

Risk-Taking and Rulemaking: Addressing Risk Compensation Behavior Through FDA Regulation of Prescription Drugs

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Despite widespread acclaim for their potential to reduce public health harms, technological advances in health and safety frequently raise the ominous specter of risk compensation behavior—the possibility that individuals protected by these technologies will increase their risk-taking on the belief that they are protected from harm. Risk compensation has been a rallying cry for opponents of new technologies such as the HPV vaccine, needle exchange programs for drug users, or prescription pills for the prevention of HIV infection. Although these concerns are frequently voiced in the language of morality and personal responsibility, it may be more productive to consider this phenomenon through the lens of behavioral science, with an emphasis on respecting individuals’ behavioral preferences. This Article aims to present the theoretical basis for risk compensation behavior, to categorize different types of risk compensation effects, to enumerate ways in which the law may address these effects, and to illustrate an application of these legal strategies to FDA regulation of prescription drugs. Throughout, this Article reframes risk compensation behavior as a presumptively rational mechanism for value conversion, by which the protective value of a health or safety technology is transformed into another type of value that may better satisfy individual preferences. But where imperfect information or negative externalities lead to harm, there may be a role for a regulatory response.

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Introduction

On July 16, 2012, the Food and Drug Administration (FDA) issued a decision that for some, “mark[ed] a catastrophe in the history of AIDS in

America.”¹ The decision was to approve the antiretroviral drug Truvada® for use as pre-exposure prophylaxis (PrEP)—the first pill effective for reducing the chance of acquiring human immunodeficiency virus (HIV) infection among adults at high risk.² Before issuing this approval, the FDA reviewed safety data and two placebo-controlled trials demonstrating Truvada’s efficacy for preventing HIV.³ Scientists lauded the decision as a “major milestone,”⁴ policy advocates hailed it as “a moment to celebrate,”⁵ and policy experts suggested that the approval “reinvigorat[es] the idea that we can reali[ze] an AIDS free generation.”⁶ Where was the catastrophe? In denouncing the FDA’s decision, the AIDS Healthcare Foundation warned of side effects and potential missed pills, but above all, the danger was “risk compensation, the phenomenon of engaging in more risky behavior when you believe you’re protected from harm.”⁷ If people taking Truvada as PrEP stop using condoms or have sex with more partners, argued the Foundation’s general counsel, PrEP “will actually increase HIV infections. . . . [and] do more harm than good.”⁸

Even without knowing the technical term “risk compensation,” most of us have heard of offsetting behavior in some form. We may fear giving liver transplants to alcoholics, providing sterile needles to drug users, vaccinating adolescent women to prevent human papillomavirus infection (HPV), or selling statins as a fast food side dish—all on the rationale that these interventions may increase the unhealthy behaviors that lead to future harm. Although these arguments often play out through claims of morality, personal responsibility, and fairness, there is indeed a scientific basis for concern about offsetting effects, also called risk compensation behavior. This Article is primarily concerned with what may be called “upward” risk compensation, by which individuals take more risks based on the expectation that some intervention (such as a bicycle helmet or a vaccine) has decreased their exposure to harm.

1. Bruce Geryk, *Truvada Gets FDA Nod for HIV Prevention*, ABC NEWS (July 16, 2012), <http://abcnews.go.com/Health/AIDS/pill-prevent-hiv-fda-approval/story?id=16789790>.

2. FDA, *Questions and Answers on Emtricitabine 200 Mg/Tenofovir Disoproxil (Marketed as Truvada)*, FDA.GOV (July 2012), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm312202.htm>.

3. *Id.*

4. David Holmes, *FDA Paves the Way for Pre-Exposure Prophylaxis*, 380 LANCET 325, 325 (2012) (quoting Dr. Kenneth Mayer); Brian Vastag, *FDA Approves First Drug to Prevent HIV Infection*, WASH. POST, July 17, 2012, at A03 (quoting FDA Commissioner Margaret A. Hamburg calling the decision an “important milestone”).

5. Mitchell J. Warren & Emily S. Bass, *From Efficacy to Impact: An Advocate’s Agenda for HIV Pre-Exposure Prophylaxis Implementation*, 44 AM. J. PREVENTIVE MED. S167, S167 (2013).

6. Holmes, *supra* note 4, at 325 (quoting former White House policy advisor Gregorio Millett).

7. Tom Myers, *HIV Prevention Pill Will Do More Harm Than Good: The Side Effects of Truvada PrEP Outweigh Its Benefits, As People Will Struggle To Take It Regularly*, U.S. NEWS AND WORLD REPORT, Aug. 3, 2012, <http://www.usnews.com/opinion/articles/2012/08/03/hiv-prevention-pill-will-do-more-harm-than-good-hiv-pill-will-give-a-false-sense-of-security> (internal quotation marks omitted).

8. *Id.*

But if we take a wider view, we can find offsetting behavior everywhere, not only in unhealthy directions, but also in helpful ways, such as driving more slowly on a foggy day, scheduling a mammogram after a close relative is diagnosed with breast cancer, or skipping dessert on days when one does not exercise. These behaviors are driven not necessarily by changes in our actual risk, but rather by changes in our perception of risk—our feelings of health and safety. Drawing on this dynamic, risk compensation theory suggests that it may be dangerous to *feel* protected, possibly to the point where health interventions might help us more if we had no idea we were getting them.

Past legal scholarship has engaged to some extent with risk compensation theory. Much of this work has assessed unexpected responses to regulations designed to have direct effects on behavior, such as seatbelt laws,⁹ gun safe-storage laws,¹⁰ protective bottle cap requirements for medications,¹¹ and airbag regulations in cars.¹² Several articles have also examined the ways in which consumers' risk compensation behavior can influence the effects of legal rules intended to achieve other goals, such as promoting fuel efficiency,¹³ safeguarding the right to obtain an abortion,¹⁴ or expanding insurance coverage for the treatment of addictions¹⁵ or diabetes.¹⁶ Theoretical legal literature has repeatedly expressed worries that risk compensation effects may undermine health and safety regulation,¹⁷ but these behaviors have generally been viewed as an "intractable" problem beyond reach of the law.¹⁸ To date, very little work has considered *whether* and *how* the law might intervene in risk compensation dynamics.

9. See Sam Peltzman, *The Effects of Automobile Safety Regulation*, 83 J. POL. ECON. 677 (1975). Several commentators have referred to offsetting behavior as the "Peltzman effect" on the basis of this study. See, e.g., Adam T. Pope & Robert D. Tollison, "Rubbin' Is Racin'": Evidence of the Peltzman Effect from NASCAR, 142 PUB. CHOICE 507 (2010).

10. Cynthia Leonardatos, Paul H. Blackman & David B. Kopel, *Smart Guns/Foolish Legislators: Finding the Right Public Safety Laws, and Avoiding the Wrong Ones*, 34 CONN. L. REV. 157 (2001); John R. Lott, Jr. & John E. Whitley, *Safe-Storage Gun Laws: Accidental Deaths, Suicides, and Crime*, 44 J.L. & ECON. 659 (2001).

11. W. Kip Viscusi, *The Lulling Effect: The Impact of Child-Resistant Packaging on Aspirin and Analgesic Ingestions*, 74 AM. ECON. REV. 324 (1984).

12. Steven Peterson, George Hoffer & Edward Millner, *Are Drivers of Air-Bag-Equipped Cars More Aggressive? A Test of the Offsetting Behavior Hypothesis*, 38 J.L. & ECON. 251 (1995).

13. Paul E. Godek, *The Regulation of Fuel Economy and the Demand for "Light Trucks"*, 40 J.L. & ECON. 495 (1997).

14. Jonathan Klick & Thomas Stratmann, *The Effect of Abortion Legalization on Sexual Behavior: Evidence from Sexually Transmitted Diseases*, 32 J. LEGAL STUD. 407 (2003).

15. Jonathan Klick & Thomas Stratmann, *Subsidizing Addiction: Do State Health Insurance Mandates Increase Alcohol Consumption?*, 35 J. LEGAL STUD. 175 (2006).

16. Jonathan Klick & Thomas Stratmann, *Diabetes Treatments and Moral Hazard*, 50 J.L. & ECON. 519 (2007).

17. See *infra* Subsection I.C.

18. Anita Bernstein, *A Model of Products Liability Reform*, 27 VAL. U. L. REV. 637, 679 (1993).

With the exception of a 2008 article discussing risk compensation as a form of placebo effect,¹⁹ legal scholarship has not yet considered offsetting behavior as a predictable consumer response to pharmaceutical products. In overlooking the literature on risk compensation behavior, we disregard a phenomenon that could undermine drug effectiveness, reduce cost-effectiveness, and expose consumers to adverse health consequences. We may also miss opportunities to minimize risk compensation behaviors, which could increase the beneficial impact of new drugs. Prescription drugs are governed by overlapping regimes of FDA regulation and tort liability for product defects, providing many legal tools for addressing risk compensation behavior. FDA approval and products liability law do more than regulate product availability—they also require companies to create specific forms of knowledge about their products and to make risks known to users. These legal requirements provide opportunities both to identify risk compensation effects and to attempt to mitigate them. Despite this potential, however, systems for approving and marketing new drugs tend to obscure the behavioral evidence we need to maximize their value; moreover, even when there is behavioral evidence of risk compensation responses, the law is poorly equipped to address them.

This Article examines the relevance of risk compensation behavior to FDA regulation of pharmaceutical products in the United States, particularly as applied to the testing, approval, and marketing of prescription drugs. Behavioral responses to medications are particularly important for drugs that are partially efficacious: some of our best new weapons against chronic and infectious illness are only partially efficacious, and improvements in health must come from both technology and behavior change. This Article also stresses that our understanding of risk compensation would benefit from a more thorough engagement with behavioral science literature, which suggests that such responses are both more complex and potentially more value-maximizing than has previously been considered. In order to better understand risk compensation behavior, we must acknowledge that individuals may perceive value in activities that are labeled “risky.” For instance, driving quickly, eating junk food, drinking alcohol, and having unprotected sex may all confer individual-level benefits, such as speed, pleasure, relaxation, social inclusion, and relationship satisfaction. As a corollary, self-protective behaviors may carry costs. For example, driving slowly increases travel time, eating healthfully may be expensive, teetotaling may be socially burdensome depending on one’s peers, and protected sex may be less pleasurable. Interventions that reduce risks, such as statins or high blood pressure medications, may have side effects and financial costs. Risk compensation is a mechanism by which individuals seek to capture the benefits that most accord with their values, striking a balance between acceptable risks and desired

19. Anup Malani, *Regulation with Placebo Effects*, 58 DUKE L.J. 411, 430 (2008).

benefits. When risk compensation occurs, one's actual risk depends on two separate independent variables: the *use of a risk-reducing intervention*, such as a drug or vaccine, and the corresponding *perception of risk-reduction*, which may lead the individual to adjust his behavior in a way that affects his and others' risks. Although the two variables are related—an individual perceives that his risks are lower because he is using a risk-reducing intervention—the effects of these two variables are distinct.

Throughout this Article, pre-exposure prophylaxis (PrEP) drugs for the prevention of HIV, such as the recently approved Truvada, will represent a case study of an emerging pharmaceutical strategy to reduce risks posed by individual health behaviors. PrEP refers to the use of antiretroviral drugs by HIV-negative people, wherein people take the drugs before engaging in behaviors that carry a risk of HIV infection, such as unprotected sex. Although Truvada is partially efficacious for preventing infection;²⁰ concerns about risk compensation have complicated plans for dissemination of this new strategy.

This discussion proceeds in five Parts. Part I describes risk compensation and its underlying theory of risk homeostasis, providing the first cross-phenomenon review of the empirical evidence that supports and challenges this model. Part II re-examines the extent to which risk compensation should be regarded as an adverse effect: although increased risk-taking may diminish the impact of health interventions, these behaviors also represent a fuller expression of preferences that serve individual ends. If we respect an individual's own preferences, someone may in fact obtain more overall benefit from a preventive drug by a combination of *some* protection from disease and *some* increased risk behavior, compared to retaining all the drug's preventive benefits. Efforts to minimize risk compensation, then, are invariably efforts to intervene in individual choice, which makes such proposals normatively suspect. This Part will characterize several different types of risk compensation effects—perfectly informed risk compensation, uninformed partial risk compensation, uninformed overcompensation, and externally hazardous risk compensation—and discuss the normative basis for using legal intervention to minimize these effects. This Article is the first to take a trans-substantive view of risk compensation behavior, as well as the first to offer a taxonomy to guide regulatory efforts.

Identifying risk compensation effects, particularly hazardous effects, leads naturally to the inclination to intervene in these processes. This impulse, however, runs the risk of producing an overly coercive response, such as barring product access or withholding product approval. Using FDA regulation

20. Jared M. Baeten et al., *Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women*, 367 NEW ENG. J. MED. 399 (2012); Robert M. Grant et al., *Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men*, 363 NEW ENG. J. MED. 2587 (2010); Michael C. Thigpen et al., *Antiretroviral Preexposure Prophylaxis for Heterosexual HIV Transmission in Botswana*, 367 NEW ENG. J. MED. 423 (2012).

of prescription drugs as a test case, this Article describes several ways in which the law might address offsetting, with increasing levels of intrusiveness: identifying risk compensation effects, attempting to modify user behavior, and only then considering limitations on product access. Part III argues that the FDA should impose on drug manufacturers a legal duty to test for risk compensation effects and associated health consequences, where preliminary testing and scientific commentary suggest that risk compensation is possible. Although risk compensation effects are not currently assessed in the FDA's multiphase framework for drug approval, they should be a legally required part of pre- and post-marketing testing. Part IV suggests ways in which FDA regulation can address the behaviors of drug users, including product labeling to warn intermediaries and consumers about possible risk compensation effects, along with other components of FDA-approved Risk Evaluation and Mitigation Strategies (REMS).

Finally, Part V assesses the role that risk compensation concerns might play during the FDA approval process, including initial approval and requirements for Phase IV testing. This Part argues that risk compensation behavior should not by default bar initial FDA approval, nor should it lead to the withdrawal of efficacious drugs from the market. To limit product access, the threshold must be extraordinarily high: the FDA should consider this option only when hazardous risk compensation effects are observed, where those effects outweigh the public health benefit of the drug, and where efforts to modify user behavior are unsuccessful. In this extreme and highly unlikely scenario, efforts to limit access to such products may be normatively defensible on public health grounds.

I. Risk Compensation and Risk Homeostasis Theory

Scientific understanding of risk compensation behavior is based on risk homeostasis theory, first proposed by Professor Gerald J.S. Wilde in the 1970s, and later refined by Professor John Adams and other scholars.²¹ The goal of this Part is to describe the evidence base for risk compensation behavior, outlining a behavioral mechanism by which individuals may adjust their risk-taking in response to a preventive intervention. Sections within this Part will describe the origins and processes of risk compensation behavior theory, summarize evidence that supports and challenges this theoretical model, and detail the ways in which legal scholarship has previously engaged with these concepts.

21. See, e.g., JOHN ADAMS, RISK 14 (1995); GERALD J.S. WILDE, TARGET RISK 2 (2001); James Hedlund, *Risky Business: Safety Regulations, Risk Compensation, and Individual Behavior*, 6 INJURY PREVENTION 82, 82-84 (2000).

A. Theoretical Basis

Activities that affect our health, safety, and security have both potential costs and expected benefits. Risk homeostasis theory²² posits that for every activity, “people accept a certain level of subjectively estimated risk to their health, safety, and other things they value, in exchange for the benefits they hope to receive from that activity ([e.g.,] transportation, work, eating, drinking, drug use, recreation, romance . . .).”²³ Wilde calls the level of acceptable risk the “target risk level,” which differs for each individual and may change, for example, due to time, experience, or social influences.²⁴ Adams has added complexity to this model, noting that our propensity to take risks also changes depending on the potential rewards, and that our perceptions of risk are affected by our past experience with our own and others’ losses.²⁵

According to risk homeostasis theory, we continually modify our risk-taking behaviors (within our ability to do so) so that our perceived risk approaches our individual target risk level. That is, we decide how much danger we find acceptable, and we make behavioral choices that we believe will bring us closer to that level of risk—similar to the way a thermostat activates heat or air conditioning when the temperature deviates from the chosen set-point.²⁶ When we feel excessively safe *and see potential benefits*²⁷ in behaving more riskily, we will increase our risk-taking to capture those benefits. For instance, instead of wearing a seatbelt *and* driving slowly, we may choose to wear a seatbelt and drive faster to gain the value of arriving quickly. Instead of taking PrEP drugs and also using condoms to prevent HIV, PrEP users may decide to use condoms less frequently to capture the benefits that may come with unprotected sex. Similarly, when we perceive unacceptably high levels of risk, we decrease our risk-taking and engage in more risk-avoidant behavior; for example, to pose a counterpoint to the landmark seatbelt study,²⁸ drivers who are accustomed to seatbelt use may drive more slowly in a car without seatbelts.²⁹ If a PrEP user can no longer afford his medication, he may use condoms more frequently. Over time, we aim for a level of perceived

22. Wilde originally called this “risk compensation theory,” but he has more recently relabeled it as “risk homeostasis.” See WILDE, *supra* note 21, at 29-30.

23. *Id.* at 5.

24. *Id.* at 5, 36-37; see also ADAMS, *supra* note 21, at 14-16.

25. ADAMS, *supra* note 21, at 15.

26. WILDE, *supra* note 21, at 5. As people engage in a risk-bearing activity, they “continuously check the amount of risk they feel are exposed to . . . compare this with the amount of risk they are willing to accept, and try to reduce any difference between the two to zero.” *Id.*

27. An extreme view of risk homeostasis theory would suggest that we increase our risk-taking solely to maintain our target risk level, even when we lack any other motivation for doing so. See Hedlund, *supra* note 21, at 87-88.

28. Peltzman, *supra* note 9.

29. See ADAMS, *supra* note 21, at 127-28 (“Most readers of this book will now be habitual users of seatbelts. . . . Might you drive a little bit more carefully if you were deprived of the protection of your seatbelt?”).

risk that is consistent with our target level. Risk homeostasis theory does not suggest that we succeed in keeping our risk constant, but rather posits that we adjust our behavior in the direction of the level where we perceive the most desirable balance between risks and benefits.

The term “risk compensation” is used to describe a change in risk-taking behavior as a response to an intervention (usually a new health or safety technology); other names for this dynamic include “risk adaptation” and “offsetting behavior.” The latter term has been used most extensively in economic and legal analyses, such as Professor Sam Peltzman’s significant study of auto safety regulations in 1975.³⁰ Peltzman used time-series data to analyze a variety of auto safety devices, such as lap seatbelts, energy-absorbing steering columns, and dual braking systems; his analysis found that auto safety regulations had not influenced the overall highway death rate, in part due to a displacement in the burden of accidents from drivers to pedestrians.³¹ Although drivers were indeed less likely to die, Peltzman found evidence that they compensated for their increased safety by driving with more “intensity”—faster and more riskily—thereby endangering others on the road.³² Increases in the nonfatal accident rate supported this explanation.³³ The energetic reaction to Peltzman’s landmark study continues today,³⁴ often parodying his work as a recommendation to affix a dagger (or spike, or explosives) to the steering wheel to encourage safer driving.³⁵ One article notes that “the weight of the evidence now suggests that if safety devices lead to less careful driving, the effect is far more modest than Peltzman suggested, and not nearly enough to offset the benefits of the devices.”³⁶ But even without fully offsetting the benefits of a health or safety intervention, offsetting at any magnitude can influence the preventive benefit, cost-effectiveness, and population-level impact of the protective measure.

Modern views of risk compensation theory have recognized complexity in these effects; an “extreme view” of risk homeostasis theory, which would predict complete offsetting and dismiss motivations other than the desire to

30. Peltzman, *supra* note 9. Legal scholars have extensively criticized Peltzman’s work over the past few decades. See, e.g., Robert S. Chirinko & Edward P. Harper, *Buckle Up or Slow Down? New Estimates of Offsetting Behavior and Their Implications for Automobile Safety Regulation*, 12 J. POL’Y ANALYSIS & MGMT. 270 (1993); John J. Donohue III, *Did Miranda Diminish Police Effectiveness?*, 50 STAN. L. REV. 1147, 1158-60 (1998) (noting that “all serious economists, econometricians, and statisticians now concede” that Peltzman’s model was flawed).

31. Peltzman, *supra* note 9, at 717.

32. *Id.*

33. *Id.*

34. See *supra* note 30 and accompanying sources.

35. See, e.g., ADAMS, *supra* note 21, at 155. See also David Bjerklie, *The Hidden Danger of Seat Belts*, TIME, Nov. 30, 2006, <http://www.time.com/time/nation/article/0,8599,1564465,00.html> (“[I]magine how it might affect the behavior of drivers if a sharp stake were mounted in the middle of the steering wheel? Or if the bumper were packed with explosives.”).

