Setting Policies for Consumer Communications: A Behavioral Decision Research Approach

Sara L. Eggers and Baruch Fischhoff

The authors offer a framework rooted in behavioral decision research for the evaluation and regulation of communications. The approach considers consumer interpretations of product communications, the sensitivity of choice to such judgments, and the acceptability of misunderstanding to regulators.

Producers often communicate with consumers through labels and other forms of advertising. If the content is accurate and understood, such communications can help consumers make choices in their own best interest. If it is not, consumers may use inappropriate products or miss beneficial ones. Consumer protection agencies work to make communications benefit consumers while protecting producers' rights. In doing so, such agencies must consider the realities of consumer decision making, namely, how consumers understand a communication's contents and apply them to their personal circumstances. Sound policies must address the variability both in how consumers process messages and in how they respond to products (in terms of experiencing costs and benefits), and they must reflect the scientific uncertainty in prediction of these effects. All this must be done in ways that reflect an agency's regulatory policy, as is expressed in its enabling legislation and subsequent rulings.

We propose a *prescriptive* approach to the evaluation of product communications in terms of their compliance with regulatory goals. As do other prescriptive approaches, ours begins with a *normative* analysis of the decisions facing consumers who are considering purchase of a product. The analysis attempts to identify the choices in consumers' best interests, making optimal usage of the information available under alternative regulatory regimes. The approach proceeds to a *descriptive* assessment of how well consumers will fare in identifying personally optimal choices, given the sensitivity of the choices to imperfections in lay inferential processes. The approach recognizes that some optimal choices are clear enough for harried consumers to identify, with a minimal set of relevant information (e.g., ephedra). In other cases, scientific uncertainties and complex trade-offs may frustrate even contemplative consumers (e.g., hormone replacement therapy).

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For any combination of information provision and consumer decision-making competence, these analyses produce a distribution of outcomes over consumers; some fare better and others worse. Regulators then can pick the combination that best represents the regulatory philosophy that they hope to implement. The policy need not be the one that produces the best overall distribution of consumer outcomes. Regulators may decide that they are not responsible for "irresponsible" consumers, or ones who neglect information that would be adequate for more conscientious consumers. Regulators may also require more information than consumers can handle, if such disclosure serves other legitimate purposes (e.g., encouragement of product reformulation, facilitation of litigation). In evaluating outcome distributions, regulators may consider only the percentage of consumers making optimal choices, or they may weight expected utilities across consumers (e.g., when they expect small benefits for many people but large risks for a few).

Adoption of this approach would make explicit the regulatory philosophy that is implicit in the usual case-specific rule making, which might ban one claim, allow another, require a disclaimer for another, and so on. Unfortunately, even when the operational intent of such rulings is clear, the regulatory philosophy that underlies them often is not. Without a clear statement, producers are left to guess the precedents that rulings set for future communications. Regulatory staff lack guidance on how to allocate their resources for evaluating (and challenging, if need be) communications. Consumer advocates cannot be sure how the regulatory process weighed their constituents' welfare. Consumers must wonder how much to trust labels to serve their needs.

Regulatory ambiguity may benefit people who are in a position to manipulate a process without clear-cut rules. However, this ambiguity is contrary to transparent, efficient regulation. Our approach is designed to reflect diverse regulatory philosophies, including both regulators' concern for consumers' welfare and their assignment of responsibility of imperfections in consumer decision making. The existence of a way to accomplish these goals might encourage a shift to regulation that is consonant with the analytical and behavioral results of behavioral decision research. That opportunity might seem particularly great given recent calls by the Food and Drug Administration (FDA) and the Office of Management and Budget for risk-based decision making (i.e., recognition that decisions involving risks typically involve other costs and benefits; FDA 2002a; Graham 2002).

An approach that makes an agency's regulatory philosophy explicit could focus debate on general issues rather than bury them in case-specific deliberations. It could reduce regulatory costs by making the system more predictable. Producers could design a communication with reasonable expectations for how it will be judged. Regulators could create a legacy of precedents that focuses staff work and reduces the number of communications that require adjudication. Consumers could approach communications with the knowledge of how competing interests have been balanced and of how much help to expect. A consistently applied communication standard might even educate consumers, expanding their range of effective decision making (as the FDA's Nutrition Facts panel may have done; Moorman 1996).

