straightforward and, in doing so, loses the relative simplicity that made rational addiction attractive to policy makers. In addition to smokers' inaccurate estimates of their personal smoking-related risks, people have little ability to predict their emotional reactions to future events. Underlying rational choice theory is the idea that

anticipated emotions drive behavior (i.e., emotions that accompany outcomes that would be experienced in the future). Despite the important role anticipated emotions play in decision-making, there is also strong evidence that people have little ability to predict their future emotional reactions to consequences of their decisions.[87, 88] Specifically, people are prone to the impact bias, which is a tendency to overestimate the intensity of their future emotional reaction to current decisions. For example, people overestimate how sad they will feel months after a failed relationship or years after professors are denied tenure.[89] The same goes for positive emotions: people overestimate how happy they will be after positive events, such as having their political candidate win an election.[90]

Predictions about the future are especially inaccurate when dealing with addictive substances such as nicotine.[49, 51] Regret and remorse are indications that people did not accurately predict future consequences at the time they made a decision. These emotions are prevalent among smokers: When asked if they would make the same decision to start smoking, 85% of adult smokers respond "no."[51] Moreover, the more a respondent smoked, the more likely he or she was to express regret about their decision to start smoking. This finding has been replicated across the globe, with approximately 90% of smokers regretting their decisions to start smoking.[16, 17] If smoking were the result of a rational decision-making process, people would have been able to accurately predict their future emotions. Instead, we have tens of millions of people in the United States and billions worldwide who smoke and regret doing so. Moreover, the limited data on former smokers' emotions towards not smoking suggest that former smokers are happier after quitting.[91] Former smokers also report better quality of life and more positive emotions compared to continuing smokers.[92] Consumer surplus calculations ignore the evidence that most smokers regret their decisions to smoke and that former smokers report more happiness after quitting even though the level of regret might exceed any "forgone pleasure" and lead to a "consumer deficit." At the very least, the data on regret demonstrates that smoking decisions are not consistent with rational choice theory's assumptions.

Empirical Evidence of Imperfect Tobacco Use-Related Knowledge

Rational choice theory also assumes that decision-makers have complete knowledge to inform their preferences and utility calculations. This assumption is particularly tenuous for decisions to start smoking or using other tobacco products, which typically happens during adolescence. Adolescents do not accurately understand the risks associated with smoking. Although youth "know" that smoking causes lung cancer, they demonstrate a lack of understanding of the magnitude of harm smoking causes.[71, 76, 77, 93, 94] For example, youth who smoke believe that smoking-related negative consequences are less likely to occur compared to youth who do not smoke.[76, 77] Youth also underestimate the extent to which smoking can shorten one's lifespan.[93] Moreover, youth incorrectly believe that health risks can be mitigated by altering their smoking behaviors, like smoking light cigarettes instead of regular cigarettes.[95] The empirical literature strongly demonstrates that youth consistently misperceive the harmful and addictive nature of smoking[15, 94]. Even describing adolescent smoking initiation as a "decision" may be inappropriate especially since it is questionable as to whether youth are capable of being "fully or adequately" informed decision-makers.[96]

The idea that smokers, particularly adolescents who are starting to smoke, do not

understand the risks of smoking has been challenged by Viscusi who analyzed national survey data concluding that smokers overestimate the risk of smoking.[97] He suggested that smokers are making rational choices in smoking and that with better information *more* people would be smokers. The data Viscusi used, however, were collected in September 1985 by a private research firm, Audits & Surveys, Inc., for several law firms retained by the tobacco companies (Arnold and Porter, Jones, Day, Reavis & Pogue and Shook, Hardy & Bacon) "in anticipation of litigation" against the tobacco companies.[98-101] In his 1997 deposition in the Mississippi's lawsuit against the major cigarette companies, Viscusi acknowledged that he knew the 1985 survey was commissioned by the law firm for the purpose of defending the tobacco companies in court.[102] Moreover, the basis for Viscusi's conclusion that smokers overestimate how dangerous smoking is rests on how respondents answered the single question, "Among 100 cigarette smokers, how many of them do you think will get lung cancer because they smoke? (If "don't know," PROBE 'Just your best guess will do.')."[97, p. 155] People are notoriously bad at estimating such abstract low probability events. The fact that the survey company instructed interviewers to "probe" if the respondent did not know the answer makes the result even more unreliable.