36. David Alan Sklansky, *Killer Seatbelts and Criminal Procedure*, 199 HARV. L. REV. F. 56, 57 (2006).

keep risk constant, is now disfavored.³⁷ In a review of this literature, Dr. James Hedlund has identified four factors that must be present to provoke a risk compensation response to a health or safety intervention: (1) the intervention must be visible because an unnoticed change will not influence risk perceptions; (2) the intervention must have some effect on the individual; that is, it must give rise to the perception of protection; (3) the individual must have a motivation to increase his risk-taking—he will not take more risks just for the sake of maintaining a constant target risk level; and (4) the individual must have sufficient control and opportunity to adjust his behavior,³⁸ which is particularly relevant given the social context of many health and safety behaviors. Each of these four conditions is complex, and there is room for extensive variation across individuals, across different health and safety products, and over time. This framework is also flexible with regard to the target risk level; individual preference for risk may also change for any number of reasons. All four of Hedlund's conditions are fulfilled for behavioral responses to prescription drugs.³⁹

1. Criticisms of Risk Homeostasis Theory

Risk homeostasis theory has been controversial. Some have criticized the theory on the grounds that individuals are incapable of precisely calibrating their risks,⁴⁰ while others have pointed to empirical evidence showing that the gains of many safety devices outweigh any behavioral adjustment.⁴¹ These criticisms, however, misunderstand the theory to require *complete* behavioral offsetting and a precisely constant level of risk. The same error is evident in the indictment of risk compensation theory as an excuse to do nothing about unsafe behaviors, on the theory that offsetting will void every benefit.⁴² But the theory of risk compensation is not so exacting—it predicts only an adjustment to the

37. Hedlund, *supra* note 21.

38. *Id.* at 88.

39. That is, individuals taking prescription drugs are conscious of their medications; these medications will likely give rise to a meaningful perception of benefit; individuals may find benefits in behaviors that confer health risks; and often individuals have the opportunity to modify their behaviors.

40. See, e.g., Frank P. McKenna, *Do Safety Measures Really Work? An Examination of Risk Homeostasis Theory*, 28 *ERGONOMICS* 489 (1985); Frank P. McKenna, *Evidence and Assumptions Relevant to Risk Homeostasis*, 28 *ERGONOMICS* 1539 (1985); Frank P. McKenna, *What Role Should the Concept of Risk Play in Theories of Accident Involvement?*, 31 *ERGONOMICS* 469-484 (1988); Brian O'Neill & Allan Williams, *Risk Homeostasis Hypothesis: A Rebuttal*, 4 *INJURY PREVENTION* 92 (1998). Cf. Gerald J.S. Wilde, *Assumptions Necessary and Unnecessary to Risk Homeostasis*, 28 *ERGONOMICS* 1531 (1985); Gerald J.S. Wilde, *Evidence Refuting the Theory of Risk Homeostasis? A Rejoinder to Frank P. McKenna*, 27 *ERGONOMICS* 297 (1984).

41. See, e.g., Leonard Evans, *Comments on Wilde's Notes on 'Risk Homeostasis Theory and Traffic Accident Data'*, 6 *RISK ANALYSIS* 103 (1986); Leonard Evans, *Risk Homeostasis Theory and Traffic Accident Data*, 6 *RISK ANALYSIS* 81 (1986); O'Neill & Williams, *supra* note 40; Harry S. Shannon, *Road-Accident Data: Interpreting the British Experience with Particular Reference to the Risk Homeostasis Theory*, 29 *ERGONOMICS* 1005-15 (1986).

42. Gerald J.S. Wilde et al., *For and Against: Does Risk Homeostasis Theory Have Implications for Road Safety*, 324 *BRITISH MED. J.* 1149 (2002).

extent that individuals have the opportunity and motivation to take more risks. These factors will vary widely, and in-depth study is necessary to understand how risk compensation will operate in any given field.

Some may counter that health and safety measures should actually lead to *reductions* in risky behavior, rather than increases, because the use of a safety measure may make risks more salient. The conscious use of a safety product may indeed make people more cognizant of underlying dangers; for instance, when a cyclist puts on a helmet, she may think more about the risk that she will crash, and therefore she may take additional precautions with this risk in mind. This result, however, is not necessarily inconsistent with risk compensation theory. The cyclist's greater focus on crashing has motivated a change in the *target risk level*, the level of risk that she is willing to accept. This change shifts the entire system of risk calculus to a lower level of preferred risk, in which the cyclist becomes less willing to trade safety in exchange for speed. Around that new target risk level, there may still be compensation effects—that is, the cyclist may ride more slowly when her helmet inspires her to think about crashing, but she may have reduced her speed *even more* if she had thought about the same risks without wearing her helmet.

Finally, some have criticized risk homeostasis theory on the grounds that individuals are insufficiently rational to engage in the decisions required for risk compensation behavior to take place.⁴³ The mechanism of risk compensation behavior is cognitive: an individual must appraise his baseline risk level, identify a change in that risk level, and compute the balance of risks and rewards attached to a risky behavior. He must then decide whether taking an additional risk will cause him to exceed his target risk level. There are many reasons to be skeptical of the individual's ability to calculate risks accurately: as Wilde has acknowledged, the degree to which an individual succeeds in maintaining his target risk level "depends upon [his] perceptual, decisional, and executorial skills."⁴⁴ But instead of requiring complete rationality and accuracy, risk compensation theory builds in a wide margin for irrational actors.⁴⁵ Our behavioral choices are based on our perceptions of risk and benefit, however irrational those perceptions may be. A rich literature has identified nonrational factors that influence our cognitions and risk perceptions, such as emotion,⁴⁶ cultural world-views,⁴⁷ cognitive biases such as optimism,⁴⁸

43. See, e.g., Frank P. McKenna, *Behavioural Compensation and Safety*, 9 J. OCCUPATIONAL ACCIDENTS 107, 117 (1987) ("[I]ndividuals do not have the computational power to assess and exactly compensate for changes in the probabilities of very infrequent events such as accidents.").

44. Gerald J.S. Wilde, *The Theory of Risk Homeostasis: Implications for Safety and Health*, 2 RISK ANALYSIS 209, 210 (1982).

45. See *id.* at 216 (identifying modifications to the risk compensation model depending on erroneous perceptions of risk).

46. Dan M. Kahan, *Two Conceptions of Emotion in Risk Regulation*, 156 U. PA. L. REV. 741 (2008).

47. Dan M. Kahan et al., *Who Fears the HPV Vaccine, Who Doesn't, and Why? An Experimental Study of the Mechanisms of Cultural Cognition*, 34 L. & HUM. BEHAV. 501 (2010); Dan

mood, social norms and beliefs, personality factors such as sensation-seeking, habits, and a variety of other factors. We may not be conscious of adjusting our risk to fit a perceived target level,⁴⁹ and we may underestimate risks when they have become very familiar.⁵⁰ Individuals may expect more benefit from new technologies at first, and then notice those benefits less once the technologies become routine.⁵¹ Several studies suggest that although we may believe that *others* will engage in risk compensation, fewer of us believe that we will do it ourselves.⁵² Behavioral adjustments may also be correlated within a community due to social influences on risk perception and behavioral norms. These are all challenges to rationality, but each may be incorporated into the risk compensation dynamic. With the right data, it would be possible to design a complex model of risk compensation that accounts for these influences.

2. Distinguishing Risk Compensation from Related Concepts

Risk compensation should not be confused with several similar concepts in the legal literature. The same term has been used by Professor Nina Crimm discussing tax exemption for charitable organizations, to suggest that tax exemption is compensation for providing “inherently risky” public services.⁵³ This usage draws on the employment compensation literature, where “risk compensation” refers to the additional financial remuneration paid to workers in hazardous jobs.⁵⁴

The behavioral phenomenon of risk compensation has a closer cognate in the concept of moral hazard, as used throughout insurance law. Moral hazard has two forms: *ex ante* moral hazard occurs when policyholders reduce the protections they take to prevent losses that are covered by insurance, while *ex post* moral hazard refers to the increased uptake of covered services (most

M. Kahan & Paul Slovic, *Cultural Evaluations of Risk: “Values” or “Blunders”*, 119 HARV. L. REV. F. 166 (2006).

48. Marie Helweg-Larsen & James A. Shepperd, *Do Moderators of the Optimistic Bias Affect Personal or Target Risk Estimates? A Review of the Literature*, 5 PERSONALITY & SOC. PSYCHOL. REV. 74 (2001).

49. Adriaan Heino et al., *Risk Perception, Risk Taking, Accident Involvement and the Need for Stimulation*, 22 SAFETY SCI. 35 (1996).

50. See Elizabeth Creyer, William Ross & Deborah Evers, *Risky Recreation: An Exploration of Factors Influencing the Likelihood of Participation and the Effects of Experience*, 22 LEISURE STUD. 239, 243 (2003); Colin Powell, *The Perception of Risk and Risk Taking Behavior: Implications for Incident Prevention Strategies*, 18 WILDERNESS & ENVTL. MED. 10, 13 (2007).

51. Malani, *supra* note 19, at 434-35.

52. Laura A.V. Marlow et al., *Mothers’ and Adolescents’ Beliefs About Risk Compensation Following HPV Vaccination*, 44 J. ADOLESCENT HEALTH 446 (2009); Nuno Nodin et al., *Knowledge and Acceptability of Alternative HIV Prevention Bio-Medical Products Among MSM Who Bareback*, 20 AIDS CARE 106 (2008).

53. Nina J. Crimm, *An Explanation of the Federal Income Tax Exemption for Charitable Organizations: A Theory of Risk Compensation*, 50 FLA. L. REV. 419, 425 (1998).

54. See, e.g., Keith A. Bender, Hosne A. Mridha & James Peoples, *Risk Compensation for Hospital Workers: Evidence from Relative Wages of Janitors*, 59 INDUS. & LAB. REL. REV. 226 (2006).

commonly health services) that policyholders would not have purchased out of pocket.⁵⁵ Ex post moral hazard is less relevant here, but ex ante moral hazard is a close analogue to risk compensation—both represent increases in risk-taking in response to a perceived reduction in risk, and at least one analysis has suggested that they are synonymous.⁵⁶ Although insurance does not reduce the *probability* of incurring harm, it reduces the *extent* of harm to which the insured person is exposed, thereby provoking increased risk-taking behavior.⁵⁷ It may be more precise to define ex ante moral hazard as a subspecies of risk compensation that requires a specific stimulus, namely, the perceived opportunity to shift financial losses to a third party.

Risk compensation may also be confused with substitution, in which an individual shifts from one costly behavior to another that fulfills similar motivations. One example of this dynamic is “addiction substitution” or “addiction transfer” among patients who receive bariatric surgery for obesity, but then develop substance use disorders in lieu of returning to a high-calorie diet.⁵⁸ Another incarnation familiar to legal scholarship is substitution in crime, in which the price of one crime rises, prompting offenders to engage in other types of crimes.⁵⁹ The extent to which substitution falls under the risk compensation umbrella depends on the level of generality we use to define the risk. For example, if we are discussing *all* risks to health, we may view a switch from overeating to substance use as part of a risk compensation response to bariatric surgery. But if we solely examine risks from overeating, we may not consider drug and alcohol use behaviors as relevant. In this way, risk compensation behavior may sometimes entail substitution, but it is not equivalent to a substitution response.

Finally, risk compensation in behavioral science literature is frequently used synonymously with behavioral disinhibition, but the two are distinct. Both are explanations for an increase in behavioral risk-taking. The mechanism of behavioral disinhibition, however, is a lack of concern for risk altogether, rather

55. See George L. Priest, *How Insurance Reduces Risks*, mimeo. 11 (1996). For a recent overview of moral hazard theory, see Michael H. LeRoy, *Do Courts Create Moral Hazard?: When Judges Nullify Employer Liability in Arbitrations*, 93 MINN. L. REV. 998 (2009).

56. Malani, *supra* note 19.

57. Interestingly, one study has found that risk compensation effects are larger in response to safety measures that reduce the likelihood of harm, compared to measures that reduce its extent. Fridulv Sagberg et al., *An Investigation of Behavioural Adaptation to Airbags and Antilock Brakes Among Taxi Drivers*, 29 ACCIDENT ANALYSIS & PREVENTION 293, 301 (1997).

58. See Valentina Ivezaj et al., “*I Didn’t See This Coming.*”: *Why Are Postbariatric Patients in Substance Abuse Treatment? Patients’ Perceptions of Etiology and Future Recommendations*, 22 OBESITY SURGERY 1308 (2012); Andrea Wendling & Andrea Wudyka, *Narcotic Addiction Following Gastric Bypass Surgery—A Case Study*, 21 OBESITY SURGERY 680 (2011) (discussing mixed evidence of postoperative narcotic dependence among bariatric surgery patients).

59. For an explanation of this theory, see Neal Kumar Katyal, *Deterrence’s Difficulty*, 95 MICH. L. REV. 2385, 2391-402 (1997).

than the recalibration of perceived risk.⁶⁰ For instance, someone who drinks diet soda may choose to eat more sweets because she perceives a lower risk of weight gain. This is risk compensation, and the mechanism embeds a continuing concern about the risk. However, behavioral disinhibition occurs when the risk itself becomes less salient; for example, someone may consume more sweets because she no longer “cares” about weight gain, or because she has decided that weight gain is unavoidable.⁶¹ While risk compensation is based on a continuing preoccupation with risk, disinhibition yields similar behavioral effects by altogether reducing the concern.⁶²

B. Empirical Basis

Empirical evidence exists both to support and to challenge risk compensation theory. Although some have called for more rigorous analyses of existing risk compensation research,⁶³ the most rigorous tests for risk compensation responses to health and safety interventions may be altogether absent. The primary reasons for this are ethical—the requirement of equipoise and the need to avoid deceiving participants.⁶⁴ This section will first examine methodological difficulties in producing empirical evidence on risk compensation, and then enumerate evidence on both sides of this theory.

1. Methodological Limitations

The gold standard for testing the effect of any intervention is a double-blinded randomized trial in which participants are randomly assigned to receive the active treatment or a comparison (e.g., a placebo or another treatment). However, a trial designed to measure risk compensation behavior would need to assign participants to two different *perceptions* of protection, not necessarily two different states of actual protection. All participants in a typical placebo-controlled drug trial are told to be uncertain about their treatment condition and drug efficacy; although participants may hold their own beliefs about drug efficacy, there is no reason to expect different trial arms to differ in the benefit they expect from the drug. Because the two groups do not differ systematically

60. Matthew Hogben & Nicole Liddon, *Disinhibition and Risk Compensation: Scope, Definitions, and Perspective*, 35 SEXUALLY TRANSMITTED DISEASES 1009, 1009 (2008).

61. See *id.* (citing a parallel example in HIV prevention literature).

62. That is, behavioral disinhibition represents a change in the target risk level, whereby an individual becomes comfortable with a greater exposure to risk.

63. See, e.g., Fred P. Rivara et al., *Research on Injury Prevention: Topics for Systematic Review*, 8 INJURY PREVENTION 161 (2002); Diane C. Thompson et al., *Risk Compensation Theory Should Be Subject to Systematic Reviews of the Scientific Evidence*, 7 INJURY PREVENTION 86 (2001).

64. See, e.g., Kristen Underhill, *Study Designs for Identifying Risk Compensation Behavior Among Users of Biomedical HIV Prevention Technologies: Balancing Methodological Rigor and Research Ethics*, SOC. SCI. & MED. (forthcoming 2013) (commenting on the lack of rigorous study designs for identifying risk compensation behavior in trials of biomedical HIV prevention technologies), available at <http://www.sciencedirect.com/science/article/pii/S0277953613001822>.

in their perceptions, a comparison of the two trial arms is inappropriate for assessing risk compensation effects.⁶⁵

The theoretically ideal study design for isolating risk compensation behavior would be to conduct a randomized trial *after* a drug has been proven efficacious. In this trial, one arm should knowingly receive the active, efficacious drug, while the other should receive no treatment. If earlier placebo-controlled trials found no behavioral differences between groups, it would be clear that the drug does not pharmacologically cause changes in risk behavior. In this new trial, therefore, any differences in risk-taking behavior between the two groups could be attributed to different *perceptions* of risk and protection, not to the drug itself. This would provide a rigorous test of risk compensation, but it would violate the requirement of clinical equipoise—the need for genuine doubt about the relative merits of the two conditions.⁶⁶ Because one trial arm would receive an effective drug while the other arm received nothing, there is little doubt that participants in the active arm would benefit more from the study, as long as they do not adjust their risk-taking behavior so much as to overwhelm the beneficial effect of the drug.⁶⁷ This study would also run afoul of ethical guidelines governing the conditions under which it is acceptable to use placebos,⁶⁸ as well as guidelines on deceiving study participants.⁶⁹

Professor Anup Malani has recently suggested an alternative study design for testing placebo effects, which would provide a method for testing risk compensation behavior as well. Instead of comparing an active treatment arm and a placebo arm in a single trial, Malani has proposed comparing the active arms of two different trials that used different probabilities of assignment to

65. Any behavioral differences observed between groups would be attributable to the pharmacological operation of the drug, rather than the cognitive mechanism of risk compensation behavior. See Kristen Underhill, Letter to the Editor, 364 *NEW ENG. J. MED.* 1374 (2011).

66. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 320 (6th ed. 2009).

67. Similar ethical objections would prevent a trial that provided active drugs to all participants but then deceived some participants into believing that the drug was a placebo. If participants in the deceived arm stopped taking their pills, there is little doubt that they would benefit less than the participants who received truthful information. It would be even less acceptable to provide placebos to all participants, but then to deceive some participants into believing that the placebos were active drugs.

68. COUNCIL FOR INT'L ORGS. OF MEDICAL SCI., *INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS* 54 (2002).

69. National Commission for the Protection of Human Subjects of Research, Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 44 *Fed. Reg.* 23,192, 23,195 (Apr. 18, 1979). Although this study design would be ethically unfeasible for scientists, an identical scenario may arise naturally in clinical service settings. For example, if a community clinic randomly selects patients to receive treatment according to a lottery system, scientists could take advantage of this context to measure behavior. One study has examined the allocation of health insurance according to a lottery system, finding increases in health care utilization and improved physical and mental health among insurance recipients. Amy Finkelstein et al., *The Oregon Health Insurance Experiment: Evidence from the First Year*, 127 *Q.J. ECON.* 1057 (2012). The study has found “no evidence of ‘ex ante moral hazard’” in smoking behavior. AMY FINKELSTEIN, *MORAL HAZARD IN HEALTH INSURANCE: DEVELOPMENTS SINCE ARROW* (1963) 14 (2012), available at http://cgt.columbia.edu/files/papers/Finkelstein_Arrow_lecture_FINAL_SLIDES_TO_POST.pdf.

treatment.⁷⁰ If participants in trial 1 knowingly have a 50% chance of assignment to treatment, and participants in trial 2 knowingly have a 70% chance of assignment to treatment, then participants in trial 2 may be more likely to believe that they are receiving an effective drug. As a result, participants in trial 2 may have a higher perception of protection, the driver of risk compensation behavior. Comparing just the active arms of each study would also ensure that the behavioral effects are in fact due to perceptions of protection, rather than any pharmacological effects of the drug itself.

To date, Malani's design has not been used to measure risk compensation. In the absence of data with randomized designs, therefore, the evidence for risk compensation has relied on less rigorous approaches, such as cohort or panel studies,⁷¹ simulation studies,⁷² within-participants designs,⁷³ open label trials without control groups,⁷⁴ and randomized studies for which a placebo control is impractical.⁷⁵ These studies do not conclusively show causality. Moreover, even a perfectly designed study may still have limited applicability to non-trial settings. Research conducted at the efficacy stage must inform participants that the efficacy of the experimental drug is uncertain, while users in the real world will have more certainty about protection. Such studies may also become outdated if perceptions of risk and protection change over time.

2. Evidence Supporting a Risk Compensation Model

With the methodological caveats above, empirical evidence from various health and safety fields tends to support risk compensation effects. Risk compensation theory first arose in the realm of driving safety, and this emphasis has continued. Drivers' speed or risk-taking has been found to increase in response to antilock brakes,⁷⁶ seatbelts,⁷⁷ road lighting⁷⁸ and

70. Anup Malani, *Identifying Placebo Effects with Data from Clinical Trials*, 114 J. POLIT. ECON. 236 (2006).

71. See, e.g., Alma Cohen & Rajeev Dehejia, *The Effect of Automobile Insurance and Accident Liability Laws on Traffic Fatalities*, 47 J.L. & ECON. 357 (2004)

72. See, e.g., A. Ian Glendon et al., *A Review of Risk Homeostasis Theory in Simulated Environments*, 22 SAFETY SCI. 15 (1996).

73. See, e.g., Barbara A. Morrongiello et al., *Risk Compensation in Children: Why Do Children Show It in Reaction to Wearing Safety Gear?*, 28 J. APPLIED DEVELOPMENTAL PSYCHOL. 56 (2007).

74. Jeffrey N. Martin et al., *Use of Postexposure Prophylaxis Against HIV Infection Following Sexual Exposure Does Not Lead to Increases in High-Risk Behavior*, 18 AIDS 787 (2004).

75. See, e.g., Robert C. Bailey et al., *Male Circumcision for HIV Prevention in Young Men in Kisumu, Kenya: A Randomised Controlled Trial*, 369 LANCET 643 (2007). Although circumcision studies may come closest to a rigorous test of risk compensation, they are still imperfect, because participants in the intervention group were uncertain whether male circumcision would be effective for preventing HIV.

76. David W. Harless & George E. Hoffer, *The Antilock Braking System Anomaly: A Drinking Driver Problem?*, 34 ACCIDENT ANALYSIS & PREVENTION 333 (2002).