Overview

Our approach builds on several interwoven research streams. One stream considers the challenges that rational-actor models of consumer decision making face with products that pose unfamiliar, uncertain risks (Fischhoff 1977). These concerns have prompted studies of risk perception that examine the extent of problems (Merz and Fischhoff 1990; Slovic 1987) and studies of risk communication that examine the opportunities to reduce them (Fischhoff, Bostrom, and Quadrel 2002; Morgan et al. 2001). A second stream considers the role of rationality in the law, including both which assumptions are made and which should be made (Hanson and Keysar 1999). It raises questions about the proper place for regulatory paternalism (Camerer et al. 2003; Jolls, Sunstein, and Thaler 1998). A third stream considers the incorporation of scientific uncertainty in regulation, which typically focuses on risks, but with analogous implications for uncertain benefits (Fischhoff 1984; Glickman and Gough 1990; National Academy of Sciences 1994). Our approach considers the uncertainty in science and the variability in human responses; thus, it provides an alternative to approaches that try to achieve a consensual definition (Calfee and Pappalardo 1991). Our approach considers the often-complex pattern of strengths and weaknesses in lay decision-making processes and thus provides an alternative to approaches that categorically treat people as rational or irrational.

We illustrate the approach in a case study that involves a major consumer protection agency (i.e., the FDA), a specific regulatory context (i.e., evaluation of the "misleadingness" of dietary supplement labels), and a specific product (i.e., saw palmetto). Because this specific case is in flux, for our purposes, we "freeze" the details of the scenario in early 2003. Because the interpretation of case details is the subject of intense litigation, anything written herein merely suggests what the parties might claim and the courts might decide. More definitive treatment requires placement of the specific case in the broader context of evolving regulatory policy. Nonetheless, we hope to capture the kinds of issues that face regulators, producers, and consumers—issues that any putative method must address.

After sketching the policy context, which focuses on health claims and nutrition information in the context of general behavioral decision-making research, we present our approach. We then apply our approach to saw palmetto, a widely used dietary supplement, first analytically and then empirically. We conclude by considering the policy questions that face any actual application and are made explicit in our approach.

Dietary Supplements

Regulatory History

In the United States, dietary supplements are a $14 billion industry that comprises 29,000 products used by more than 50% of consumers (FDA 2000b). The FDA regulates supplements' safety and labeling, with the goal of ensuring that label information is truthful, not misleading, and adequate to communicate any risks. Until 1994, supplements were subject to the same regulations as foods under the Nutrition Labeling and Education Act (1990). Congress then passed the Dietary Supplement Health and Education Act (1994, § 2 [b][1]) to "improve … health status … and help constrain runaway health care spending by ensuring that the Federal Government erects no regulatory barriers that impede the ability of consumers to improve their nutrition through the free choice of safe dietary supplements." The act classifies supplements as neither drugs nor food additives and thus not subject to many of the regulations governing them. Supplements are now treated as "reasonably expected to be safe" unless adulterated. The FDA bears the burden of proof for demonstrating the risk of harm from the product itself, from its manufacturing process, or from associated communications.

In this context, labels have become the focus of deliberations over product communications. The FDA defines "label" as printed and graphic material on any product, including containers, wrappers, and accompanying material (General Accounting Office 2000). Any health claim that makes an explicit statement about the relationship between a product and disease is subject to FDA approval. To disallow the claim, the FDA must demonstrate lack of significant scientific agreement among qualified experts. The FDA has no such authority over claims regarding supplements' contribution to bodily structure or function (e.g., that make users stronger or more alert), as long as they make no implicit or explicit claims about disease. However, structure and function claims must include the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." Safety information is required only when it is material to the evaluation of a product's effects. As long as a product meets these conditions, the FDA can only suppress claims that would be potentially misleading to a reasonable consumer (FDA 2002c).