In contrast, Schoenbaum[103] examined whether adult smokers recognize that smoking is likely to shorten their lives and, if so, whether they understand the magnitude of this effect by comparing people's expectations about their chances of reaching age 75 to epidemiological predictions from life tables for never, former, current light, and current heavy smokers. He found that among men and women, the survival expectations of never, former, and current light smokers were close to actual survival probabilities. In contrast, among current heavy smokers, expectations of reaching age 75 were nearly twice as high as actuarial predictions, indicating that heavy smokers significantly underestimate their risk of premature mortality. Despite the fact that the majority of people believe that smoking is dangerous and could cause death, smokers tend to doubt that they, personally, would die from smoking, even if they smoked for 30 or 40 years.[71] Smokers also tend to underestimate the risk of addiction and overestimate their abilities to quit smoking[93, 104] and widely hold self-exempting beliefs that prevent them from thinking about the risks of smoking. Smokers tend to be skeptical of smoking risks and believe that smoking-related diseases will be cured by the time they might contract these diseases.[105] Moreover, although smokers may be aware of particular risks, they may not understand or appreciate the knowledge enough to be considered an "aware" decision-maker.[96] The empirical evidence is strong that people, including adolescent initiators who are not yet addicted, do not have perfect knowledge regarding smoking.

Empirical Evidence of Cognitive Limitations in Tobacco Use-Related Decisions

A major assumption of rational choice theory is that people are economically efficient decision-makers: the processes by which they make decisions is not only based on correct information, but the information about costs and benefits is weighed appropriately.[9, 10, 26] Empirical evidence that human decision-making sometimes deviates far from efficiency comes from two areas of research: neurological work on prefrontal cortex and emotions[106-108] and cognitive work on natural developmental processes.[109, 110] These areas of empirical work are particularly relevant when considering initiation and continuation of an addictive behavior such as smoking and use of other tobacco products.

Prefrontal Cortex and Emotions

Neuroscientists who focus on the role of the prefrontal cortex in decision-making have made important linkages between emotions and decision making processes. Work on patients with brain damage to the prefrontal cortex shows impaired abilities to experience emotions. These patients also are unable to make decisions that maximize gains and minimize costs.[108] The same pattern of cognitive inefficiency exists among people who are addicted to drugs.[106]

Cognitive inefficiency among patients with prefrontal cortex damage and people with substance addictions, including tobacco use,[111] is demonstrated through the Iowa Gambling Task, in which research participants are presented with four decks of cards with varying levels and probabilities of payoffs. Participants are asked to select cards that either reward or punish (via sums of money) from four desks. The decks are set up so that some decks produce modest rewards and punishments in the short-term, but result in long-term gains. Other decks produce high rewards and punishments in the short-term and result in long-term losses. Most people are able to resist decks that may give them high reward but also high punishments. These people tend to choose decks that provide smaller rewards, smaller punishments, and subsequently, long-term gains. However, some people, particularly people with pre-frontal cortex damage and addicts, lack the ability to resist the high reward/high punishment decks. Even though they experienced huge losses when choosing from high-risk decks, they were unable to anticipate future outcomes and continued to follow the strategy of pursuing large rewards at the risk of large punishments and long-term losses.[106-108] This inability to anticipate future outcomes and pursue strategies that do not benefit them in the long run suggests that at least people with prefrontal cortex damage and substance addicts do not make decisions with the cognitive efficiency specified in rational choice theory. These two groups represent myopic decision makers who do not appropriately value future consequences against current preferences.

Substance use, including smoking, also impacts neurological systems that control impulsivity and aid decision-making.[106, 107, 111] Cues to addictive substances may trigger the amygdala, which may modulate (or hijack) more "rational" neurological systems.[106] It is possible that people are willing to smoke despite known health and financial costs, not because they are acting rationally and maximizing utility, but because the cues that remind them of their addiction bypass cognitive systems that control impulses and activate systems that are emotional and impulsive. This impulsivity and poor affective decision-making significantly increases youth susceptibility to peer influence and smoking in the future.[111]