77. John Adams, *Seat Belt Laws: Repeal Them?*, 4 SIGNIFICANCE 86 (2007); Mark McCarthy, *The Benefit of Seat Belt Legislation in the United Kingdom*, 43 J. EPIDEMIOLOGY & COMMUNITY HEALTH 218-22 (1989); Fredrich M. Streff & E. Scott Geller, *An Experimental Test of Risk*

visibility,⁷⁹ head and neck restraint systems for racecar drivers,⁸⁰ airbags,⁸¹ driving four-wheel-drive vehicles,⁸² and driving in familiar locations.⁸³ Meanwhile, analyses have also shown reductions in speed when drivers are talking on the phone,⁸⁴ intoxicated,⁸⁵ or performing more difficult tasks⁸⁶—all times of greater risk. Studies of safety equipment have mirrored these findings.⁸⁷

Several legal articles have conducted empirical tests of risk compensation models, all using regression analyses. These have included analyses of seat belt legislation,⁸⁸ airbags,⁸⁹ automobile insurance mandates,⁹⁰ fuel economy standards,⁹¹ consumer product safety regulations (including medication

Compensation: Between-Subject Versus Within-Subject Analyses, 20 ACCIDENT ANALYSIS & PREVENTION 277 (1988). These findings, however, are controversial. See, e.g., Murray Mackay, *Seat Belts and Risk Compensation*, 291 BR. MED. J. 757 (1985) (citing studies for the proposition that risk compensation does not occur among drivers using seat belts).

78. Terje Assum et al., *Risk Compensation—The Case of Road Lighting*, 31 ACCIDENT ANALYSIS & PREVENTION 545 (1999).

79. Neville A. Stanton & Marcel Pinto, *Behavioural Compensation by Drivers of a Simulator When Using a Vision Enhancement System*, 43 ERGONOMICS 1359 (2000).

80. Pope & Tollison, *supra* note 9.

81. David W. Harless & George E. Hoffer, *Testing for Offsetting Behavior and Adverse Recruitment Among Drivers with Airbag-Equipped Vehicles*, 70 J. RISK & INS. 629 (2003); Richard Kent et al., *The Field Performance of Frontal Air Bags: A Review of the Literature*, 6 TRAFFIC INJURY PREVENTION 1 (2005); Peterson et al., *supra* note 12.

82. Lesley Walker et al., *Unsafe Driving Behaviour and Four Wheel Drive Vehicles: Observational Study*, 333 BRIT. MED. J. 333 (2006).

83. Tom Rosenbloom et al., *Women Drivers' Behavior in Well-Known Versus Less Familiar Locations*, 38 J. SAFETY RES. 283 (2007).

84. D.E. Haigney et al., *Concurrent Mobile (Cellular) Phone Use and Driving Performance: Task Demand Characteristics and Compensatory Processes*, 3 TRANSP. RES. 113 (2000).

85. Jean-Pascal Assailly, *The Prevention of Young Driver's DWI (Driving While Intoxicated) and RWDI (Riding with a Driver Under Influence) in Europe: A Social-Sequential Model*, 5 TRAFFIC INJURY PREVENTION 237 (2004).

86. Ray Fuller, *Towards a General Theory of Driver Behaviour*, 37 ACCIDENT ANALYSIS & PREVENTION 461 (2005).

87. Decreased vigilance or increased risk-taking has been observed in response to a variety of technologies. See, e.g., J. Adams & Mayer Hillman, *The Risk Compensation Theory and Bicycle Helmets*, 7 INJURY PREVENTION 89-90 (2001) (citing evidence related to the use of bicycle helmets); Daniel H. Daneshvar et al., *Helmets and Mouth Guards: The Role of Personal Equipment in Preventing Sport-Related Concussions*, 30 CLINICAL SPORTS MED. 145, 157 (2011) (concerning protective gear in sports); Brent Hagel & Willem Meeuwisse, *Risk Compensation: A "Side Effect" of Sport Injury Prevention?*, 14 CLINICAL J. SPORT MED. 193 (2004) (considering protective gear in sports; good visibility of trails for skiers); Morrongiello et al., *supra* note 73 (analyzing the use of safety equipment for children); Robert B. Noland, *Perceived Risk and Modal Choice: Risk Compensation in Transportation Systems*, 27 ACCIDENT ANALYSIS & PREVENTION 503 (1995) (analyzing improvements in bicycle safety); Stephen E. Ryan, *Injury Risk Compensation in Children with Disabilities: Could Assistive Technology Devices Have a Dark Side?*, 5 DISABILITY & REHABILITATION: ASSISTIVE TECH. 199 (2010) (focusing on assistive devices for disabled children); Viscusi, *supra* note 11 (considering child-resistant packaging of medications).

88. Anindya Sen, *An Empirical Test of the Offset Hypothesis*, 44 J.L. & ECON. 481 (2001).

89. Peterson et al., *supra* note 12.

90. Cohen & Dehejia, *supra* note 71.

91. Godek, *supra* note 13.

packaging rules),⁹² gun safe-storage laws,⁹³ mandated insurance for diabetes⁹⁴ and addictions treatment,⁹⁵ and the legalization of abortion.⁹⁶ Nearly all of these analyses found support for risk compensation effects, although the strength of these effects varied.⁹⁷ No analysis found evidence that safety precautions lead to overall *decreases* in risk-taking.

In public health, risk compensation dynamics have featured prominently in the HIV prevention literature,⁹⁸ as new prevention strategies such as PrEP, male circumcision, post-exposure use of antiretroviral drugs, and vaccines have undergone testing. The literature on PrEP has not yet provided a rigorous test of risk compensation behavior, although double-blinded studies have not found increases in risk behavior over the course of trial activities.⁹⁹ Qualitative and survey studies suggest that risk compensation may occur among users of PrEP¹⁰⁰ and HIV prevention vaccines.¹⁰¹ In the three existing randomized trials of male circumcision for HIV prevention, behavioral outcomes from every trial point in the direction of risk compensation (i.e., newly circumcised men reported riskier behaviors than men in the control group), but the difference was statistically significant in only one trial.¹⁰² Survey research has also identified relationships between risky sexual activities and beliefs about the preventive impact of antiretroviral treatment,¹⁰³ as well as increases in sexual activity (number of partners and frequency of sex) among people who use

92. W. Kip Viscusi, *Consumer Behavior and the Safety Effects of Product Safety Regulation*, 28 J.L. & ECON. 527 (1985).

93. Lott, *supra* note 10.

94. Klick & Stratmann, *supra* note 16.

95. Klick & Stratmann, *supra* note 15.

96. Klick & Stratmann, *supra* note 14.

97. See Cohen & Dehejia, *supra* note 71; Godek et al., *supra* note 13; sources cites *supra* notes 14-16; Peterson et al, *supra* note 12; Sen, *supra* note 88; Viscusi, *supra* note 92.

98. Lisa A. Eaton & Seth Kalichman, *Risk Compensation in HIV Prevention: Implications for Vaccines, Microbicides, and Other Biomedical HIV Prevention Technologies*, 4 CURRENT HIV/AIDS REP. 165 (2007).

99. See, e.g., Baeten et al., *supra* note 20, at 405 (reporting behavioral analyses of a double-blinded randomized controlled trial of PrEP among heterosexual couples); Grant et al., *supra* note 20, at 2598 (reporting results of a double-blinded randomized trial of PrEP among transgender women and men who have sex with men); Thigpen et al., *supra* note 20, at 428 (reporting results of a double-blinded randomized trials of PrEP among heterosexual men and women).

100. Sarit A. Golub et al., *Preexposure Prophylaxis and Predicted Condom Use Among High-Risk Men Who Have Sex with Men*, 54 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 548, 552 (2010); Nodin, *supra* note 52, at 112.

101. See, e.g., Peter A. Newman et al., *Preventive HIV Vaccine Acceptability and Behavioral Risk Compensation Among a Random Sample of High-Risk Adults in Los Angeles (LA VOICES)*, 44 HEALTH SERVICES RES. 2167, 2174 (2009).

102. See Nandi Siegfried et al., *Male Circumcision for Prevention of Heterosexual Acquisition of HIV in Men* (Oct. 7, 2009) (on file with Cochrane Library) (concluding that “these more risky behaviours could indicate possible disinhibition among circumcised men”); see also Seth Kalichman et al., *Circumcision for HIV Prevention: Failure to Fully Account for Behavioral Risk Compensation*, 4 PUB. LIBR. SCI. MED. 597, 597 (2007).

103. See, e.g., Nicole Crepez et al., *Highly Active Antiretroviral Therapy and Sexual Risk Behavior: A Meta-Analytic Review*, 292 JAMA 224 (2004).

condoms.¹⁰⁴ In studies of HPV vaccine acceptability, interview findings suggest that some women predicted that they may engage in more sexual activity as a result of receiving the vaccine.¹⁰⁵

Risk compensation and risk homeostasis theories have more gradually been incorporated outside the sexually transmitted infection field. Studies have suggested risk compensation effects of Lyme disease vaccination (which led to a decrease in preventive behaviors such as using tick repellent),¹⁰⁶ drinking beer as compared to hard alcohols (which may lead to more consumption because beer is perceived as safer),¹⁰⁷ consuming diet sodas (which may lead to overconsumption of other calories),¹⁰⁸ using low-tar or filtered cigarettes (which are linked with increased smoking),¹⁰⁹ and taking fish oil supplements (which may increase other risk behaviors leading to heart disease).¹¹⁰ Among health care staff, studies have found that a perception of increased blood safety has increased rates of blood transfusion.¹¹¹ Cultural beliefs that inform changed perceptions of risk can also play a role in risk compensation; for example, one study has found that the belief in elevated risk during “ghost month” in southern China may reduce drowning deaths, as people avoid risky activities such as swimming during this time.¹¹²

3. Evidence Against Risk Compensation

To be sure, some evidence also runs counter to risk compensation theory. Studies seeking risk compensation effects have yielded nonsignificant or weak findings in studies of bicycle helmet use,¹¹³ seatbelts,¹¹⁴ airbags,¹¹⁵ vehicle

104. Steven D. Pinkerton, *Sexual Risk Compensation and HIV/STD Transmission: Empirical Evidence and Theoretical Considerations*, 21 RISK ANALYSIS 727, 728 (2001).

105. Loretta Brabin et al., *A Survey of Adolescent Experiences of Human Papillomavirus Vaccination in the Manchester Study*, 101 BRIT. J. CANCER. 1502, 1503 (2009).

106. Noel T. Brewer et al., *Risk Compensation and Vaccination: Can Getting Vaccinated Cause People To Engage in Risky Behaviors?*, 34 ANNALS BEHAV. MED. 95 (2007); Marlow et al., *supra* note 52.

107. John D. Rogers & Thomas K. Greenfield, *Beer Drinking Accounts for Most of the Hazardous Alcohol Consumption Reported in the United States*, 60 J. STUD. ALCOHOL 732 (1999).

108. See Sharon P. Fowler et al., *Fueling the Obesity Epidemic? Artificially Sweetened Beverage Use and Long-Term Weight Gain*, 16 OBESITY 1894, 1899 (2008) (citing studies).

109. Robert J. Maccoun, *Testing Drugs Versus Testing for Drug Use: Private Risk Management in the Shadow of Criminal Law*, 56 DEPAUL L. REV. 507, 531 (2007); Kenneth E. Warner & John Slade, *Low Tar, High Toll*, 82 AM. J. PUB. HEALTH 17 (1992).

110. Michael L. Burr et al., *Lack of Benefit of Dietary Advice to Men with Angina: Results of a Controlled Trial*, 57 EUR. J. CLINICAL NUTRITION 193, 193-200 (2003).

111. Mo Amin et al., *Does a Perception of Increased Blood Safety Mean Increased Blood Transfusion? An Assessment of the Risk Compensation Theory in Canada*, 4 BMC PUB. HEALTH 1 (2004).

112. C.-H. Yang et al., *Belief in Ghost Month Can Help Prevent Drowning Deaths: A Natural Experiment on the Effects of Cultural Beliefs on Risky Behaviours*, 66 SOC. SCI. & MED. 1990 (2008).

113. Pablo Lardelli-Claret et al., *Risk Compensation Theory and Voluntary Helmet Use by Cyclists in Spain*, 9 INJURY PREVENTION 128 (2003).

114. See, e.g., David J. Houston & Lilliard E. Richardson, *Risk Compensation or Risk Reduction? Seatbelts, State Laws, and Traffic Fatalities*, 88 SOCIAL SCI. Q. 913, 936 (2007); Shinji

safety inspections,¹¹⁶ snowboard helmets,¹¹⁷ children's safety equipment,¹¹⁸ hypertension medications,¹¹⁹ statins,¹²⁰ participation in a needle exchange programs,¹²¹ and wearing socks over one's shoes to get better traction on icy sidewalks.¹²²

Evidence that undermines risk compensation theory should not be dismissed. But without rigorous studies capable of manipulating risk perceptions as the independent variable, correlational evidence remains problematic for concluding whether risk compensation effects occur. Mixed evidence across different health and safety behaviors may simply indicate that risk compensation is context-specific. The fact remains, however, that systematic risk compensation behavior *has been* observed in some contexts, that the direction of these behaviors is predictable, and that this behavioral phenomenon has altogether escaped our notice in the regulation of pharmaceutical products.

C. Risk Compensation in Legal Scholarship

Beyond the empirical studies cited above, legal literature has frequently engaged with offsetting behavior in theoretical discussions. These primarily focus on the extent to which risk compensation may undermine the benefits of products or regulations intended to improve health and safety. Such discussions, however, generally highlight the lack of empirical evidence to determine whether risk compensation is occurring. Legal commentators have raised these concerns across a variety of fields, including the regulation of consumer products and environmental risks,¹²³ the regulation of behaviors

Nakahara et al., *Seatbelt Legislation in Japan: High Risk Driver Mortality and Seatbelt Use*, 9 INJURY PREVENTION 29, 29-32 (2003); Harry S. Shannon & Peter Szatmari, *Seat-Belt Legislation and Risk Homeostasis: Further Analysis of the British Data*, 26 ACCIDENT ANALYSIS & PREVENTION 803, 803-05 (1994).

115. O'Neill & Williams, *supra* note 40; Peterson et al., *supra* note 12.

116. Marc Poitras & Daniel Sutter, *Policy Ineffectiveness or Offsetting Behavior? An Analysis of Vehicle Safety Inspections*, 68 S. ECON. J. 922, 932 (2002).

117. Michael D. Scott et al., *Testing the Risk Compensation Hypothesis for Safety Helmets in Alpine Skiing and Snowboarding*, 13 INJURY PREVENTION 173 (2007).

118. I. Barry Pless et al., *Risk-Compensation Behavior in Children: Myth or Reality?*, 160 ARCHIVES PEDIATRICS ADOLESCENT MED. 610 (2006).

119. Andrew Steptoe & Anne McMunn, *Health Behaviour Patterns in Relation to Hypertension: The English Longitudinal Study of Ageing*, 27 J. HYPERTENSION 224 (2009).

120. Craig I. Coleman et al., *The Effect of Statins on the Development of New-Onset Type 2 Diabetes: A Meta-Analysis of Randomized Controlled Trials*, 24 CURRENT MED. RES. & OPINION 1359 (2008); Devin M. Mann et al., *Dietary Indiscretion and Statin Use*, 82 MAYO CLINIC PROCEEDINGS 951 (2007).

121. Martin T. Schechter et al., *Do Needle Exchange Programs Increase the Spread of HIV Among Injection Drug Users: An Investigation of the Vancouver Outbreak*, 16 AIDS F45 (1999).

122. Lianne Parkin et al., *Preventing Winter Falls: A Randomised Controlled Trial of a Novel Intervention*, 122 N.Z. MED. J. 31 (2009).

123. See, e.g., Bernstein, *supra* note 18, at 679 (discussing regulation of consumer product safety); Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV.

including sports and driving,¹²⁴ gun safety and ownership,¹²⁵ health behaviors in the context of antidiscrimination law,¹²⁶ and the behavior of individuals who are insured against risk.¹²⁷

Concerns about risk compensation behavior have addressed not only physical risk-taking, but also financial and ethical risk-taking. For instance, authors have considered offsetting behavior as potentially undermining legal rules designed to regulate financial markets,¹²⁸ regulations requiring that

851, 907-08 (1996) (analyzing regulation of consumer product safety); Frances L. Edwards, *Worker Right-to-Know Laws: Ineffectiveness of Current Policy-Making and a Proposed Legislative Solution*, 15 B.C. ENVTL. AFF. L. REV. 1, 27 (1987) (discussing mandated provision of safety information to workers); John D. Graham, *Legislative Approaches to Achieving More Protection Against Risk at Less Cost*, 1997 U. CHI. LEGAL F. 13, 19-20 (1997) (describing EPA regulation and other regulatory programs); Michael S. Greve, *Preemption Choice: The Theory, Law, and Reality of Federalism's Core Question*, 26 CONST. COMMENT 679, 689 (2010) (discussing general health and safety regulation); Donald P. Judges, *Of Rocks and Hard Places: The Value of Risk Choice*, 42 EMORY L.J. 1, 84 n.277 (1993) (considering regulation of consumer product safety); Malani, *supra* note 19 (examining the regulation of prescription drug products); J. Gregg Miller, Jr., Comment, *Risk Homeostasis and California Design Defect Products Liability: Rethinking the Consumer Expectations and Risk-Benefit Tests*, 32 U.S.F. L. REV. 587, 595-99 (1998) (considering anti-lock brake installation); Ross D. Petty, *Regulation vs. the Market: The Case of Bicycle Safety* (pt. 2), 2 RISK 93 (1991) (discussing bicycle safety regulation); C. Gregory Ruffennach, *Free Markets, Individual Liberties and Safe Coal Mines: A Post-Sago Perspective*, 111 W. VA. L. REV. 75, 109 (2009) (discussing mining safety regulation); Cass R. Sunstein, *Is Tobacco a Drug? Administrative Agencies as Common Law Courts*, 47 DUKE L.J. 1013, 1026 n.67 (1998) (discussing a potential ban on tobacco); Jonathan Tetzlaff, *Risk Management in a Dangerous World: Practical Approaches*, 12 DEPAUL BUS. L.J. 291, 296-97 (1999-2000) (considering corporate management of physical and environmental risks).

124. Daniel A. Farber, *A Place-Based Theory of Standing*, 55 UCLA L. REV. 1505, 1541 n.160 (2008) (discussing possible offsetting behavior by drivers when gasoline use is regulated); Robert W. Hahn & Patrick M. Dudley, *The Disconnect Between Law and Policy Analysis: A Case Study of Drivers and Cell Phones*, 55 ADMIN. L. REV. 127, 149-150 (2003) (discussing banning the use of cell phones while driving); Lawrence Lessig, *The Regulation of Social Meaning*, 62 U. CHI. L. REV. 943, 968 n.68 (1995) (discussing rules requiring hockey players to wear helmets); Robert J. MacCoun, *Testing Drugs Versus Testing for Drug Use: Private Risk Management in the Shadow of Criminal Law*, 56 DEPAUL L. REV. 507, 522-23, 531-32 (2007) (discussing rules for drug-testing athletes and permitting harm-reduction organizations to test club drugs for safety); Eric A. Posner & Cass R. Sunstein, *Dollars and Death*, 72 U. CHI. L. REV. 537, 577-78 (2005) (discussing offsetting behavior by parents when regulations require purchase of safety equipment for their children).

125. David B. Kopel, *Treating Guns Like Consumer Products*, 148 U. PA. L. REV. 1213, 1236-37, 1239 (2000); Leonardatos, Blackman & Kopel, *Smart Guns/Foolish Legislators*, *supra* note 10, at 209-10, 217-18; John R. Lott, Jr. & David B. Mustard, *Crime, Deterrence, and Right-to-Carry Concealed Handguns*, 26 J. LEGAL STUD. 1, 11-12 (1997); Jens Ludwig, *Gun Self-Defense and Deterrence*, 27 CRIME & JUST. 363, 387 (2000).

126. Adam R. Pulver, *An Imperfect Fit: Obesity, Public Health, and Disability Antidiscrimination Law*, 41 COLUM. J.L. & SOC. PROBS. 365, 408-09 (2008) (suggesting that by "reducing the quality of life costs" associated with obesity, antidiscrimination laws that protect obese people "may lead people to take less care in avoiding" obesity).

127. Robert Charles Clark, *Does the Nonprofit Form Fit the Hospital Industry?*, 93 HARV. L. REV. 1417, 1424 n.18 (1980) (discussing the provision of health insurance to uninsured people); Shari Seidman Diamond & Neil Vidmar, *Jury Room Ruminations on Forbidden Topics*, 87 VA. L. REV. 1857, 1875 n.57 (2001) (noting that carrying insurance may affect risk-taking, and ascribing this view to "risk compensation theorists").

128. Jane K. Winn, *Are "Better" Security Breach Notification Laws Possible?*, 24 BERKELEY TECH L.J. 1133, 1141 (2009).

corporations disclose waivers of ethics codes,¹²⁹ and laws providing uninsured people with health insurance (on the theory that newly insured people will reduce financial saving practices).¹³⁰ Concerns about “self-licensing” may be another example; when individuals are given the opportunity to establish their credentials as nonbiased (reducing the risk of being perceived as prejudiced), they are later more likely to express prejudiced attitudes.¹³¹ Rules forcing physicians to disclose conflicts of interest (ostensibly reducing the risk that advice will improperly bias patients) may lead the physicians to provide more biased advice.¹³²

Several articles to date have applied risk compensation theory to FDA regulation and products liability law. Malani’s analysis of placebo effects comes closest to the present inquiry.¹³³ His proposal calls for the FDA to consider positive placebo effects, but not risk compensation effects when approving new drugs; he also notes that proper labeling may help to reduce risk compensation effects by limiting the expectations that give rise to risk behaviors. Several products liability articles have also addressed risk compensation behavior. Robert Spendlove has noted that consumer offsetting behavior may change a safety product “from a risk reducing technology to a new utility technology,” engaging in value-creating behavior (e.g., driving faster), that would not be possible without the safety technology (e.g., airbags).¹³⁴ One proposal has suggested that risk homeostasis theory should prompt revision of legal tests that depend on consumer expectations to identify product defects;¹³⁵ other proposals for products liability reform have designated offsetting behavior as irremediable,¹³⁶ noting regrettably that “the human being cannot be redesigned.”¹³⁷ Economic analyses of products liability rules have also engaged with moral hazard and the costs associated with careful behavior.¹³⁸ For instance, consumers can reduce accidents by purchasing fewer units of a product; if they insure against product-related accidents, however,

129. Geoffrey A. Manne, *The Hydraulic Theory of Disclosure Regulation and Other Costs of Disclosure*, 58 ALA. L. REV. 473, 487-88 (2007).

130. Todd J. Zywicki, *An Economic Analysis of the Consumer Bankruptcy Crisis*, 99 NW. U. L. REV. 1463, 1521-22 (2005).

131. See Benoit Monon & Dale T. Miller, *Moral Credentials and the Expression of Prejudice*, 81 J. PERSONALITY & SOC. PSYCHOL. 33 (2001).

132. See George Lowenstein, Sunita Sah & Daylian M. Cain, *The Unintended Consequences of Conflict of Interest Disclosure*, 307 JAMA 669, 669 (2012).

133. Malani, *supra* note 19.

134. Robert Dan Spendlove, Note, *Speed Bumps on the Road to Progress: How Product Liability Slows the Introduction of Beneficial Technology—An Airbag Example*, 13 GEO. MASON L. REV. 1143, 1150 n.62 (2005-2006).

135. J. Gregg Miller, Jr., *Risk Homeostasis and California Design Defect Products Liability: Rethinking the Consumer Expectations and Risk-Benefit Tests*, 32 U.S.F. L. REV. 587 (1998).

136. Bernstein, *supra* note 18, at 679.

137. Robert A. Prentice, “Tort Reform” and the Liability “Revolution”: Defending Strict Liability in Tort for Defective Products, 27 GONZ. L. REV. 251, 284 (1991-1992).

138. See, e.g., A. MITCHELL POLINSKY, AN INTRODUCTION TO LAW AND ECONOMICS 113-23 (2011).

they may compensate for the reduced risk of loss by purchasing more product units.¹³⁹ Consumers may also purchase too many product units if they do not bear the costs of possible harms to third parties,¹⁴⁰ a parallel to the “externally hazardous” risk compensation discussed later in this Article.

Building on this scholarly groundwork, this Article advances legal inquiry into risk compensation effects by categorizing several forms of risk compensation behavior, highlighting the potential for variability in risk compensation effects, and proposing legal strategies to identify and address risk compensation behavior through FDA regulation.

II. When, Why, and How the Law Might Intervene in Risk Compensation Behavior

In both popular and scholarly conversations, risk compensation behaviors are viewed as problematic, and concerns about offsetting behavior have been marshaled to argue against expanding access to efficacious health technologies. Economic analyses have been more dispassionate, but although such analyses do classify offsetting behavior as rational, few have suggested that it may also be value-maximizing.¹⁴¹ This Part suggests that risk compensation is not only rational, but also potentially optimal depending on individual preferences. When risk compensation leads to harms, however, it may be justifiable for the law to intervene. This Part will discuss four forms of risk compensation effects, which present different normative bases for legal intervention.

When an individual engages in risk compensation as a response to the use of a health and safety product, it is possible to classify these effects by several criteria. First, we may organize effects on the basis of whether the individual has perfect or imperfect information about risks and benefits. Second, we can categorize effects based on whether the individual’s new actual risk level, including both product use and behavioral adjustments, is higher or lower than it was before using the product (baseline risk). For the purposes of this discussion, we will assume that actual risk that exceeds the baseline risk is hazardous and undesirable. Third, we can identify whether the individual’s new actual risk matches his *intended* risk (the target risk level), and his intended allocation of risks and benefits. We will assume that actual risk exceeding one’s target risk level is also undesirable, as is behaving in a way that is inconsistent with one’s optimal balance of risks and benefits. Finally, we can

139. *Id.* at 119. Incentives for consumer precautions also depend on available defenses for manufacturers. If manufacturers cannot raise the defense of contributory negligence, consumers may not take precautions because they do not bear the complete risk of loss. But even when a defense of contributory negligence is available, consumers who underestimate product risks will not take the appropriate precautions. *Id.* at 121. This discussion aligns with the risk compensation model, which depends on the perception of risk to motivate behavioral adjustments.

140. *Id.* at 122.

141. Spendlove’s arguments are an exception. *See supra* note 134 and accompanying text.

classify risk compensation effects based on the allocation of benefit and harm—where risk compensation behavior increases harms relative to baseline risk, are those harms borne by the individual (internal hazards), third parties (external hazards), or both? This taxonomy yields four primary forms of risk compensation behavior: perfectly informed risk compensation, uninformed partial risk compensation, uninformed overcompensation, and externally hazardous risk compensation (which may overlap with any of the former categories).

A. *Perfectly Informed Risk Compensation*

People undertake risks for reasons—they obtain some utility from risky behavior, and risk compensation will not occur if an individual lacks a reason to increase his risk-taking.¹⁴² In short, it is a necessary precursor of risk compensation that people *would prefer* to engage in riskier behaviors—they expect rewards for taking more risks¹⁴³—but they choose not to do so because they fear incurring harm.¹⁴⁴

When a new safety or health technology is available, users have access to a larger set of behavioral options that are consistent with their level of acceptable risk. Because the technology reduces the risk of harm, it creates a *protection surplus*, which an informed individual can now allocate according to his preferences. For example, assume that PrEP drugs reduce the risk of acquiring HIV by approximately 70%. At one extreme, a PrEP user may retain all this protection and make no change in his behavior, and he will be 70% safer than he was before. At the other extreme, he may “spend” the entire surplus by increasing his risk behaviors to the point of fully offsetting the protection; he will be just as safe as he was before, but will capture 70% more of the rewards of risky behavior. These rewards, for example, could include greater relationship satisfaction and longevity, increased perceptions of trust and intimacy between partners, or increased sexual pleasure.¹⁴⁵ Between the

142. Hedlund, *supra* note 21, at 88.

143. See, e.g., WILDE, *supra* note 21, at 32.

144. A corollary of this theory is that risk compensation will not produce infinite increases in risk behavior—users of health and safety products will only take more risks to the extent that they have motivation to do so. This produces ceiling effects; for example, someone who is already behaving at a maximally risky level will engage in less compensatory behavior, compared to someone whose baseline behavior is inhibited by fear of risk.

145. See, e.g., Barry D. Adam, Alan Sears & E. Glenn Schellenberg, *Accounting for Unsafe Sex: Interviews with Men Who Have Sex with Men*, 37 J. SEX RES. 24, 28 (2000) (“Unsafe sex . . . within an ongoing relationship . . . was viewed as a means of expressing or maintaining a feeling of intimacy or romance.”); Mary E. Randolph et al., *Sexual Pleasure and Condom Use*, 36 ARCHIVES SEXUAL BEHAV. 844 (2007) (describing reductions in sexual pleasure for protected sex compared to unprotected sex); Tim Rhodes & Linda Cusick, *Love and Intimacy in Relationship Risk Management: HIV Positive People and Their Sexual Partners*, 22 SOC. HEALTH & ILLNESS 1, 9 (2000) (explaining that among HIV-positive individuals, “[i]ntimate relationships characterised by non-condom use were described as more ‘complete’ as well as more ‘permanent’”); Teela Sanders, *The Condom as Psychological Barrier: Female Sex Workers and Emotional Management*, 12 FEMINISM & PSYCHOL. 561, 565 (2002) (drawing

two extremes—keeping or spending the entire protection surplus—the individual could also choose a mixed allocation. For instance, he may choose to engage in 20% more risk behavior, but also have 50% more protection from HIV. If he is only *motivated* to increase his risk by 20%, this would mean that he can completely satisfy his preferences while still remaining 50% safer than he was before. The opportunity to completely satisfy one's behavioral preferences is especially likely when health and safety technologies are highly efficacious, meaning that the protection surplus is large.

In this view, risk compensation is potentially utility-maximizing—a route to the fuller expression of behavioral preferences, and to the capture of value that was previously too costly to access.¹⁴⁶ Moreover, the value introduced by a health and safety measure is not limited to the protection surplus. The *opportunity to decide* how to divide this surplus is valuable in itself. When an individual decides how to adjust his behavior in response to a health and safety intervention, he exercises a new measure of decisional freedom, which could add independent utility.¹⁴⁷ We might also consider the extent to which the opportunity to engage in risk compensation can influence beneficial *ex ante* behavior. For instance, the motivation to increase one's risk behavior may be one reason for purchasing and using new technologies in the first place.

on a series of interviews with female sex workers to conclude that “[i]n romantic relationships unprotected sex symbolizes some form of trust and a separation from commercial sex”).

146. The premise that individuals act rationally to maximize their utility has long been the basic assumption of the Chicago School of economic theory. See, e.g., Gregory S. Crespi, *Does the Chicago School Need To Expand Its Curriculum?*, 22 L. & SOC. INQUIRY 149, 150 (1997) (describing the Chicago School premise “that all economic actors, whether individuals or other legal entities, can be regarded as if they are engaging in rational maximization of their utility”); Robert A. Prentice, *Chicago Man, K-T Man, and the Future of Behavioral Law and Economics*, 56 VAND. L. REV. 1663, 1665 (2003) (discussing the “Chicago-man,” a “rational maximizer of his expected utilities”). Research in psychology and behavioral economics has long ago eroded the assumption that individuals do indeed act in rational ways to successfully achieve maximal utility. See, e.g., Daniel Kahneman & Richard H. Thaler, *Utility Maximization and Experienced Utility*, 20 J. ECON. PERSPECTIVES 221 (2006) (describing a series of studies documenting flaws in this model); Daniel Kahneman & Amos Tversky, *Prospect Theory: An Analysis of Decision Under Risk*, 47 ECONOMETRICA 263 (1979) (identifying a set of “choice problems” revealing biases and deficiencies in utility theory). But although individuals may predictably err in their attempts to pursue utility, “utility maximization is usefully thought of as a goal. People are trying to make choices that will, on average, make them as well-off as possible” Kahneman & Thaler, *supra*, at 231.

147. “[D]ecades of psychological theory and research . . . [have] repeatedly demonstrated, across many domains, a link between the provision of choice and increases in intrinsic motivation, perceived control, task performance, and life satisfaction.” Sheena S. Iyengar & Mark R. Lepper, *When Choice Is Demotivating: Can One Desire Too Much of a Good Thing?*, 79 J. PERSONALITY & SOC. PSYCHOL. 995, 995 (2000). Emerging evidence, however, suggests that there may be limits to the benefits of choice. See, e.g., Barry Schwartz, *Self-Determination: the Tyranny of Freedom*, 55 AM. PSYCHOL. 79 (2000) (identifying ways in which “unconstrained freedom” can undermine decisions and satisfaction). For example, Iyengar and colleagues have identified a “choice overload” effect, by which a larger number of choice options may undermine motivation and dissatisfaction. Iyengar & Lepper, *supra* note 147, at 1003. The value of choice may also vary by culture and decision contexts. Simona Botti & Sheena S. Iyengar, *The Psychological Pleasure and Pain of Choosing: When People Prefer Choosing at the Cost of Subsequent Outcome Satisfaction*, 87 J. PERSONALITY & SOC. PSYCHOL. 312, 312-13 (2004). Future research on risk compensation behavior should examine how individuals experience these behavioral choices.

Qualitative research has indicated that individuals' *intentions* to engage in more unprotected sex may play an important role in creating user demand for an efficacious HIV prevention vaccine.¹⁴⁸ For products such as drugs, which often require adherence to regular dosing regimens (e.g., a pill each day), intentions to take risks may also motivate better adherence. In these ways, risk compensation behavior may help drive markets for health and safety technologies, as well as maintain the consistent and accurate use of these products.

Under conditions of perfect information, a product user may adjust her risk-taking precisely to her target risk level, enabling her to capture the maximum allowable benefits of risk-taking behavior. If the user is rational, her new risk level will be less than or equal to the baseline risk level, assuming her preference for risk has not changed.¹⁴⁹ This risk compensation behavior would be either "partial" (the individual spends some of the protection surplus by increasing her risk-taking) or "complete" (the individual spends the entire protection surplus, resulting in a new risk level that is equal to baseline risk). This condition, therefore, represents a net improvement over baseline, and it matches the individual's intended risk. Internalized harms are absent in this condition, although there may be externalized harms (to be discussed below).

When risk compensation does not yield net harm for the individual or for others, there is no persuasive ethical justification to intervene coercively—even if risk compensation entirely negates the benefits of a new technology. Those who may engage in elevated risk behavior should not be disqualified from accessing new health and safety technologies. If they are not harming others and are cognizant of their own risks, they should retain freedom to access the protection surplus and to allocate it as they choose. Even individuals with complete knowledge about risk may rationally choose to engage in detrimental health behaviors—and however much health advocates may try to change individuals' preferences, they should remain free to make those choices. This view may seem inimical to public health, but a normative defense of offsetting behavior as promoting individual choice can bolster arguments for expanding access to health technologies *despite* risk compensation concerns.¹⁵⁰

148. Newman et al., *Preventive HIV Vaccine Acceptability*, *supra* note 101.

149. Her new risk level may exceed the baseline risk level if her preference for risk has increased. But under conditions of perfect information, this result would be attributable to the preference change, not risk compensation effects.

150. For example, a 2012 editorial opposed FDA approval of Truvada® for PrEP, arguing, "Because many people will not take Truvada properly, but think they are protected, it is entirely likely that widespread use of PrEP will actually increase HIV infections." Myers, *supra* note 7. This argument assumes that individuals cannot understand the extent of PrEP's protection, the requirements of PrEP use, or the HIV-related risks that they incur. There is no proof yet that these misconceptions exist. If we instead allow that some users *do* understand PrEP and HIV risk accurately, risk compensation-based objections simply announce a preference for allocating the entire protection surplus to a single type of benefit (reduced risk of infection), rather than other potential benefits. If we cannot ensure that users will spend the entire protection surplus on risk-reduction, this objection argues, it is preferable to withhold access entirely. This view devalues users' own priorities. Reducing the risk of infection is a vital goal,

Importantly, however, even risk compensation that is perfectly informed and value-maximizing has implications for the financing of health and safety products, which is largely the remit of private or public health insurers. Where risk compensation does diminish or fully offset the expected pharmacological impact of a drug, a healthcare payer may no longer find that drug cost-effective. This is a classic problem of incentives; the user captures two kinds of benefits (partial protection from disease, partial benefit from increasing risk behaviors), but the healthcare payer only reaps financial rewards if the drug actually prevents disease. If risk compensation results in perfect offsetting or undermines cost-effectiveness too much, healthcare payers may decide to refrain from paying full cost for this care, although making these decisions on a case-by-case basis is problematic due to the problems of accurate detection and the potential for abuse of discretion.

Although perfectly informed risk compensation behavior should not be coercively prevented, such as by blocking product access, a concern for public health would ethically justify efforts to *non-coercively* promote safer behaviors among individuals using health and safety technologies. This is justified by the imperative to ensure that public health resources are spent in a way that is maximally effective. Non-coercive efforts to minimize rational risk compensation behavior can help ensure that health and safety technologies produce their intended gains.¹⁵¹

B. *Uninformed Partial Risk Compensation*

Although risk compensation *can* be utility-maximizing, it may not always be so. Product users may lack information about how products and their own behaviors may affect their risks. Even when accurate information is available, cognitive biases and neglect of certain risks can impair product users' ability to appraise risks accurately. For instance, they may overestimate the benefits they receive from an intervention, or underestimate the risks they continue to run while using a health or safety product. Under these conditions, we might call risk compensation behavior "uninformed."

Behavioral economics literature can help explain why we may underestimate the risks and overestimate the protection we get from health and safety technologies. Many studies have demonstrated the influence of optimism bias, wherein people are overly optimistic regarding their vulnerability to

but it may not be the only (or most important) priority for individual users. Where prescription drugs such as PrEP can increase utility in multiple ways, a respect for users' autonomy demands that we acknowledge other benefits beyond risk reduction, and that we assure users a voice in decisions about access. Objections to PrEP based on risk compensation threaten to bar access to an entire class of individuals without acknowledging this implicit debasement of their values.

151. For instance, PrEP can be delivered along with behavioral counseling to minimize risk compensation effects. Underhill et al., *supra* note 65; Kristen Underhill et al., *Packaging PrEP To Prevent HIV: An Integrated Framework To Plan for Pre-Exposure Prophylaxis in Clinical Practice*, 55 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 8, 8-13 (2010).

adverse consequences.¹⁵² The effects of this bias may be compounded in risk compensation behavior—an optimistic individual may not only underestimate his risks, but also overestimate the protection provided by a preventive drug. Bounded rationality will also affect our understanding of probabilistic information about risk and drug efficacy; for instance, we tend to neglect significant differences when dealing with low probabilities,¹⁵³ and our understanding of risk is sensitive to the way information about risks and benefits is framed.¹⁵⁴ When risks increase with repeated exposure (e.g., repeated sexual contacts), behavioral science literature suggests that we may overestimate the probability that we will avoid risk in *all* of the exposures—that is, we overestimate the probability of conjunctive events (I will avoid infection in all three exposures) compared to disjunctive events (one of the three exposures will result in infection).¹⁵⁵ We may also focus disproportionately on certain risks due to availability biases, such as salience or imaginability.¹⁵⁶ For example, someone who takes PrEP may be very focused on the risk of HIV infection (which is reduced), but neglect the more likely risks of infection with herpes or chlamydia (which are not reduced). And as discussed above, perceptions of risk diminish as those risks become familiar,¹⁵⁷ and our perception of protection may be amplified or reinforced by feedback over time. For instance, a football player wearing a helmet may experience collisions as lower-impact, giving him motivation to hit as hard or harder in the next tackle.¹⁵⁸

To compound the operation of cognitive biases, some health risk behaviors take place when people are in states of (even further) diminished rationality. For example, sexual risk-taking is influenced by the use of alcohol and other substances,¹⁵⁹ which can influence risk perception. Smoking

152. See, e.g., Neil D. Weinstein, *Unrealistic Optimism About Future Life Events*, 39 J. PERSONALITY & SOCIAL PSYCHOL. 806 (1980); Christine Jolls et al., *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471 (1998) (addressing this and other biases); Barbara Luppi & Francesco Parisi, *Beyond Liability: Correcting Optimism Bias Through Tort Law*, 35 QUEEN'S L.J. 47 (2009).

153. Cass R. Sunstein, *Probability Neglect: Emotions, Worst Cases, and the Law*, 113 YALE L.J. 61 (2002).

154. Andrew J. Rothman & Peter Salovey, *Shaping Perceptions To Motivate Healthy Behavior: The Role of Message Framing*, 121 PSYCHOL. BULL. 3 (1997); Amos Tversky & Daniel Kahneman, *The Framing of Decisions and the Psychology of Choice*, 211 SCIENCE 453, 453 (1981).

155. Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, 185 SCIENCE 1124, 1129 (1974).

156. *Id.*

157. See *supra* note 50.

158. A.S. McIntosh, *Risk Compensation, Motivation, Injuries, and Biomechanics in Competitive Sport*, 39 BRIT. J. SPORTS MED. 2, 2-3 (2005).

159. See, e.g., David D. Celentano, Amanda D. Latimore & Shruti H. Mehta, *Variations in Sexual Risks in Drug Users: Emerging Themes in a Behavioral Context*, 5 CURRENT HIV/AIDS REP. 212, 217 (2010); William H. George & Susan A. Stoner, *Understanding Acute Alcohol Effects on Sexual Behavior*, 11 ANN. REV. SEX RES. 92 (2000); William H. George, et al., *Indirect Effects of Acute Alcohol Intoxication on Sexual Risk Taking: The Role of Subjective and Physiological Sexual Arousal*, 38 ARCHIVES OF SEXUAL BEHAV. 498 (2009).

behaviors are also influenced by the use of alcohol.¹⁶⁰ These and many other health risk behaviors are also related to psychological conditions such as depression or anxiety, and these psychological states can make it difficult to appraise risks accurately. To further complicate the problem, perception of risk can also vary in positive emotional states; for example, optimism bias may be more pronounced among individuals in a good mood.¹⁶¹

Under conditions of imperfect information, an individual product user who engages in risk compensation behavior may not accurately appraise his new risk level. When “partial” risk compensation behavior occurs, the individual’s new risk level is an improvement over his baseline risk. When “complete” risk compensation behavior occurs, the individual’s new risk level is equal to his baseline risk (but he is capturing more value from risk-taking activities). In both of these scenarios, the individual is better off than he was at baseline.¹⁶² But in both situations, it is still possible for the individual’s new risk level to differ from his *intended allocation of risks and benefits*. This difference may occur in either direction; with perfect information, he may prefer to decrease his risk-taking to retain more of the protection surplus, or he may prefer to increase his risk-taking to convert more of surplus into other types of value.