Bernheim and Rangel[112] developed an economic theory that seeks to integrate these advances in cognitive neuroscience. Their model posits that people exist in two states – a hot state where decisions are not made based on rational behavior and a cool state in which the usual assumptions of rational behavior apply. This model incorporates several elements that are more closely aligned with actual behaviors. First, it allows for addictive behaviors to be mistakes where behaviors and preferences are not congruent (i.e., even addicts themselves characterize their behaviors as mistakes, even while consuming). Second, it recognizes that addictive behaviors make people even more susceptible to environmental cues. As discussed above, even though people who exhibit trait-like impulsivity tend to seek short-term rewards over long-term consequences, this tendency can be affected by environmental cues[85] that can encourage or

discourage impulsive behaviors that underlie unhealthy behaviors such as smoking. Third, the model accounts for the empirical finding that continued use of addictive substances changes neurological pathways. These alterations affect people's ability to forecast future costs and benefits, making them particularly susceptible to external cues that override rational processes. To account for these lapses in rational thought Bernheim and Rangel include a stochastic component to represent the influence of memory and experiences, which are subjective, dependent upon situational context, and vary across time. Significantly, when Bernheim and Rangel use this theory to conduct a welfare analysis of different addiction-related policies they do not include the concept of consumer surplus.

Cognitive Development and Decision-Making

In addition to neurological variation that leads to decision-making deficits, rational choice theory does not account for the fact that decision-making processes are prone to developmental changes. Adults tend to make decisions using schemas and gists (i.e., shortcuts or vague representations of underlying meaning of information/trace information from memories), and cognitive shortcuts or heuristics.[9, 10, 109] Youth tend to make decisions based on emotions and social influences,[113-115] particularly emotions associated with sensation seeking, the thrill of a new experience, and bonding with friends.[110, 113] While still imperfect in their decision-making abilities, most adults have more developed psychosocial skills to navigate decisions without relying on impulse or emotional states, compared to youth who tend to make riskier decisions because they lack the necessary psychosocial maturity to constrain their impulsivity.[116-118] The inability to constrain impulsivity also explains why youth tend to be more vulnerable to smoking initiation than adults; instead of a decision-making process consisting of a cost-benefit analysis based on forward-thinking hedonic predictions (which, as noted above, even adults often do not exhibit in decisions related to smoking and use of other tobacco products), youth often make risky decisions that heavily rely on emotions and social contexts.[110, 113, 116-118] This reliance on emotions and social context may also explain why youth are particularly susceptible to tobacco industry marketing and advertising.[15]

The Application of a Consumer Surplus will Increase Health Disparities

The approach that the FDA applies in its RIA also serves to perpetuate health disparities among vulnerable groups. While smoking prevalence is higher among disadvantaged groups who suffer a greater burden of tobacco-induced disease,[122-125] there are differences in preferences and attitudes toward smoking that would, if a literal application of the rational choice model were applied, suggest a higher value be placed on current smoking (and thus higher consumer surplus) among disadvantaged groups than the population as a whole.[126] This application of consumer surplus would have the effect of reducing the value of FDA regulations, including the warning labels and sales restrictions in the proposed rule, on these vulnerable groups, thereby increasing health disparities.

The RIA Violates the Standards Set Out in OMB Circular A-4 for Regulatory Cost-Benefit Analysis

As discussed above, the FDA RIA is based on a theory that is contradicted by a large

body of empirical evidence (including the evidence summarized on pages 23146 and 23159 of the proposed rule{Food and Drug Administration, 2014 #187}). Although rational choice theory has advanced classical economic theory, there are major important flaws in applying it to multidimensional addictive behaviors, particularly those initiated in youth such as smoking. This issue is of more than passing concern because Office of Management and Budget (OMB) Circular A-4,[119] which lays out principles for regulatory cost-benefit analyses, lists specific cautions regarding the measurement of consumer surplus using revealed preferences. OMB notes that revealed preference methods are appropriate "[i]f the market participant is well informed and confronted with a real choice" and that "the goods and services affected by the regulation are traded in well-functioning competitive markets." Neither of these conditions applies to addictive substance use, particularly smoking and other tobacco use, when most people become addicted as youth.