Although uninformed partial or even uninformed complete risk compensation behavior does not represent a net loss compared to baseline, this outcome is undesirable; uninformed risk compensation is likely to be a net loss compared to the individual’s optimal allocation of risk and benefit. This category of behavior may not demand a regulatory response on the basis of preventing new harm, so long as it does not externalize harms to third parties. But it may call for a regulatory response to remedy informational deficiencies, in order to minimize the disparities between intended and actual risk.

C. *Uninformed Overcompensation*

When product users’ information is incomplete, risk compensation behavior may not always yield net benefits relative to baseline. In some scenarios, an increase in risk-taking can overwhelm the protection surplus, a phenomenon we may call “overcompensation.” When this occurs, the product user may overestimate and overspend the protection surplus, causing a net deficit in protection compared to baseline. Assuming that the individual’s

160. See, e.g., Mark B. Reed, et al., *The Relationship Between Alcohol Use and Cigarette Smoking in a Sample of Undergraduate College Students*, 32 ADDICTIVE BEHAV. 449 (2007).

161. See, e.g., Helga Fehr-Duda et al., *Risk and Rationality: The Effects of Mood and Decision Rules on Probability Weighting*, 78 J. ECON. BEHAV. & ORG. 14 (2011); Gregory Mitchell, *Why Law and Economics’ Perfect Rationality Should Not Be Traded for Behavioral Law and Economics’ Equal Incompetence*, 91 GEO. L.J. 67, 101-02 (2002).

162. If the individual had achieved his target risk level at baseline, and if his target risk level has not changed, his new actual risk level may be below the target risk level. But the allocation of risks and benefits may still fall short of the allocation he would find optimal.

preference for risk has remained constant, this represents a net loss compared not only to her baseline risk, but also to her target risk level. In these cases, the new product will do the user more overall harm than good, and she will be unknowingly acting in ways that exceed her acceptable level of risk. This form of risk compensation behavior can lead to adverse health consequences for the intended beneficiaries of health and safety products. The remainder of this Article will refer to this as uninformed overcompensation, where the user herself incurs net harm.

Product features of a health or safety technology may contribute to overcompensation behavior. Few drugs or safety products completely remove risk; most are only partially efficacious for averting harm. When safety products are of low efficacy, product users have a smaller protection surplus—if they adjust their behaviors, they must do so within a narrower range, and it may be more difficult to avoid overcompensating. Overcompensation may also occur when a drug insulates against only one of several harmful consequences of risky behavior, and when the user underestimates the additional harms.

Where uninformed overcompensation occurs, the intended beneficiaries of health and safety products behave in ways that do not match their own preferences regarding risk, and they incur unintended harm as a result of product use. In this scenario, there are clear information asymmetries that may justify legal efforts to interrupt risk compensation effects.¹⁶³ Such efforts may be viewed as paternalistic, but it is important to clarify that they do not seek to change individuals' values; efforts to intervene in overcompensation seek to bring individuals' behaviors closer to what they themselves would choose given their target risk level and ideal allocation of risks and benefits.

D. *Externally Hazardous Risk Compensation*

Risky activities often pose risks for multiple parties. When one party increases his or her risk-taking as a result of using a new health and safety technology—whether the adjustment consists of perfectly informed risk compensation, uninformed partial risk compensation, or uninformed overcompensation—these behaviors may cause harm to others. To take Peltzman's example, drivers who increase their "driving intensity" while using seatbelts are not more likely to die in traffic accidents, but they are more likely to kill pedestrians.¹⁶⁴ In the same way, airbag laws may increase risks for passengers and drivers of non-airbag-equipped vehicles,¹⁶⁵ and auto insurance

163. This resonates with the "libertarian paternalism" emphasis of Sunstein and Thaler. Cass R. Sunstein & Richard H. Thaler, *Libertarian Paternalism Is Not an Oxymoron*, 70 U. CHI. L. REV. 1167 (2003).

164. Peltzman, *supra* note 9, at 717.

165. See Peterson, *supra* note 12.

laws may increase the likelihood that drivers and pedestrians will be hit.¹⁶⁶ People who decrease their use of condoms while taking PrEP may impose greater risks on their sexual partners; people who smoke more cigarettes because they are low-tar may impose additional risks of second-hand smoke; people who increase their consumption of unhealthy foods while taking medication for cholesterol may influence other family members to eat in unhealthy ways. Even if these risk compensation behaviors are perfectly informed and value-maximizing for product users, they externalize some harms to non-users.

The line between internalized and externalized harms is not always clear. Some harms imposed by suboptimal health behaviors may fall heavily on an individual's family members. For example, an international study of smoke exposure found that women and children who live with smokers have an elevated risk of premature death due to second-hand smoke exposure.¹⁶⁷ Although these family members are third parties, their illness or death may be devastating to the individual smoker. It may thus be inaccurate to classify these harms as purely "externalized," and the balance of internal and external harms should inform regulatory efforts to intervene in risk compensation effects.¹⁶⁸ The remaining sections in this Article will not repeat this caveat, but it should be understood that externalized and internalized harms may in some cases overlap.

In addition to the direct effects of increased risk-taking, risk compensation behavior can also harm third parties indirectly by influencing social norms. For example, consider a highway on which 30% of drivers are wearing seatbelts and driving an additional 5 miles an hour over the speed limit. Those drivers may exert sufficient influence on the drivers around them to raise everyone's speed by a few miles an hour, even among drivers who are not wearing seatbelts, due to the instinct to match the speed of surrounding traffic. The drivers who are not wearing seatbelts are placed at higher risk when they increase their speed, which will manifest itself at the population level as an increase in injuries among this group. Even if it is perfectly rational for the seatbelt-wearing drivers to increase their speed, the influence of these drivers on social norms may lead to a net loss at the population level. In the same way, if users of PrEP routinely decrease or stop the use of condoms, social norms in the community may change to (further) stigmatize or disfavor condom use.

166. That is, because insured drivers do not bear the risk of an accident, they may drive less carefully. Insurance laws yield an increase in the proportion of drivers who are insured, which in turn may increase traffic fatalities. See Cohen & Dehejia, *supra* note 90, at 388.

167. Heather Wipfli, *Secondhand Smoke Exposure Among Women and Children: Evidence from 31 Countries*, 98 AM. J. PUB. HEALTH 672, 672 (2008).

168. We might also consider the extent to which the benefits captured by risk compensation behavior are shared with third parties. For example, passengers in a car benefit from the driver's speed, all family members may enjoy unhealthy foods, and both members of a couple may enjoy unprotected sex.

This would make it difficult for nonusers to insist on condom use with their sexual partners, which would yield increased rates of sexually transmitted infection among this group. In each of these examples, risk compensation behavior among the beneficiaries of a health or safety technology may lead to harms incurred by non-beneficiaries.

Where risk compensation behavior leads to harms among third parties, the balance of interests will be complex. This form of risk compensation behavior, however, furnishes the strongest rationale for intervention, given concerns about equity and the likelihood that transactions costs will prevent parties from reaching other solutions. It is necessary in this case to weigh the benefits accruing to product users against the type and extent of harm imposed on others.

The remainder of this Article will group together uninformed overcompensation and externally hazardous risk compensation, simply classifying them as *hazardous* risk compensation effects. In these two scenarios, risk compensation behavior may cause health and safety technologies to produce net harms relative to baseline risk. Uninformed partial or complete compensation is also suboptimal: although individuals in this scenario do not experience harm compared to baseline, their actual allocation of risk and benefit does not match their own preferences, and future overcompensation is possible. Finally, only the narrow case of perfectly informed risk compensation behavior without externalized harms could be described as optimal.

E. Forms of Legal Intervention

The scientific and legal literatures have yielded few ways to address hazardous risk compensation effects (to minimize harm), uninformed partial risk compensation effects (to amend information deficiencies), or perfectly informed risk compensation behavior (to reduce the target risk level and maximize intervention benefit). Depending on their severity, these effects may call for regulation due to incomplete consumer information, the operation of cognitive biases, transactions costs that may undermine private solutions to externalized hazards, and the potential for population-level harms. Efforts to address risk compensation effects through legal mechanisms could fall into several categories with increasing levels of intrusiveness:¹⁶⁹ (1) interventions designed to identify risk compensation behavior, (2) informational interventions to modify individual behaviors, (3) financial incentives to modify

169. I am grateful to Professor Bill Sage for suggesting this framework, which uses his work on antibiotic resistance as a model. William M. Sage & David A. Hyman, *Combating Antimicrobial Resistance: Regulatory Strategies and Institutional Capacity*, 84 TUL. L. REV. 781, 799-820 (2010) (identifying methods of regulation along a continuum of intrusiveness).

individual behaviors, and (4) command-and-control regulation specifying standards or conditions of product use.¹⁷⁰

1. Identifying Risk Compensation Behavior

Before attempting to intervene in risk compensation dynamics, it is necessary to understand the type and extent of the effect. Currently, little is known about the factors that may drive risk compensation behavior as a response to any given technology. The law offers opportunities to incentivize the production of information about these effects, including public health surveillance mechanisms, the funding of risk compensation research through government grants, and the use of regulatory requirements to incentivize data collection by product manufacturers. These strategies may help to overcome current obstacles to rigorous research on risk compensation behavior, which may include a scarcity of funding, a lack of interest or knowledge among manufacturers and healthcare payers, and a tendency to focus exclusively on product efficacy without considering product use as a behavioral phenomenon. If legal structures could be used to incentivize data collection regarding risk compensation behavior, these data may help us maximize product effectiveness, increase cost-effectiveness, and minimize product-related harms.

2. Informational Interventions to Modify Individual Behaviors

Where risk compensation effects arise, the least intrusive intervention is the provision of warnings to encourage users to modify their behavior.¹⁷¹ Legal mechanisms such as required disclosures and product labeling are well-suited to intervene in this way. For instance, product labels or required patient counseling could emphasize imperfect product efficacy or direct users to behave in safer ways regardless of product use. Another option is to specifically warn product users about tendencies to engage in risk compensation behavior, although the efficacy of this approach is uncertain.¹⁷² Where risk compensation harms are wholly or partially attributable to cognitive biases, a variety of specific messaging strategies are available to counteract them. Professors Christine Jolls and Cass Sunstein have proposed providing

170. Risk compensation harms may also be reduced through interventions that aim to limit risk-taking overall, such as by incentivizing safer behaviors or reducing the motivation to take risks. Wilde has enumerated strategies for reducing risk behavior by influencing motivation, such as efforts to increase the perceived costs of risky behavior. WILDE, *supra* note 21, at 195, 202-07. Legal research is similarly full of efforts to limit risk-taking and incentivize care; these efforts, however, are ways of changing the target risk level, rather than intervening specifically in the risk compensation mechanism.

171. See Christine Jolls & Cass R. Sunstein, *Debiasing Through Law*, 35 J. LEGAL STUD. 199, 207 (2006).

172. Evidence to support the strategy of instructing people directly about cognitive biases is mixed. See, e.g., Stephen J. Choi & A.C. Pritchard, *Behavioral Economics and the SEC*, 56 STAN. L. REV. 1, 66-68 (2003); Cassandra Burke Robertson, *Judgment, Identity, and Independence*, 42 CONN. L. REV. 1, 34-35 (2009).

people with information about “a concrete incidence” of a risk materializing,¹⁷³ and they have reviewed methods of framing information to emphasize the potential costs of unsafe behavior.¹⁷⁴ Framing strategies are promising, although it may also be important to monitor the extent to which such messages may inadvertently undermine the consistent use of health and safety technologies.

Deception strategies may be a tempting way to minimize hazardous risk compensation effects—for example, by conveying the message that health and safety products are less efficacious than they actually are, or by providing such products without alerting consumers (e.g., requiring that new cars be outfitted with airbags or braking systems without informing car purchasers). However, deception strategies are practically, ethically, and legally unacceptable in medical treatment and consumer safety. For example, the provision of deceptive information about drug effects would undermine informed consent to medical treatment,¹⁷⁵ which should entail the provision of “unbiased information on the risks and benefits of all treatment options.”¹⁷⁶ Undermining patients’ expectations of drug efficacy may also result in poor drug adherence or lower levels of uptake, including among patients who would not have overcompensated if they had been given accurate information. More generally, false advertising regulations and product labeling requirements prevent the provision of information that misstates product efficacy or obscures safety characteristics, even if such messages help avert behaviorally induced harms. Furthermore, many products cannot be used without active user participation, and it would be impossible to introduce even passive safety measures such as airbags without consumers’ awareness.

Beyond the provision of warnings, informational strategies to influence users’ behavior could include monitoring and publicizing risk compensation effects, possibly aggregated on the basis of drug, prescriber, or pharmacy. This mechanism may be useful for both identifying behavior and motivating behavioral change directly,¹⁷⁷ as well as incentivizing prescribers and providers to address risk compensation in their own practices. Even simply assessing self-reported user behavior on a regular basis could help users to remain mindful of their behavioral adjustments. Privacy concerns loom large in this proposal; where behaviors are private, such as sexual activity, and/or highly stigmatizing, such as substance use, interventions that rely on publicizing information may

173. Jolls & Sunstein, *supra* note 171, at 210 (citing studies).

174. *Id.* at 210-11. In the psychology and health behavior literature, this is known as loss- and gain-framing. See, e.g., Rothman & Salovey, *supra* note 154.

175. For an overview of the legal and ethical obligations of informed consent, see Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429 (2006).

176. *Id.* at 436-37.

177. See Sage & Hyman, *supra* note 169, at 801 (noting that public reporting/disclosure interventions can produce information as well as motivate behavior).

be unacceptable. This may even be true when data are publicized in aggregate. A less public strategy may be to collect behavioral data, then provide users with private feedback on their risk behavior in comparison to other product users.¹⁷⁸ Any such strategy, however, would rely on users to accurately report behaviors, introducing a variety of biases. Informational strategies that aim to influence risk compensation behavior by product users require rigorous empirical study, but are appealing because they may be less intrusive than manipulating financial incentives or restricting product access.

3. Financial Incentives to Modify Individual Behaviors

A variety of financial options may be used to motivate behavioral change, as discussed by other scholars.¹⁷⁹ Where risk compensation behavior imposes external harms, one remedy may be to tax the product in such a way that requires users to internalize these harms (Pigouvian taxation).¹⁸⁰ It is also possible to combine taxation with warnings to encourage individuals to attend to risks they might otherwise underestimate.¹⁸¹ For example, individuals purchasing statins could receive a dietary warning and pay a higher co-pay.¹⁸² Because the demand for prescription drugs may be relatively inelastic, it may be most sensible to tax all purchases of a given drug, then to use that revenue to reduce the harms associated with risk compensation behavior.¹⁸³

A potentially more intrusive, financially-driven option would be to ask drug users to sign a private commitment contract through the online service StickK.com to commit to certain behaviors as a condition of product use, in which the user would forfeit money if those behaviors were not maintained.¹⁸⁴ A number of health behavior interventions have tested the use of financial incentives to encourage desirable behaviors;¹⁸⁵ these programs have raised

178. For example, providing individuals with feedback about their energy consumption relative to other customers has been shown to reduce consumption. Ian Ayres, Sophie Raseman & Alice Shih, *Evidence from Two Large Field Experiments That Peer Comparison Feedback Can Reduce Residential Energy Usage*, J.L. ECON. & ORG. 1 (2012).

179. See, e.g., Sage & Hyman, *supra* note 169, at 803-15 (describing multiple options for the design of financial incentives to reduce behaviors associated with antimicrobial resistance).

180. *Id.* at 806.

181. *Id.*

182. Financial incentives may have limited power to influence behavior among users of prescription drugs when users are insulated from health care costs by insurance. For example, if an insurance company finances statins without a co-pay, statin users may not be influenced by co-pay rules.

183. Sage & Hyman, *supra* note 169, at 806.

184. See STICKK, <http://www.stickk.com/> (last visited Aug. 5, 2012). An individual signing a StickK contract sets a behavioral goal, a deadline by which she commits to achieve that goal, and a financial penalty to pay in the event of failure. If she fails to achieve her goal in the allotted timeline, the StickK website will charge her credit card for the penalty she has set. For an example of a StickK contract process, see IAN AYRES, *THE \$500 DIET: WEIGHT LOSS FOR PEOPLE WHO ARE COMMITTED TO CHANGE* (2011).

185. For a review of financial incentives for behavior change, see Kim Sutherland, Jon B. Christianson & Sheila Leatherman, *Impact of Targeted Financial Incentives on Personal Health Behavior: A Review of the Literature*, 65 MED. CARE RES. & REV. 36S (2008).

important questions about sustainability, autonomy, paternalism, discrimination, and the role of intrinsic motivation.¹⁸⁶ Unfortunately, however, individual-level strategies may also diminish user demand for health and safety products, as well as deterring potential users who would not have engaged in hazardous risk compensation behavior.

Regulatory efforts can also include financial incentives for private and public researchers to develop strategies for identifying and minimizing risk compensation effects. These may consist of prizes for developing interventions that reduce risk compensation behavior,¹⁸⁷ grant funding for research, or patent extensions¹⁸⁸ or priority review vouchers¹⁸⁹ for manufacturers who successfully minimize risk compensation behavior among drug users.

4. Command-and-Control Regulations

When risk compensation effects are hazardous and efforts to modify user behavior are unsuccessful, the most intrusive legal response is to specify standards for product use, prescription, and access. These are “command-and-control” regulations: rules that “require or proscribe specific conduct” on penalty of fines, injunctions, and other enforcement consequences.¹⁹⁰ For the present case of prescription drugs, the FDA’s imposition of warning and labeling requirements can also be classified as command-and-control regulation, given that labeling is mandatory for drug sale.¹⁹¹ But beyond warnings, this category of regulation could also include withholding products from all or some users, or withdrawing drug approval if risk compensation reaches the very high bar of being so hazardous as to outweigh the benefits of an intervention at the population level. Even then, it is unlikely that *every* individual who uses a product will engage in hazardous behavior; risk compensation may be less pronounced among those who are more risk-averse, or who lack the motivation to increase their risk-taking. It could be unjust to

186. For some discussion of these issues, see IAN AYRES, *CARROTS AND STICKS: UNLOCK THE POWER OF INCENTIVES TO GET THINGS DONE* (2010); Kristin M. Madison, Kevin G. Volpp & Scott D. Halpern, *The Law, Policy, and Ethics of Employers’ Use of Financial Incentives To Improve Health*, 39 J.L. MED & ETHICS 450 (2011); Adam Oliver & Lawrence D. Brown, *A Consideration of the User Financial Incentives To Address Health Inequalities*, 37 J. HEALTH POL. POL’Y & L. 201 (2012).

187. See, e.g., Sage & Hyman, *supra* note 169, at 810 (describing the use of prizes to reward innovation).

188. *Id.* at 811.

189. *Id.* at 810 (describing the use of priority review vouchers as an incentive for manufacturers).

190. Richard B. Stewart, *Regulation, Innovation, and Administrative Law: A Conceptual Framework*, 69 CAL. L. REV. 1256, 1264 (1981); see also Jon D. Hanson & Kyle D. Logue, *The Costs of Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation*, 107 YALE L.J. 1163, 1174-75 (1998) (describing the difference between command-and-control regulations and incentive-based regulations).

191. See, e.g., Jon D. Hanson & Kyle D. Logue, *Smokers’ Compensation: Toward a Blueprint for Federal Regulation of Cigarette Manufacturers*, 22 S. ILL. U. L.J. 519, 524 n.19 (classifying FDA warning requirements and advertising restrictions as command-and-control regulations).

deny such consumers products that would increase their overall utility, simply because other consumers might cause hazards. This scenario would lead to difficult decisions about regulation, especially when it is difficult or impossible to differentiate between users who are likely or unlikely to cause risk compensation-related harms.

One option is to tailor product marketing or partially limit access to certain users. For example, it may be possible to assess users' behaviors during product use, and to intensify the provision of counseling and warnings to individuals who exhibit hazardous risk compensation behavior. If efforts to minimize risk compensation hazards are unavailing, and if hazardous risk compensation is sustained over time, it may be justifiable to limit product access. Private and public healthcare payers might also withhold payment for health technologies if individuals do not commit to behaviors that make such interventions cost-effective. But this introduces the potential for abuse of discretion in deciding who receives prescriptions or insurance coverage for new technologies, which would make a selective limitation strategy problematic. Another clear limitation of individual-level access policies is the need to rely on self-reported user behavior, and users may be unwilling to report behaviors accurately if they run the risk of losing product access. This may also incentivize the reporting of extremely high-risk behaviors before product use, so that subsequent behaviors will be ascribed to ordinary risk-taking rather than risk compensation effects. Finally, a third serious defect of individual-level access limitations is that they may unfairly punish unrelated increases in risk-taking as hazardous risk compensation behavior. For example, consider someone with high cholesterol who is prescribed statins. At his next checkup, he may report consuming far more cholesterol-rich foods, and his weight may increase. These results are consistent with risk compensation, but they may instead have been driven by an increase in his target risk level—for instance, he may have decided that his high cholesterol is inevitable, and that it was no longer worthwhile to watch his diet carefully. Or, he may have increased his consumption of cholesterol-rich foods for another unrelated reason, such as moving to a neighborhood where access to healthy food is poor. These behaviors may appear to be risk compensation, but, in fact, they had little to do with whether he was taking statins. Moreover, taking the statin drugs away from this user would leave him without an efficacious prevention tool, while doing little to reverse his increased risk-taking behavior.

Instead of basing access on individuals' self-reported behaviors, an alternative is to limit access to groups according to a blanket policy based on population-level research evidence. It may be impossible to reliably identify risk compensation behavior at the level of the individual. But in a large enough sample of users, individual variations in the target risk level over time should have a minimal influence on the data, allowing risk compensation effects to be isolated with greater certainty. Group-level policies run the risk of being discriminatory, so it is crucial that any such policy be based entirely on

empirical evidence. Even an evidence-based group-level policy is also imperfect: it is unfair to members of such groups who would not actually have engaged in risk compensation, but who fall on the wrong side of the access line. But although group-level policies may be unfair to some potential users, they may cause marginally less harm than individual-level policies, for the reasons described above.

F. Prescription Drugs as a Test Case

The remaining Parts address how legal intervention may help to address risk compensation dynamics related to prescription drug use. As noted in the introduction, prescription drugs present an optimal test case for these forms of legal intervention. The law governing prescription drugs already furnishes means of obtaining information from drug manufacturers, influencing user behavior through risk management plans and FDA-enforced warnings, and controlling access to prescription drugs through FDA regulation.

As a preliminary point, it is possible to conceptualize drug-related risk compensation behavior in several ways. First, offsetting behavior could itself be seen as a non-pharmacological effect of the drug. But this view would sideline the complex social and behavioral processes driving risk compensation behavior—for instance, the formation of expectations about a drug's efficacy, the use of the drug, and the subsequent perception of protection. Second, offsetting behavior could be viewed as an independent decision made by drug consumers, deriving from individual preferences and unaffected by any characteristic of the product. However, this view may neglect opportunities to adapt the design and marketing of products to help consumers avoid hazardous or uninformed risk compensation behavior, and to thereby maximize drug effectiveness and cost-effectiveness.

A third way, and the most helpful for this discussion, is to view risk compensation behavior as a predictable causal mechanism by which a drug has an effect, where the effect is a change in users' risk of incurring adverse health consequences.¹⁹² This allows for complexity in the risk compensation mechanism, but preserves incentives for drug manufacturers, regulators, and intermediaries to identify and address offsetting behaviors. Users who engage in risk compensation and experience adverse health effects may also seek to place responsibility for those effects with drug manufacturers and prescribers. Although many features of risk compensation are beyond manufacturers' control, product labeling and advertising will doubtless help to shape the perceptions of drug users. Product use is also a but-for cause of risk compensation behavior. It may therefore be appropriate to structure legal

192. The changed risk would arise not from changed vulnerability to harm, but rather from a change in frequency of exposure to harm through risk behavior.

incentives to encourage drug manufacturers and other actors to identify and seek to minimize risk compensation and its associated harms.¹⁹³

III. Identifying Drug-Associated Risk Compensation Effects: FDA-Required Testing

Administrative law offers several mechanisms for incentivizing manufacturers to investigate risk compensation behavior, both before and after marketing new drugs. These data could inform guidelines for drug prescription and clinical follow-up, labeling and approval, the development of behavioral interventions to mitigate risk compensation effects, cost-effectiveness calculations, and the efforts of public health authorities to anticipate shifts in disease burden and healthcare costs. Analyses to identify risk compensation behavior are not routine; the FDA does not currently consider effects derived from user expectations in any phase of the drug approval process.¹⁹⁴ However, testing for risk compensation effects is feasible and should play a role in FDA requirements for drug approval and postmarketing testing.¹⁹⁵

The FDA requires drug manufacturers to collect and present specific forms of data about drug safety and efficacy, both before and after drug approval. Minor changes to FDA requirements could ensure that data on users' behavioral adjustments are included at both time points.

A. Pre-Approval Testing

Current FDA requirements for new drug approvals do not incentivize the collection of data on risk compensation behaviors. In order to approve a New Drug Application, the FDA requires three sequential phases of clinical evidence, none of which assesses risk compensation behaviors. Phase I identifies a new drug's pharmacological effects and safety in approximately 20-80 "patients or normal volunteer subjects";¹⁹⁶ Phase II consists of a controlled clinical study to assess efficacy of the drug for a particular indication in several

193. Because risk compensation is behavioral, it could also be perceived as a form of drug misuse or abuse. If the label specifically warns patients to avoid increased behavioral risk-taking, risk compensation behavior may be perceived variously as unapproved use, off-label use, drug abuse, or misuse—each of which carries specific consequences in drug regulation.

194. See, e.g., Malani, *supra* note 19, at 436.

195. Many states also impose on drug manufacturers an independent "duty to test" for adverse effects that are foreseeable based on the current state of scientific knowledge, discoveries, and advances. See, e.g., *Enright by Enright v. Eli Lilly & Co.*, 570 N.E.2d 198 (N.Y. 1991). FDA approval does not insulate a drug manufacturer from liability for negligently failing to test for foreseeable and scientifically discoverable product dangers. See *Stromsodt v. Parke-Davis & Co.*, 257 F. Supp. 991 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969). This duty should arguably extend to the identification of risk compensation effects, but this assessment is beyond the scope of this paper. Risk compensation testing may also form part of a broader duty of "product stewardship," although this broad duty has been controversial. See Lars Noah, *Platitudes About 'Product Stewardship' in Torts: Continuing Drug Research and Education*, 15 MICH. TELECOMM. & TECH. L. REV. 359, 360 (2009).

196. 21 C.F.R. § 312.21(a) (2011).

hundred patients for whom the drug is expected to provide a therapeutic benefit; and Phase III consists of randomized trials among hundreds or thousands of patients, intended to identify drug effectiveness in a more routine clinical setting.¹⁹⁷ The FDA generally requires two or more Phase III studies before approving a New Drug Application, although studies in Phases II and III may be combined in a fast-track approach for drugs for serious or life-threatening illness, with increased post-marketing surveillance.¹⁹⁸

The double-blinded, randomized trial designs required in Phases II and III are profoundly limited in identifying risk compensation effects, as described above.¹⁹⁹ However, it may also be too burdensome to add a separate, freestanding study to assess risk compensation behavior before drug approval: delays in the FDA approval process have received extensive attention,²⁰⁰ and even hazardous risk compensation may not be severe enough to merit additional delay. One potential solution to the lack of evidence is to change FDA requirements to include studies with different probabilities of assignment to treatment groups.²⁰¹ Simply adding several supplementary analyses in the FDA's existing requirements, however, may also improve the assessment of risk compensation without manipulating assignment probabilities.

One possibility is to conduct a combination of longitudinal analyses and qualitative interviews. Researchers could assess the risk behaviors of all participants before and during the trial, and track any changes over time. Adverse changes in risk behavior over time *may* be due to expectations of benefit from the medications; even though this design could not conclusively identify risk compensation as the causal mechanism for such changes, the finding of increased risk behavior would be a useful prompt for further investigation.²⁰² Conducting qualitative interviews with trial participants to explore their perceptions of pill efficacy could also help identify how these expectations shaped behavior throughout the study.

A more promising option is to compare participants based on their self-reported expectations of drug effectiveness. Researchers could ask participants which group they *believe* they are in, and whether they believe they are taking an efficacious drug. It would then be possible to compare the behaviors of

197. See 21 C.F.R. § 312.21 (2011) (overview of FDA investigational phases); see also Malani, *supra* note 19, at 436; Judy Vale, *Expanding Expanded Access: How the Food and Drug Administration Can Achieve Better Access to Experimental Drugs for Seriously Ill Patients*, 96 GEO. L.J. 2143, 2147-48 (2008).

198. See Vale, *supra* note 197, at 2148; see also 21 C.F.R. § 314.500-560 (2011) (governing accelerated FDA approval for drugs intended to treat serious or life-threatening illnesses).

199. See *supra* Subsection I.B.1.

200. See, e.g., Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003, 1023 (2003).

201. See Malani, *supra* note 19; Malani, *supra* note 70.

202. An even better strategy for this goal would be to include a third study arm that received no treatment—not even placebo—and compare the active and placebo arm against this no-treatment control. However, adding a study arm would add substantially to study costs and the time needed for recruitment.

participants who were confident they were receiving a beneficial drug, against participants who were confident that they were receiving an inefficacious drug or placebo.²⁰³ Limitations of this study design would include potential confounding due to optimism bias (among other confounders); more optimistic participants may be more likely to believe they are in the active arm, as well as more likely to overestimate the benefits of an active drug. Another weakness is the fact that even participants who believed they received an efficacious drug would lack information about the *actual* effect. However, this comparison may yield a closer approximation of risk compensation than is possible in a pre-post comparison.²⁰⁴ Each of these analyses would place some burden on drug developers—namely, the requirement of adding behavioral questionnaires, qualitative interviews, and questions to ask about participants' perception of treatment assignment and drug benefit. However, this burden is minimal compared to the need for an entirely separate study.

Regardless of methodology, pre-approval analyses will not be perfectly applicable to users who begin taking the drug after it is approved, since users outside trials will receive information stating that the drug *is* effective. These changes, however, could help to flag risk compensation behavior early, indicating a greater need to conduct postmarketing surveillance of user behavior.

B. Postmarketing Surveillance

The FDA could also prompt the collection of data on risk compensation effects after approval. The decision to require these studies should be subject to specific and empirically derived criteria for determining when risk compensation is a legitimate concern, such as when it is observed in pre-approval studies. After drug approval, the FDA engages in postmarketing surveillance “to detect adverse events not previously observed, improve understanding of the potential severity of previously unanticipated risks, detect events resulting from drug interactions or drug effects in particular populations, and assess the potential for causal relationships.”²⁰⁵ Sources of information in postmarketing studies include mandatory reporting of adverse events by manufacturers (including reports drawn from medical literature), monitoring the medical literature, soliciting reports of adverse events from health professionals, and, on occasion, requiring that manufacturers conduct

203. I have suggested this design in more detail elsewhere. Underhill, *supra* note 65; Underhill, *supra* note 64.

204. A pre-post comparison is like the longitudinal analysis described in the prior paragraph, in which researchers measure participant behavior before and after an intervention takes place, but without a control group.

205. Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 587, 600 (2005); see also Eva B. Stensvad, *Immunity for Vaccine Manufacturers: The Vaccine Act and Preemption of Design Defect Claims*, 95 MINN. L. REV. 315, 340 n.196 (2010) (citing additional commentary).

postmarketing clinical studies (Phase IV studies to further assess “serious risk[s]”) as a condition of drug approval.²⁰⁶ Postmarketing studies are intended to provide more information about specific drug effects, and before drug approval, “any interested person” may propose that the FDA require an additional or continued postmarketing study.²⁰⁷ The FDA’s authority to mandate postmarketing studies and “risk evaluation and mitigation strategies” (REMS) was expanded in 2007 and took effect in March 2008; the Food and Drug Administration Amendments Act (FDAAA) explicitly recognized FDA authority to require a postapproval study to assess “serious risks,” on penalty of drug withdrawal from the marketplace.²⁰⁸ The FDA most recently reported to Congress on outstanding postmarketing studies in March 2012; according to the most current data available at this time, 198 approved New Drug Applications and Abbreviated New Drug Applications had an outstanding mandatory postmarketing study requirement or voluntary postmarketing study commitment.²⁰⁹ These commitments included 675 unmet or pending postmarketing requirements, and 75 requirements that had been met within the past year.²¹⁰

Data collected after drug approval would be most useful for assessing risk compensation effects, because users of approved drugs will have justifiably higher expectations of benefitting from the product. At present, however, neither postmarketing surveillance of adverse events nor Phase IV studies are designed to reach risk compensation behavior. Mandatory reporting of adverse

206. See Struve, *supra* note 205 (reviewing the FDA’s postmarketing surveillance system); see also 21 U.S.C. § 355(o)(3)(B) (2007) (permitting the Secretary to require postapproval studies “(i) To assess a known serious risk related to the use of the drug . . . (ii) To assess signals of serious risk related to the use of the drug . . . (iii) To identify an unexpected serious risk when available data indicates the potential for a serious risk”). “Serious risk” refers to the risk of an adverse drug experience that results in death, risk of death, inpatient hospitalization, persistent incapacity to carry on normal life functions, birth defect, or that “based on appropriate medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent these consequences.” 21 U.S.C. § 355-1(b)(4)-(5) (2007). Uninformed overcompensation may not immediately pose this severe level of harm; however, because it can cause harm and cannot be assessed thoroughly in preapproval studies, it is appropriate to require postmarketing studies for this purpose.

207. 21 C.F.R. § 310.303(b) (2011).

208. See Food and Drug Administration Amendments Act, Pub. L. No. 110-85, § 901, 121 Stat. 823, 922-43 (2007); Jacqueline R. Berman, *FDA’s Increasing Role in Post-Approval Control over Pharmaceutical Products*, 12 J. HEALTH CARE COMPLIANCE 31 (2010).

209. FDA, REPORT ON THE PERFORMANCE OF DRUG AND BIOLOGICS FIRMS IN CONDUCTING POSTMARKETING REQUIREMENTS AND COMMITMENTS; AVAILABILITY, 77 Fed. Reg. 13,339, 13,341 (Mar. 6, 2012), available at <http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5302.pdf>.

210. *Id.* More recent data are available in the Postmarketing Requirements and Commitments Database File, which is up to date as of October 2012 (but does not disaggregate voluntary and mandatory commitments). This file lists 1036 commitments for 219 drugs approved since March 25, 2008, of which 214 commitments had been terminated, submitted, fulfilled, or released. The remaining 822 were open, pending, or delayed. The number of study commitments per year was 112 from March to December 2008, 225 in 2009, 256 in 2010, 261 in 2011, and 182 in January to October 2012. FDA, POSTMARKETING REQUIREMENTS AND COMMITMENTS: DOWNLOADABLE DATABASE FILE, available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/ucm070777.htm>.

events according to 21 C.F.R. § 314.80(a) extends to “adverse drug experience[s]” identified in any source, including medical practice, the scientific literature, postmarketing studies. These are “any adverse event[s] associated with the use of a drug in humans”;²¹¹ however, the FDA’s definition for postmarketing reports does not specifically mention adverse *behavioral* effects other than drug abuse or overdose.²¹² Revising adverse event reporting requirements to include increased behavioral risk-taking and associated consequences would be one way to improve these regulations. Phase IV clinical studies could also be designed to collect behavioral data in some of the ways mentioned above, such as by comparing product users to matched controls who receive no treatment, comparing behaviors before and during product use,²¹³ or combining qualitative interviews with behavioral assessments to understand how users’ perceptions of benefit might influence risk-taking. Although these studies are not currently routine, the FDA could use both postmarketing surveillance and the postmarketing study commitment mechanism to promote the investigation of risk compensation effects. There is already some indication that the FDA is interested in the collection of postmarketing data on risk compensation behavior. The approval of Truvada for use as PrEP was conditional on several postmarketing studies, including the validation of an adherence questionnaire that will assess “sexual and non-sexual behaviors related to increased risk of HIV infection.”²¹⁴

Admittedly, the FDA’s capacity to collect postmarketing data on risk compensation behavior is limited. The FDA system for postmarketing surveillance and monitoring Phase IV studies has been heavily criticized, and commentators assert that the agency prioritizes new drug applications while lacking the resources needed to process and respond to the “deluge of information” it receives regarding adverse events—already more than 200,000 adverse event reports per year regarding drugs and biologic products, and over 80,000 reports regarding medical devices.²¹⁵ If clinicians who monitor patients do not consistently ask about health behaviors, or if patients do not report them accurately, hazardous or uninformed risk compensation effects may not be detected. Furthermore, even if risk compensation effects are detected, they may be perceived as a problem of personal responsibility rather than as reportable adverse events attributable to product use. Phase IV studies required by the FDA may not be conducted; one report suggested in 2002 that only 37% of all

211. 21 C.F.R. § 314.80(a) (2011).

212. *Id.*

213. For an example of this study design, see Martin et al., *supra* note 74.

214. Letter from FDA to Dara Wambach, Associate Director, Regulatory Affairs, Gilead Sciences Inc., Re: Supplement Approval, 8 (July 16, 2012), http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/021752Orig1s030ltr.pdf.

215. Struve, *supra* note 205, at 601 (citing additional commentary); see also 21 C.F.R. § 310.303(a) (2011) (“[T]he Food and Drug Administration may approve the new drug application on condition that the necessary long-term studies will be conducted and the results recorded and reported in an organized fashion.”).

FDA-required postmarketing studies had been completed, and many had not begun.²¹⁶ Commentators also note that the FDA lacks a “systematic approach to identifying possible pre-marketing drug-safety problems and translating them into high-quality post-marketing studies.”²¹⁷ As mentioned above, the monitoring of risk compensation effects will also be limited by privacy concerns and the validity of self-reported data on behaviors. These concerns may vary depending on the type of drug and behavior at issue, and each context may demand a different balance of privacy and rigorous postmarketing research.

Despite these limitations, however, the FDA could still do more to incentivize the collection of data on risk compensation behavior during the postmarketing phase. Explicitly revising 21 C.F.R. § 314.80(a) and expanding requests for postmarketing study commitments could together focus manufacturers’ attention on this goal, even if the FDA cannot ensure complete enforcement. Administrative attention and explicit acknowledgement of risk compensation effects may also incentivize independent researchers to undertake behavioral studies of product users, bringing risk compensation effects to the attention of research funders such as the National Institutes of Health.²¹⁸

IV. Modifying Prescription Drug Users’ Behavior: FDA Labeling and REMS Requirements

To address the adverse health effects posed by hazardous or uninformed risk compensation effects, drug manufacturers should have incentives to mitigate these dangers. This Part will explore two legal mechanisms that the FDA can use to influence users’ behavior: FDA-required labeling and REMS requirements. Because this Article focuses on FDA regulation, this section will

216. Struve, *supra* note 205, at 605-06 n.85 (citing Marie R. Griffin et al., *Commentary: Postmarketing Surveillance for Drug Safety: Surely We Can Do Better*, 75 *CLINICAL PHARMACOLOGY & THERAPEUTICS* 491, 492 (2004)); *see also* Bruce Patsner, *Marketing Approval Versus Cost of New Medical Technologies in the Era of Comparative Effectiveness: CMS, Not FDA, Will Be the Primary Player*, 3 *J. HEALTH & LIFE SCI. L.* 38, 49 (2010) (“The FDA has not been able to enforce standing Phase IV commitments by sponsors for drugs approved for marketing under accelerated approval programs in more than 90 percent of cases . . .”).

217. Bruce M. Psaty & Sheila P. Burke, *Protecting the Health of Our Public—Institute of Medicine Recommendations on Drug Safety*, 355 *NEW ENG. J. MED.* 1753, 1754 (2006); *see also* INST. OF MED., *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC* 17 (Alina Baciu et al. eds., 2007) (“FDA does not have adequate resources or procedures for translating preapproval safety signals into effective postmarketing studies . . .”).

218. The NIH has funded several studies in this area, including my own work (National Institute of Mental Health, Grant #5K01MH093273). A search of the NIH Research Portfolio Online Reporting Tools grant database identifies 12 currently active grants that specifically refer to risk compensation behavior. An additional 181 active grants include the term “behavioral disinhibition,” but this term is used in a variety of different ways and does not always refer to the mechanism of interest here. *See Research Portfolio Online Reporting Tools*, NAT’L INST. OF HEALTH, <http://projectreporter.nih.gov/reporter.cfm> (last visited Mar. 30, 2013) (Advanced Text search: “risk compensation” OR “behavioral disinhibition”).

not discuss financial strategies for modifying users' behaviors, such as product pricing or taxation.

Where risk compensation has been observed, the FDA should address these concerns through labels intended for both patients and intermediaries, and manufacturers may take additional steps to maximize drug effectiveness through an FDA-approved REMS. Fulfilling this duty may help reduce hazardous or uninformed risk compensation effects and maximize the benefit from new drugs, while avoiding the more intrusive path of restricting access. Although warnings impose costs on manufacturers, these costs may be less than the potential lost revenue if healthcare payers refuse coverage for such drugs due to risk compensation concerns; moreover, the cost of warnings is less than the potential cost of withdrawing such drugs from the marketplace due to hazardous risk compensation effects.

In addition to FDA requirements, some may seek to impose on manufacturers an independent duty to warn intermediaries and end users of hazardous risk compensation effects under products liability law.²¹⁹ Although this Article will not address the claim in detail, claimants litigating on this basis may find it difficult to recover due to the burden of showing causation, or due to defenses including assumption of risk, contributory negligence, or obviousness of the risk.²²⁰ Given the likely limitations of litigation in this area, FDA requirements will be the principal incentives for manufacturers to impose warnings and take other actions to encourage safer behavior by users. This Part will conclude by examining the potential dangers of overwarning.

A. FDA Labeling

The primary way in which the FDA acts to influence user behavior is by imposing labeling requirements on drug manufacturers. If risk compensation has been observed in pre-approval or postmarketing studies, the FDA should ensure that product labels warn intermediaries and consumers of these effects. Manufacturers must amend labels with new warnings “as soon as there is reasonable evidence of an association of a serious hazard with a drug . . . [even

219. This duty to warn encompasses both the duty to warn of product dangers, as well as the duty to instruct consumers in appropriate product use. DAVID G. OWEN, *PRODUCTS LIABILITY LAW* 584 (2d ed. 2008).