Even more to the point, OMB directs that "the statistical and econometric models employed should be appropriate for the application and the resulting estimates should be robust in response to plausible changes in model specification and estimation technique." This requirement is particularly relevant to tobacco regulation because Laux[42] demonstrated that peer group effects, which are generally overlooked in welfare analysis of tobacco regulations, make it impossible to identify the welfare consequences of regulating a product from observed demand curves. Citing these difficulties, Cutler et al.[120] declined to consider consumer surplus in their analysis of the economic effects of the Master Settlement Agreement that resolved litigation by many of the states against the major cigarette companies. In response to public comment of the warning label rule criticizing the FDA's use of Cutler's[13] theoretical suggestion that, for a completely rational person for whom the costs and benefits of reduced smoking are linear in the number of cigarettes giving up, the consumer surplus equaled half the health benefits, the FDA presented additional theoretical arguments for using the 50% discount in its final warning label rule.[1, p. 36772-4] The FDA did not, however, present any robust empirical estimates of consumer surplus to support such a prediction. The FDA explicitly recognized the lack of empirical evidence in making this assumption, stating in the final rule, "FDA does not claim that 50 percent is the correct ratio … it may be near zero or near 100 percent…"[1, p. 36774]

Conclusion

Rational choice theory and its associated constructs (e.g., consumer surplus) are predicated on assumptions that behavior is guided in a very specific, circumscribed manner in which the decision-maker considers all information and makes a decision that is based on weighing benefits and risks without undue influence from others factors. These assumptions may be appropriate for certain kinds of behavior and situations: (1) situations in which the decision criterion is one-dimensional, clear and observable (e.g., dollars), (2) when decisions are not cognitively too complex (e.g., confined to amount willing to pay and the emotional component is negligible), (3) when people have the cognitive capability to make decisions consistent with the utility calculations, and (4) when the decision environment drives people toward the optimal behavior or drives out suboptimal decisions (e.g., when there are active markets). None of these conditions exist in decisions to start or continue smoking. The decision to start or continue smoking involves a substance (nicotine) that alters the brain and creates addiction that entail complex outcomes (e.g., costs and benefits are not captured within a one-

dimensional metric), where decision-makers may lack the cognitive capability to make rational complex decisions (e.g., children deciding whether to start smoking, thereby "creating" addicted adults), and where there is no "market" to drive out behaviors that are suboptimal in the long run. As a result, the application of rational choice theory and ad hoc estimates of consumer surplus are inappropriate.

The empirical evidence on smoking behavior shows that the fundamental assumptions underlying application of the concept of consumer surplus to smoking behavior are not supported by empirical evidence. Although these models account for lapses in rationality by incorporating stochastic or dynamic components to their mathematical models, the models still adhere to the basic rational choice premise.[25] What is largely absent from the economic literature is the possibility that rational choice may not be an appropriate framework for addictive behaviors, particularly tobacco use. Indeed, as McFadden observed, a model based on rational expectations "is vulnerable to behavioral rejection, because the solution of these programs involves levels of complexity and computation that fairly clearly exceed human cognitive capacity, because it is unrealistic to assume that historical experience and market information and discipline are sufficient to homogenize subjective expectations, particularly for rare events, and because the axiomatic foundations for utility jointly additively separable in time and uncertain outcomes are not persuasive."[121]

The increasing realization that the theoretical models used to estimate consumer surplus are likely misspecified and, so, fail to reflect actual human smoking behavior makes it imperative that the FDA ensure that its RIA is consistent with the robust empirical evidence the FDA itself summarizes on 23146 and 23159 of the proposed rule{Food and Drug Administration, 2014 #187} and which is supported by the empirical evidence summarized in this comment stop applying a consumer surplus discount to this and all subsequent rulemaking related to tobacco products.

The major deviations from the assumptions underlying these theoretical models makes it likely that consumer surplus is an inappropriate concept to apply to addictive behavior, thus contradicting the OMB's guidelines.

Considering that consumer surplus based on rational choice theory is not consistent with observed tobacco use behavior, the FDA should, as it does in the draft rule, recognize that concepts based on the rational choice framework are not appropriate for RIA of regulations involving addictive substances like tobacco (nicotine) and stop including consumer discounts in its RIA analyses. Continuing to apply a consumer surplus discount to the analysis of this and future regulations will, likewise, undermine sensible policies to reduce smoking and other tobacco use and promote public health.

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