220. These warnings will also be subject to ongoing debate over whether FDA-approved labels preempt warning requirements that may be imposed by state products liability suits. *See, e.g.,* *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) at 2581 (finding that a brand-name drug manufacturer is subject to both state and federal law for warning labels, but that a generic drug manufacturer need only comply with the FDA-required label); Elizabeth J. Cabraser, *When Worlds Collide: The Supreme Court Confronts Federal Agencies with Federalism in Wyeth v. Levine*, 84 *TUL. L. REV.* 1275, 1281 (2010) (noting that currently state tort claims, including warning defects, are currently preempted for medical devices, but not for drugs).

if a] causal relationship between the serious hazard and the drug has not been proven.”²²¹

1. Labels Designed for Intermediaries

The FDA requires several different categories of labeling requirements for prescribing intermediaries.²²² The categories most relevant for risk compensation behavior include “Indications and Usage,” “Contraindications,” “Warnings and Precautions,” and “Patient Counseling Information.”²²³ Warning may not be necessary in all of these sections; however, information about hazardous and uninformed risk compensation effects should be included in at least one section.

According to FDA regulations, the “Indications and Usage” section must denote whether “a drug is used for an indication only in conjunction with a primary mode of therapy (e.g., diet . . . [or] behavior changes . . .),” as well as whether “specific conditions . . . should be met before the drug is used on a long term basis.”²²⁴ If risk compensation is observed, the FDA could consider labeling requirements that indicate that a drug should only be used “in conjunction” with counseling to mitigate increases in risk behavior.²²⁵ If hazardous risk compensation effects have been observed, the label could specify that a user should demonstrate an ability or commitment to avoid increased risk-taking behavior before a drug is prescribed for long-term use.²²⁶

The “Contraindications” section “must describe any situations in which the drug should not be used because the risk of use clearly outweighs any possible therapeutic benefit,” including when users “have a substantial risk of being harmed by the drug and for whom no potential benefit makes the risk acceptable.”²²⁷ This may be a logical place to include dangers associated with uninformed overcompensation behavior, and particularly to note that patients who increase their risk-taking beyond the drug’s benefit are at a substantial risk of harm. Whether the benefits of increased risk-taking make the risks “[un]acceptable” is a value judgment, and disagreement on this point could suggest that the warning belongs in another section.

221. 21 C.F.R. § 201.57(e) (2011).

222. *See id.* § 201.56(d)(1).

223. *Id.* The “Use in Specific Populations” category is largely used for warnings related to drug abuse. *Id.* § 201.57(c)(10)(ii) (2011). It is unlikely that risk compensation behavior could be classified in this way.

224. *Id.* § 201.57(c)(2)(i)(A).

225. This could be changed to the requirement that patients engage in safer behaviors (rather than simply receive behavioral counseling), but this would undermine patients’ freedom to make decisions about the allocation of risk and the protection surplus.

226. There are of course limitations here: patients’ motivations to engage in risky behaviors will likely change over time, and they may not report behaviors accurately to physicians.

227. 21 C.F.R. § 201.57(c)(5) (2011).

The “Warnings and Precautions” section is another logical place for warnings about risk compensation behavior. This section “must describe clinically significant adverse reactions[,] . . . other potential safety hazards[,] . . . limitations in use imposed by them[,] . . . steps that should be taken if they occur . . . [and] any special care to be exercised by the practitioner for safe and effective use.”²²⁸ Because risk compensation behavior itself is non-pharmacological, it may not fall under the definition of “adverse reaction.”²²⁹ However, the biomedical consequences of risk compensation could fall under this category, if the FDA identifies these as either adverse events caused by the drug (through risk compensation) or “potential safety hazards.” The label’s description of monitoring requirements or special care precautions could also include the need to ask patients about their continuing risk behaviors during drug use.

Finally the “Patient Counseling Information” may be the most important and appropriate place to address hazardous and uninformed risk compensation effects. The FDA specifies that this section must “contain information necessary for patients to use the drug safely and effectively,” as well as reprint the full text of “[a]ny FDA-approved patient labeling.”²³⁰ This is a natural place for a manufacturer to advise intermediaries to counsel patients about risk compensation behavior and its potentially hazardous effects, and the FDA should require language to this effect.

The recent labels approved for Truvada as PrEP have already incorporated warnings aiming to ensure that PrEP should be “only part of a comprehensive prevention strategy . . . and that other preventive measures should also be used.”²³¹ In the “Indication and Prescribing Considerations” section, the label states that the provider must “only prescribe TRUVADA as part of a comprehensive prevention strategy.”²³² In “Warnings and Precautions,” the label further emphasizes that “Truvada . . . should be used only as part of a comprehensive prevention strategy that includes other prevention measures, such as safer sex practices. . . . Counsel uninfected individuals at high risk about safer sex practices, including: Using condoms consistently and correctly. . . .”²³³ Although these statements do not specifically warn that patients using

228. *Id.* § 201.57(c)(6)(i)-(ii).

229. *Id.* § 201.57(c)(7) (defining an adverse reaction as “an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence . . . for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event”).

230. *Id.* § 201.57(c)(18).

231. Gilead Sciences, Inc., Risk Evaluation and Mitigation Strategy 1, July 16, 2012, available at <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM312304.pdf>.

232. Important Safety Information About TRUVADA for a Pre-exposure Prophylaxis (PrEP) Indication, in Gilead Sciences, *supra* note 231, at *21.

233. *Id.* at *22.

PrEP may take more behavioral risks, they do suggest that counseling to avoid this possibility is warranted.

2. Labels Designed for Patients

FDA regulations also require manufacturers to warn patients directly of risks in a Medication Guide when “it is necessary to patients’ safe and effective use of drug products.”²³⁴ The FDA makes this determination on a case-by-case basis in writing,²³⁵ but regulations note that the FDA will require a Guide under the following conditions:

(1) The drug product is one for which patient labeling could help prevent serious adverse effects . . . (2) The drug product is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients’ decision to use, or to continue to use, the product . . . [and] (3) The drug product is important to health and patient adherence to directions for use is crucial to the drug’s effectiveness.²³⁶

Where risk compensation behavior is observed in pre-approval or post-approval studies, the FDA should require that any adverse effects and instructions to avoid risk compensation be included in a Medication Guide.

Like warnings for intermediaries, Medication Guides for patients must also provide warnings under specified headings. The most relevant headings for this discussion are “What is the most important information I should know about (name of drug)?”,²³⁷ “How should I take (name of drug)?”,²³⁸ and “What should I avoid while taking (name of drug)?”²³⁹ Under “What is the most important information,” a Guide must state “the particular serious and significant public health concern that has created the need for the Medication Guide,” along with “what the patient should do or consider because of that concern, such as, weighing particular risks against the benefits of the drug, avoiding particular behaviors (e.g., activities, drugs) . . . or engaging in particular behaviors.”²⁴⁰ Where risk compensation has been observed, a Medication Guide should highlight this risk, counsel patients to take note of the adverse effects attributable to behavior change, advise patients to avoid taking more risks, and encourage patients to engage in safer behaviors.

234. 21 C.F.R. § 208.1(b) (2011). A Medication Guide is an FDA-approved written label intended to inform patients directly about drugs that pose “a serious and significant public health concern.” *Id.* § 208.1(a). These Guides are generally intended for drugs used in outpatient settings. *Id.*

235. *See id.* § 208.1(b).

236. *Id.* § 208.1(c)(1)-(3).

237. *Id.* § 208.20(b)(2).

238. *Id.* § 208.20(b)(5).

239. *Id.* § 208.20(b)(6). Because most consumers likely associate “side effects” with pharmacological rather than behavioral mechanisms, this discussion omits the heading “What are the possible or reasonably likely side effects of (name of drug)?” *Id.* § 208.20(b)(7).

240. *Id.* § 208.20(b)(2).

In the “How should I take (name of drug)?” section, the FDA requires “a statement describing any special instructions on how to administer the drug product, if they are important to the drug’s safety or effectiveness.”²⁴¹ This is another natural place to warn of hazardous and uninformed risk compensation effects, as avoiding risk compensation will enable users to maximize the effectiveness of the drug.

Finally, labeling may do most to encourage users to avoid risk compensation behaviors under the heading “What should I avoid while taking (name of drug)?”, which includes “statements of specific, important precautions patients should take to ensure proper use of the drug, including . . . [a] statement that identifies activities . . . that patients should avoid when using the medication.”²⁴² This would be a natural place for the FDA to require a short statement instructing patients to avoid taking more behavioral risks as a consequence of product use.

Again, FDA-approved labeling of Truvada as PrEP is instructive. In the Medication Guide for patients, the manufacturer warns that “Just taking TRUVADA may not keep you from getting HIV . . . You must still practice safer sex at all times. Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom . . . You must also use other prevention methods to keep from getting HIV.”²⁴³ This is reiterated in the package insert, which alerts users to “still practice safer sex at all times” and “use other methods to keep from getting HIV-1.”²⁴⁴ This labeling does not specifically state the possibility of increases in risk behavior among PrEP users, but it does seek to minimize risk compensation effects.

3. Severity of Risk Compensation Should Influence Labeling

The severity of hazardous risk compensation effects as observed in clinical studies should factor into FDA decisions about the placement and strength of warnings. Risk compensation effects may not always be sufficiently serious to merit warning prescribers and users. The placement of information about risk compensation in a drug label should depend on the extent and severity of the effects that are empirically documented in clinical research. One scholar has described ways in which the FDA classifies risks for prescription drugs into different labeling categories: “Contraindications” include risks that “clearly outweigh any possible benefit;” “Rare adverse reactions” include “non-serious side effects that occur with a frequency of less than one in a thousand;” and “Warnings” include “risks that are more serious than adverse reactions but are not so serious as to clearly outweigh possible benefits of a

241. *Id.* § 208.20(b)(5)(ii).

242. *Id.* § 208.20(b)(6).

243. Gilead Sciences, *supra* note 231, at *40.

244. *Id.* at *28.

drug.”²⁴⁵ Beyond this scheme, FDA-required boxed warnings also indicate “certain contraindications or serious warnings, particularly those that may lead to death or serious injury.”²⁴⁶ Following this guidance, only uninformed overcompensation appears serious enough to be listed immediately as a Contraindication, and it may not be sufficiently serious to qualify for a boxed warning. The FDA should consider on a case-by-case basis whether other forms of risk compensation pose a sufficiently serious threat to merit warnings in other sections.

In their current form, admittedly, Medication Guides are far from a perfect solution for influencing users’ behaviors. Analyses of FDA-approved Guides have consistently identified limitations on their effectiveness. For example, several studies have found that Medication Guides have a relatively high mean reading level of 10-12th grade, and further analyses have found that most are unsuitable for use with adults of low literacy.²⁴⁷ Studies assessing patient comprehension and memory of Guide information are likewise disappointing; a recent study examined comprehension among adults of varying literacy levels, finding limited comprehension in every subgroup.²⁴⁸ These limitations, however, may indicate failures in the creation of Guides that are appealing and informative, rather than a failure of the strategy itself; one recent study found that exposure to a Guide may indeed contribute to knowledge about medication risks and usage.²⁴⁹ Additional research is necessary to understand how to craft Medication Guides of maximal efficacy.

B. REMS Plans

Before the Food and Drug Administration Amendments Act (FDAAA) took effect in 2008, manufacturers of products that posed risks to some classes of patients entered voluntary agreements with the FDA to implement risk management plans (RiskMAPs).²⁵⁰ These efforts to modify user behavior and

245. Lars Noah, *The Imperative To Warn: Disentangling the “Right To Know” from the “Need To Know” About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 327-28 (1994).

246. 21 C.F.R. § 501.57(c)(1) (2012).

247. Michael S. Wolf et al., *A Critical Review of FDA-Approved Medication Guides*, 62 PATIENT EDUC. & COUNSELING 316 (2006) (identifying problems with the reading level and scope of 40 currently-approved Medication Guides); Michael S. Wolf et al., *Usability of FDA-Approved Medication Guides*, 27 J. GEN. INTERNAL MED. 1714 (2012) (analyzing 185 Medication Guides to show that they fall below acceptable standards of accessibility); see also William S. Shrank & Jerry Avon, *Educating Patients About Their Medications: The Potential and Limitations of Written Drug Information*, 26 HEALTH AFF. 731 (2007) (reviewing research on the deficiencies of written drug information).

248. Wolf, *Usability*, supra note 247.

249. Louis A. Morris, Morris S. Whitcup & Keith LaMattina, *Failure To Communicate: Medication Guide or Memory?* 45 DRUG INFO. J. 775 (2001) (finding that knowledge of nonsteroidal anti-inflammatory drug risks was best among participants who had just read the Medication Guide and worst among participants with no exposure to the Guide).

250. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(b), 121 Stat. 823, 926 (2007); 21 U.S.C. § 355-1 (2007); see also Jennifer L. Bragg & Maya P. Florence,

limit product access included warnings to intermediaries, restricting the channel of distribution, limiting refills, limiting prescribing authority to physicians with certain qualifications, or requiring mandatory educational programs for physicians and patients.²⁵¹ Since 2008, the FDAAA has provided the agency with authority to *require* that any drug manufacturer present a Risk Evaluation and Mitigation Strategy (REMS) as part of the drug approval process. In addition, the FDA may also mandate that manufacturers revise REMS plans as needed after approval to ensure that drug benefits outweigh drug risks.²⁵² When a REMS exists, sales of the drug are prohibited without compliance with the REMS.²⁵³ As of January 2013, the FDA website listed active REMS approved for 72 individual drugs and 4 categories of drugs; an additional 132 drugs had been released from a REMS.²⁵⁴ REMS requirements can also include mandatory efforts to influence user behavior, primarily through requiring manufacturers to provide additional information and training about drug risks. Through a REMS, the FDA can require manufacturers to take actions such as disseminating revised Medication Guides and package inserts, sending letters to health care providers, publicizing the REMS to health care providers, disseminating information about serious drug risks through health care professional societies, and training health care providers.²⁵⁵ The FDA can also require certification of pharmacies distributing the drugs, as well as patient monitoring and registration.²⁵⁶ The FDA requires manufacturers to submit assessments of the REMS at specified time periods to evaluate whether the strategy meets its stated goals, and to allow opportunity for modification.²⁵⁷

Life with a REMS: Challenges and Opportunities, 13 J. HEALTH CARE L. & POL'Y 269, 269 (2010) (describing the difference between voluntary RiskMAPs and mandatory REMS).

251. See Gilhooley, *supra* note 275, at 938-45.

252. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(b), 121 Stat. 823, 926 (2007) (codified at 21 U.S.C. § 355-1(g)). The Secretary may impose a REMS requirement based on factors including the size of the population likely to use the drug, the seriousness of the disease to be treated, the expected benefits of the drug, and the seriousness of any known or potential adverse events that may be related to the drug. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(b), 121 Stat. 823, 926 (2007). "New safety information" that can prompt a review and revision of a REMS can include adverse event reports and postapproval studies. *Id.* 121 Stat. at 926-27.

253. 21 U.S.C. § 355(p)(1). See also David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-To-Warn Claims*, 96 GEO. L.J. 461, 491 n.144 (2008) ("The goal of the REMS is to detect serious risks with drugs as quickly as possible and to permit the FDA to respond with appropriate measures, including, when necessary, withdrawal of approval.").

254. See FDA, *Approved Risk Evaluation and Mitigation Strategies*, <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm> (last visited Jan. 21, 2013).

255. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(b), 121 Stat. 823, 929-32 (2007).

256. *Id.*

257. 21 U.S.C. § 355-1(d) (denoting timetable for assessments); 21 U.S.C. § 355-1 (g)-(h) (describing procedures for assessments and modifications).

When a manufacturer does not follow a REMS, the FDA may impose penalties including civil sanctions, seizure of the drug, and the withdrawal of approval.²⁵⁸

Where hazardous risk compensation effects are observed and deemed to be sufficiently serious, the FDA should address these effects through REMS requirements. Of particular interest in these plans may be the training of health care providers to provide behavioral counseling and monitoring of behavioral risk-taking, as well as certification of pharmacies to reinforce these warnings at the time of prescription. Patients could be registered and regularly surveyed about their behaviors, which may not only increase information about risk compensation effects, but also serve as an intervention to remind users about their behavioral risks.²⁵⁹ The combination of REMS elements for a given drug will depend on the context and behaviors, but the REMS provides multiple options for intervention.

Under the REMS for Truvada as PrEP, the manufacturer must address risk compensation behavior in several ways.²⁶⁰ These include providing an online training course for prescribers, disseminating information and safety fact sheets to professional organizations, publishing safety information in pre-specified clinical journals targeting prescribers, sending providers a “Dear Healthcare Provider (DHCP) letter” with the Prescribing Information and Medication Guide, providing materials for prescribers to use in educating patients, providing an Agreement Form for prescribers and patients to sign before and during PrEP use (which confirms that the patient understands that Truvada must be part of “a complete prevention strategy” that includes “always practicing safer sex by using condoms correctly”²⁶¹), providing prescribers with a checklist for counseling patients, and posting all provider information and training materials online as a Program Kit available at least 3 years after approval. These strategies provide an example of the options for addressing risk compensation effects through REMS requirements, and suggest that the FDA would be open to addressing these risks for other types of medications.

258. See Bragg & Florence, *supra* note 250, at 270 (“[A] manufacturer’s failure to comply with a requirement of an approved REMS may subject a responsible person to criminal sanctions as well as significant civil monetary penalties.”); Barbara J. Evans, *Seven Pillars of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era*, 85 NOTRE DAME L. REV. 419, 521-22 (2010) (“The drug can be deemed misbranded, which allows FDA to pursue various sanctions against the manufacturer including seizure of the drug.”); Cory Fox, *Resisting Antibiotic Resistance: Legal Strategies To Maintain Man’s Dominion over Microbes*, 12 HOUS. J. HEALTH L. & POL’Y 35, 58 (2011) (“The FDA may also use a REMS restriction to . . . withdraw the approval of existing drugs.”).

259. One helpful strategy may be “motivational interviewing,” in which an interviewer encourages risk-reduction behaviors by identifying and resolving patients’ ambivalence about behavioral changes. See Eileen Britt, Stephen M. Hudson & Neville M. Blampied, *Motivational Interviewing and Health Settings: A Review*, 53 PATIENT EDUC. & COUNSELING 147, 147 (2004).

260. Gilead Sciences, *supra* note 231, at 2-6.

261. *Id.* at 61.

C. *Overwarning and Public Policy Concerns*

This Article's proposal to impose labeling requirements for risk compensation effects has weaknesses. Overwarning is a concern for prescription drugs for a number of reasons described above—for instance, the concern that too many warnings will deter the use of helpful products, cause consumers to disregard important risks,²⁶² subject consumers to unreasonable fears of harm,²⁶³ and lead to reduced use of beneficial drugs. Concerns about overwarning have encouraged the FDA to reject certain categories of warning information, such as warnings for off-label uses.²⁶⁴ These criticisms are well-founded, and the hazards of overwarning are legitimate.²⁶⁵ Required warnings also impose costs on manufacturers (which may be passed on to consumers and healthcare payers).

In addition to the concern of overwarning, there may be some worry that locating the duty to warn exclusively with manufacturers may chill the development of other interventions to address risk compensation behavior, such as counseling. For instance, if products that may give rise to risk compensation are equipped with labels discussing this risk, there may be less motivation for providers, clinical staff, pharmacists, and health educators to develop strategies to encourage healthier behaviors among drug consumers. Because these other strategies may be better tailored to individual behaviors or local risk factors, replacing these efforts with general product warnings may paradoxically undermine opportunities to address risk compensation effects more effectively.

Another fear of requiring warnings for risk compensation behavior is that warnings will exacerbate opposition to making drugs more accessible, regardless of whether this opposition is grounded in evidence for a particular group of patients. The HPV vaccine is an example of an intervention that has sparked widespread resistance due to fears of risk compensation behavior. Parents have reported concern that adolescent girls who receive the HPV

262. Noah, *supra* note 245.

263. See, e.g., David G. Owen, *Dangers in Prescription Drugs: Filling a Private Law Gap in the Healthcare Debate*, 42 CONN. L. REV. 733 (2010) (suggesting that manufacturers' duties to warn consumers of the risks of birth control pills had contributed to unreasonable fears of pill use).

264. See Lars Noah, *Platitudes About 'Product Stewardship' in Torts: Continuing Drug Research and Education*, 15 MICH. TELECOMM. & TECH. L. REV. 359, 370-71 & nn.46-51 (2009). Professor Lars Noah has argued that the FDA "would never tolerate" some of the information that other scholars have recommended as additions to warning labels. *Id.* at 370.

265. See *id.* at 376 & n.71 (citing scholarship and court cases critical of overwarning); William Funk, *Judicial Deference and Regulatory Preemption by Federal Agencies*, 84 TUL. L. REV. 1233, 1250 (noting that overwarning "could result in the warnings losing their significance . . . [or] in patients being dissuaded from taking the drugs when it would be in their best interest to take them"); Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 DUKE L.J. 1123, 1191 (2011) ("Overwarning about every imaginable risk may drive doctors and patients to overlook truly significant precautionary information, deter doctors from prescribing worthwhile drugs, or scare patients out of taking drugs that would benefit them. These risks are real.").

vaccine will engage in more sexual activity,²⁶⁶ and some adolescents have reported similar concerns about hypothetical vaccines for HIV.²⁶⁷ The evidence regarding whether warnings in fact do shape consumer behavior is mixed.²⁶⁸ Wilde points out that warnings must be mindful of reactance—the possibility that overwarning may in fact stimulate riskier behaviors if it is perceived to be coercive.²⁶⁹ Warning may also stimulate riskier behavior among people with a high preference for risk (e.g., sensation-seeking behavior); however, this group may be less interested in using safety measures altogether.²⁷⁰ If warnings fail to change behavior, but instead succeed in providing ammunition to groups seeking to prevent access to users who would otherwise benefit, they may do more harm than good.

These concerns do not seem fatal to the overall project of acknowledging risk compensation behavior in the testing, labeling, and marketing of prescription drugs. Although the FDA should judge the risks of overwarning on a case-by-case basis for each product, few consumers are likely to be deterred from product use due to the fear that they will be unable to control their own behavior. Warnings do impose costs on manufacturers, but these may be less than the possible costs of warning defect litigation if warnings are not provided—particularly when risk compensation effects have been noted in the scientific literature or in product trials. Moreover, if warnings lead users to avoid increased risk-taking, they will help to maximize product effectiveness, which can appeal to healthcare payers. Even if warnings are too blunt a tool to reduce risk compensation behavior, they would be a first step in addressing the behavioral effects that undermine the efficacy of health and safety interventions.

It is unknown whether FDA-required warnings would supplant other strategies to influence users' risk-taking. If drug labels bear warnings about risk compensation behavior, will they deter prescribers from counseling patients directly about their risk-taking? In the absence of empirical evidence, this fear seems ill-founded. Instead, warnings can alert prescribers that risk compensation is possible, and validate concerns among providers who had already considered risk compensation effects. By bringing risk compensation to providers' attention, the warnings may instead encourage *more* behavioral counseling at the time of prescription, and more development of interventions that reduce risk-taking. If warnings exacerbate calls to restrict product access,

266. See, e.g., Loretta Brabin et al., *Future Acceptance of Adolescent Human Papillomavirus Vaccination: A Survey of Parental Attitudes*, 24 VACCINE 3087, 3092 (2006); Kahan et al., *supra* note 47; Marlow et al., *supra* note 52.

267. Patrick M. Webb et al., *HIV Immunization: Acceptability and Anticipated Effects on Sexual Behavior Among Adolescents*, 25 J. ADOLESCENT HEALTH 320 (1999).

268. Jennifer J. Argo & Kelley J. Main, *Meta-Analyses of the Effectiveness of Warning Labels*, 23 J. PUB. POL'Y & MARKETING 193 (2004).

269. See WILDE, *supra* note 21, at 199-202.

270. See, e.g., *id.* at 201-02.

this could be a detrimental public policy outcome. But this Article has only suggested that warnings are appropriate *when risk compensation behavior is actually observed* in empirical studies, which will limit warnings in cases where disclosure does more harm than good.

V. Limiting Prescription Drug Availability: FDA Approval and Access Restrictions

New drugs must receive FDA approval before sale in interstate commerce.²⁷¹ One of the FDA's primary roles is "to help ensure that only drugs that, on balance, are beneficial to some class of patients ever reach the healthcare market."²⁷² Because prescription drugs pose both greater benefits and greater risks to life and health than other product categories, the FDA's regulatory power exceeds that of other agencies designed to regulate consumer products.²⁷³ The FDA's determination of drug safety is based on the three phases of evidence collection discussed above.²⁷⁴ Drawing on this evidence, the Secretary may deny drug approval of a new drug if testing is not "adequate by all methods reasonably applicable to show whether or not such drug is safe for use" or if it discloses that the drug is actually unsafe.²⁷⁵ The Secretary may also withdraw approval of an existing drug if postmarketing data show that the drug is unsafe for use or if there is "a lack of substantial evidence that the drug will have the effect it purports or is represented to have."²⁷⁶

271. See Federal Food, Drug, and Cosmetic Act, Pub. L. No. 717, § 505(a), 52 Stat. 1040, 1052 (1938) (codified as amended at 21 U.S.C. § 355(a)); see also Katrice Bridges Copeland, *Enforcing Integrity*, 87 IND. L.J. 1033, 1039 (2012) ("The Federal Food Drug and Cosmetic Act (FDCA) and the FDA's implementing regulations generally prohibit manufacturers of new drugs from distributing products in interstate commerce for any "intended use" that the FDA has not approved as safe and effective or, in the case of generic drugs, cleared through a substantial equivalence determination.")

272. Owen, *supra* note 263, at 741.

273. *Id.*; see also OWEN, *supra* note 219, at 568 ("All prescription drugs . . . possess substantial costs as well as benefits. This is because most drug hazards are inherent and unavoidable.")

274. See *supra* Subsection I.B.1; 21 U.S.C. § 355(b) (requiring as part of a new drug application "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use"); 21 C.F.R. § 314.105 (2011) ("FDA will approve an application after it determines that the drug meets the statutory standards for safety and effectiveness . . ."); *id.* § 314.50(d)(5) (listing the clinical data that must be included in a new drug application). The information required in a new drug application does not include any language specifically requesting data on the behavior of research participants. Without changes to this language, behavioral data could still be sought under the general provision of "any other data or information relevant to the evaluation of the safety and effectiveness of the drug product," or under the category of drug "abuse" ("a description and analysis of studies or information related to abuse of the drug"). See 21 C.F.R. §§ 314.50(d)(5)(iv), 314.50(d)(5)(vii).

275. 21 U.S.C. § 355(d). For a summary of FDA approval processes, see also Margaret Gilhooly, *When Drugs Are Safe for Some But Not Others: The FDA Experience and Alternatives for Products Liability*, 36 HOUS. L. REV. 927, 938-39 (1999) (providing a brief overview of FDA approval and labeling).

276. 21 U.S.C. § 355(e). Another means of limiting access to health and safety products after approval is through products liability litigation, specifically through claiming that a product is defective in design. A judicial finding that a product contains a design defect will ordinarily result in eliminating the entire product line and ending consumer access. OWEN, *supra* note 219, at 499. Generally, courts do

Evidence of risk compensation effects can inform FDA decisions about whether and how a drug should be available to consumers. When evidence of risk compensation is used in legal decisions about drug availability, however, it is crucial to weigh the value of drug access against the type and extent of hazardous risk compensation effects. This Part will consider approval and access restrictions under three conditions: when perfectly informed or uninformed partial risk compensation is observed, when hazardous risk compensation is observed, and when hazardous risk compensation is observed and cannot be reduced through mechanisms such as labeling and provider education or restricted access.

A. When Perfectly Informed or Uninformed Partial Risk Compensation Is Observed

Risk compensation effects alone should not prompt FDA rejection or withdrawal of a drug if these behaviors do not create hazards—that is, when users and third parties do not experience an increased risk of harm relative to baseline. As described above, risk compensation behavior should be presumed rational, even if it completely offsets a drug's benefits, because it can result in a net benefit for the users of pharmaceutical products.²⁷⁷ Although this type of offsetting behavior poses a problem for healthcare payers in the form of reduced cost-effectiveness, cost-effectiveness is not a consideration in FDA approval.²⁷⁸ This is not to say that the FDA should do nothing about perfectly informed or uninformed partial risk compensation effects—efforts to diminish risk compensation, such as warnings to educate intermediaries and users, may yet be helpful. As noted, where risk compensation is observed in clinical studies before drug approval, the FDA could qualify drug approval by requesting a postmarketing study to monitor for future hazardous effects.²⁷⁹ But where it does not create harms relative to baseline, risk compensation behavior should not be the basis for refusing drug approval.

not rule on the merits of design defect claims for prescription drugs, and a claim of design defect based on risk compensation effects may be unlikely to succeed. *See id.* at 37.

277. *See* Section II.A. In the case of perfect offsetting behavior, however, the FDA may determine that the drug's benefits (permitting increased risk-taking) do not outweigh the risks of side effects.

278. *See* Asha S. Geire, *Price Wars and Patent Law: Reducing the Cost of Health Care Through Medical Device Price Transparency*, 12 TUL. J. TECH. & INTELL. PROP. 239, 255 (2009) ("In fact, it is said that if a device company sought approval for a \$1 million 'gold-plated billiard stent' that functions as it should, the FDA must approve it even if a \$127 version of the same stent is already available in the market.") (citing Richard A. Deyo, *Gaps, Tensions, and Conflicts in the FDA Approval Process: Implications for Clinical Practice*, 17 J. AM. BOARD FAM. PRAC. 142 (2004)).

279. *See* 21 U.S.C. § 355(o).

B. When Hazardous Risk Compensation Is Observed

Where hazardous risk compensation effects are observed, either before or after drug approval, decisions about approval will be more complex. As before, hazardous risk compensation consists of uninformed overcompensation and any risk compensation that results in externalized harms. Because users' risk perceptions and motivations to engage in risk behavior will vary, *some* users will likely not engage in hazardous behavior. These users would derive benefit from the drug without harming others. However, others might engage in hazardous behavior—and at the extreme, the drug may cause net harm at the population level. When hazardous risk compensation effects are detected, or even suggested, during premarketing testing, the FDA should not bar approval outright. Instead, the agency should consider requiring additional studies to identify individual and contextual factors associated with risk compensation effects, potential strategies to predict and modify risk compensation behavior among users, and the efficacy of warnings designed to minimize hazardous behavior. With this information, the FDA should first respond by requiring revisions to warnings for prescribers and consumers (where applicable), and evaluate the effects of these mitigation strategies. Where warning and counseling patients reduces hazards, the FDA should not restrict product access, but rather should continue to enforce product labeling, provider education, and other elements of the REMS. This maximizes the availability of beneficial drugs, which is a central goal of the FDA approval process.

If hazardous risk compensation persists among users after warnings and other REMS provisions are added, the FDA response should depend on the type of harm, the extent of harm, and distribution of harm among users and nonusers. One option for an FDA response may be to limit drug access rather than to withdraw the drug from the marketplace. This approach would avoid penalizing consumers who do not engage in hazardous behavior. For this purpose, hazardous risk compensation behaviors may be considered similar to drug misuse or abuse—other uses contrary to product labeling. A drug's potential for abuse may factor into drug approval decisions,²⁸⁰ but rather than taking the restrictive step of withdrawing approval, the FDA may instead use its authority to restrict approval and drug access to only the class of patients who will benefit.²⁸¹ Elements of a REMS can include strategies designed to limit product access, such as informing health providers which types of patients should receive drugs, imposing controls to assure training of health care providers, certifying pharmacies, narrowing the class of patients who may

280. See 1 Food and Drug Administration § 13:75 (2010) (noting the FDA's definition of "safety" for over-the-counter drugs: "Safety means a low incidence of adverse reactions or significant side effects under adequate directions of use and warnings against unsafe use as well as low potential for harm which may result from abuse under conditions of widespread availability.").

281. See, e.g., Gilhooly, *supra* note 275, at 938-45 (discussing FDA actions to reduce the likelihood that physicians will prescribe drugs to patients likely to experience harm).

receive the drugs and the settings in which they receive them, and monitoring and registering patients.²⁸² In the risk compensation context, it is highly problematic to presume that we can predict *ex ante* which patients (or classes of patients) are likely to adjust their risk behaviors in response to a prescription drug. Existing data are sparse, and even a predictive model with high accuracy would run the risk of misidentifying patients who would *not* have increased their risk-taking. Instead, it may be more appropriate to rely on physicians to periodically assess users' behaviors after prescribing beneficial drugs, and to consider whether a drug is still clinically indicated for a user who reports large increases in risk behavior that are not responsive to counseling.²⁸³

An FDA decision to limit product access would not be without problems. Selectively restricting drug access to a subset of patients based on predictions of behavior is problematic due to problems detecting risk compensation in individual users,²⁸⁴ as well as concerns about fairness and abuses of discretion in limiting access. All patients who take the drug may well receive a pharmacological benefit—the drug could “work” for everyone, despite whether some patients reverse those effects by overcompensating. Even if FDA decisions could be tailored to approve drugs for only some patients, these drugs could still be prescribed off-label to others.²⁸⁵ Finally, denying drugs to a subset of patients implies that they will always behave hazardously, neglecting the extent to which risk perception, motivations, and behaviors may change over time. These factors should be part of FDA decisions on selective approval due to hazardous risk compensation effects.

C. *When Hazardous Risk Compensation Cannot Be Reduced*

At the extreme, it may be impossible to reduce hazardous risk compensation effects through warning and REMS plans, and in the most exceptional circumstances, population-level data may suggest that a drug's risk compensation hazards outweigh its benefits. This scenario would be truly extraordinary, and it would require a heavy burden of proof to show that a drug causes net harm in real-world settings. To provoke withdrawal of the drug from the marketplace in this extreme case, the population-level harms posed by risk compensation behavior must be so severe as to pose an “imminent hazard to

282. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(b), 121 Stat. 823, 929-32 (2007) (codified as amended at 21 U.S.C. § 355-1).

283. This strategy is still limited because it relies on accurate self-reporting of behaviors by users. It also raises the question of whether patients are increasing their risk behavior due to risk compensation or another circumstance, such as a change in the underlying target risk level. Furthermore, it will require judgment (which is vulnerable to discrimination), including judgment regarding participants who exhibited risk compensation once, but now want to resume taking the drugs.

284. See discussion *supra* Subsection II.D.3.

285. Off-label prescription is legal in the US, and Noah has noted empirical evidence to show “that package inserts often fail to ensure rational prescribing.” Noah, *supra* note 264, at 385 (2009).

public health.”²⁸⁶ If the evidence on hazardous compensation supports this finding (which is unlikely), the Secretary may reject or withdraw approval of a drug entirely,²⁸⁷ even though recalling an approved drug from the market is both difficult and rare.²⁸⁸ A withdrawal of drug approval on this basis would be a major shift in FDA policy, given that uses contrary to label warnings are generally not part of safety considerations for drugs that are not also classified as controlled substances.²⁸⁹ These drugs would remain safe for use as labeled, but unsafe for users who do not follow the warnings to avoid increased risk-taking. In order for the FDA to evaluate drug approval on the basis of uses that contravene product warnings, the agency would bear the burden of demonstrating “a reasonable possibility of misuse,” as decided in a 1978 administrative ruling.²⁹⁰ The FDA would therefore need to demonstrate the extent and severity of harm posed by hazardous risk compensation behavior. The procedure for withdrawing approval would be complex, including due notice and an opportunity for a hearing.²⁹¹

One scholar has also pointed out that the FDA’s power to withdraw a product or control its distribution out of a concern for drug abuse, or other user behaviors, may be challenged by *American Pharmaceutical Ass’n v. Mathews*.²⁹² This D.C. Circuit decision concerned the FDA’s regulation of methadone, which was also a controlled substance under the authority of the Justice Department. In light of evidence documenting methadone abuse, the FDA sought to restrict the distribution of methadone to specified outlets, thereby barring most “community pharmacies” from drug distribution.²⁹³ The lower court found, and the D.C. Circuit agreed, that while the FDA has “primary responsibility” for initial drug approval, drugs that are controlled substances are subsequently under the jurisdiction of the Justice Department; the FDA lacked authority to restrict drug distribution out of concern for

286. 21 U.S.C. § 355(e).

287. *Id.* § 355(e); see also Gilhooley, *supra* note 275, at 940 (citing Legal Status of Approved Labeling for Prescription Drugs, 37 Fed. Reg. 16,503, 16,504 (Aug. 15, 1972) (specifying conditions under which the FDA may take this action)).

288. See Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 IND. L.J. 623, 668-69 (2007). Legislative proposals have suggested expanding the FDA’s recall authority. See Berman, *supra* note 208, at 67-68 (describing draft legislation proposed in 2010).

289. 1 Food and Drug Administration § 13:75 (2010).

290. See 1 Food and Drug Administration § 13:75 (2010) (citing Initial Decision, Benylin Expectorant, Docket 76N-0483, slip op at *8 (FDA 1978) (“Consideration of safety evidence relating to uses of a drug outside of the label requirements necessitates a showing that there is a reasonable probability that such non-label indicated uses can be expected to occur.”)).

291. See 21 U.S.C. § 355(e).

292. Gilhooley, *supra* note 275, at 941-42 (citing *Am. Pharmaceutical Ass’n v. Mathews*, 530 F.2d 1054 (D.C. Cir. 1976) (upholding *Am. Pharmaceutical Ass’n v. Weinberger*, 377 F. Supp. 824 (D.D.C. 1974))).

293. *Am. Pharmaceutical Ass’n v. Weinberger*, 377 F. Supp. 824, 825 (D.D.C. 1974). The *Mathews* court affirmed on the basis of the *Weinberger* opinion. *Am. Pharmaceutical Ass’n v. Mathews*, 530 F.2d 1054, 1054 (1976).

abuse.²⁹⁴ A subsequent case has interpreted *Mathews* to signify that the FDA may only impose limitations based on a drug's "inherent safety . . . only when used for its intended purposes."²⁹⁵ Under the Federal Food Drug and Cosmetic Act, "safety" explicitly denotes "safe[ty] . . . under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."²⁹⁶ It is important to acknowledge that FDA regulations do not specify precisely what "safety" entails; the Supreme Court, however, has stated that "safety" requires only that "the expected therapeutic gain justifies the risk entailed by its use," making a drug "unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit."²⁹⁷

Given these precedents, *Mathews* and subsequent rulings seem unlikely to impede FDA regulation of drugs for which risk compensation is pervasive, harmful, and unresponsive to other means of risk reduction. The drugs for which risk compensation behavior is relevant, including the examples discussed in this Article, are not controlled substances under the purview of another administrative body. It is a murkier point to argue that risk compensation influences a drug's "inherent" safety, but the phenomenon does indeed assume that the drug is being used for its "intended purposes"—a user has selected the drug for its potential to reduce risks, then subsequently divided the benefit among risk-reduction and other priorities. But it may be most persuasive to note that risk compensation behavior affects the balance between "therapeutic gain" and "the risk entailed by its use," the precise calibration that, according to the Supreme Court, determines whether a drug is "safe" for FDA purposes. On this analysis, risk compensation that tips the balance from net benefit to harm, and that cannot be limited through user education or other less intrusive means, seems likely to fall within the purview of the FDA for a determination of drug safety.

Risk compensation effects that pose so severe a danger as to be "imminent[ly] hazardous to public health" are highly unlikely, and FDA withdrawals of approval on this basis would face tremendous opposition. The alternative responses discussed above—warnings, REMS provisions, and less restrictive limitations on access—preserve maximal freedom for users who

294. *Am. Pharmaceutical Ass'n v. Weinberger*, 377 F. Supp. 824, at 830.

295. *Ass'n Am. Physicians & Surgeons, Inc., v. U.S. Food & Drug Admin.*, 226 F. Supp. 2d 204, 217 (D.D.C. 2002) (emphasis added) (citing *Am. Pharmaceutical Ass'n v. Weinberger*, 377 F. Supp. 824, 829 (D.D.C. 1974)) (finding that the FDA exceeded its authority by adopting the Pediatric Rule, which required manufacturers to test drugs for pediatric patients and suggest pediatric doses, even where drugs were solely intended for adult use).

296. 21 U.S.C. § 355(d); *see also Ass'n Am. Physicians & Surgeons*, 226 F. Supp. 2d, at 216-17.

297. *U.S. v. Rutherford*, 442 U.S. 544, 555-56 (1979); *see also Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 121 (2000) ("[A]ny product regulated by the FDA that remains on the market must be safe and effective for its intended use That is, the potential for inflicting death or physical injury must be offset by the possibility of therapeutic benefit.").

would receive a net benefit from drugs, while minimizing internalized and externalized harms.

VI. Conclusion

This Article has argued that risk compensation behavior—increased behavioral risk-taking based on the expectation that one is protected from harm—is a measurable, presumptively rational, and potentially value-maximizing response to the use of health and safety products. But despite the benefits that individuals may gain from increases in risky behavior, risk compensation behaviors may undermine the effectiveness of health and safety interventions. At the extreme, behavioral adjustments can fully offset the beneficial effects of health and safety products, undermine individual preferences (uninformed partial risk compensation), expose the users of such products to harm when they miscalculate (uninformed overcompensation), or expose third parties to harm (externally hazardous risk compensation). Although risk compensation behavior and its conceptual cognates have received some attention in legal scholarship, the mechanism and adverse consequences of risk compensation have received very little attention in FDA regulation of prescription drugs.

This Article has attempted to remedy this neglect, noting that FDA law provides useful tools to incentivize research into risk compensation effects, to acknowledge risk compensation as a potential effect of drug use, and to attempt to influence users' behaviors to obtain the maximum benefit from prescription drugs. The FDA-required labeling and REMS requirements for Truvada as PrEP may indicate that the agency is already concerned about risk compensation effects, and the Truvada experience may provide lessons for a more systematic approach to addressing user behaviors. The FDAAA has expanded the authority of the FDA to require manufacturer-led postmarketing studies and risk-reduction plans, and there is a firm public health justification to use this authority to both investigate and address risk compensation effects. Future work is needed in this field, including scholarship assessing ways to improve the effectiveness of consumer warnings; clarifying the duties of providers and intermediaries; exploring ways to encourage the development of other types of risk-reduction strategies; and investigating the applicability of risk compensation concepts in other areas of consumer protection, including medical devices, safety technologies, direct regulation of risk behavior, and financial products. This Article, however, has made a start in addressing risk compensation effects in the prescription drug market. As we learn more about risk perception and the context of individual health behaviors, legal reasoning that incorporates these insights can play a key part in improving public health.