Recent court decisions have further challenged the FDA's authority to suppress claims. Supplement manufacturers and consumer groups have successfully argued for an expansive right to make health-related claims as a way to provide information to consumers. In *Pearson v. Shalala* (1999), the U.S. Court of Appeals ruled that the FDA had violated the First Amendment right to free speech when it denied approval of four health claims for lack of "significant scientific evidence." The court rejected the FDA's contention that claims lacking significant scientific agreement cannot be

verified and thus are inherently misleading to consumers and should be suppressed. Instead, the court argued that an unverified claim might benefit consumers, as long as they understand the state of evidence. The court held that "[w]hen government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a 'far less restrictive' means" (164 F.3d, p. 658). As a result, the court left it up to consumers to decide whether information is beneficial.

This decision recognized a new class of claim for dietary supplements: the "qualified health claim," which must reflect the weight of scientific evidence (i.e., more evidence for than against) but need not meet the standard of significant scientific agreement (which still applies to food). The FDA can ban a claim as "incurable by disclaimer," if the weight of evidence contradicts it or if it is misleading, even with the prescribed disclaimer. The court ordered the FDA to draft one or more alternative disclaimers from which manufacturers can select rather than have their claims suppressed.

Formalizing the Conditions for Denying Claims

The meaning of the law depends on how terms such as the ones discussed previously are defined. Some terms pertain to the evidence in support of a claim; others pertain to its impact on consumer decision making. Proper definitions should capture the spirit of the court's ruling, which aimed both to allow labels that increased consumers' ability to make decisions in their own best interest and to end the "FDA's paternalistic approach … based on the counterintuitive notion [that] consumers lack the sophistication necessary to evaluate truthful and nonmisleading health information" (Emord 2000, p. 140). The extent to which the court's intentions actually occur is an empirical question that our approach aims to formalize.

The parties to this controversy characterize consumer behavior in ways that support their positions (Mason and Scammon 2000). Arguing for commercial freedom of speech, Emord (2000, p. 141) states that "people will perceive their own best interests if only they are well enough informed,… [and] the best means to that end is to open the channels of communication rather than to close them." Arguing for the FDA, Vladeck (2000, p. 138) states that disclaimers "contain no information that sheds light on the consumer's appraisal" of products' safety or efficacy. The few studies that directly evaluate the FDA's disclaimer have found that it had little effect on consumers' evaluation of dietary supplement claims. For example, Mason and Scammon (2000) find that people tend to ignore the disclaimer and thus not realize that the claims might not be substantiated. The General Accounting Office (2000) concludes that consumers (1) assume that the regulatory standards for foods apply to dietary supplements and (2) do not distinguish between health claims and structure and function claims, thereby incorrectly inferring that structure and function claims mean that a supplement can prevent or cure disease.

The conflicting claims are special cases in the general debate over the degree of cognitive performance to be assumed in situations that involve a duty to inform. In general, advocates of the law and economics movement accept the descriptive validity of the rational-actor model of neoclassical economics, which leads to optimistic expectations. Adherents of the behavioral law and economics movement acknowledge the sort of suboptimal behavior studied in behavioral decision research (Hanson and Keysar 1999). In the disclaimer controversy, the FDA effectively sides with the latter and its opponents with the former. The FDA (2002c) posits a reasonable consumer standard, which treats consumers as "active partners in their own health care who behave in health-promoting ways when they are given accurate health information." However, the FDA doubts consumers' ability to extract the information that they need from product communications.

Research into consumers' processing of nutrition information that is embedded in food claims (e.g., Greiger 1998) provides a basis for anticipating the analogous processes in consumers' evaluation of dietary supplements. However, it cannot replace dedicated empirical studies because of the differences between supplements and conventional foods and in benefits, risks, marketing, and regulation. Nor does the existing research directly address the adequacy of consumer understanding. Some decisions are more difficult and important than others: The same information may be inadequate in one case and overkill in another. Some facts matter more than others do.

Under the assumption that people process information about potentially overlooked risks in a way similar to how they process information about potentially nonexistent benefits, circumstantial evidence regarding these claims is also found in the voluminous literature on warning labels (e.g., Wogalter, Young, and Laughery 2001). Although some studies have found that on-product warning labels have little effect on behavior, most researchers believe that there is value in well-designed labels that concisely communicate a potential hazard (Cox et al. 1997). Studies of warnings focus on situations that have one correct response (e.g., not using hair dryers in the bathtub) rather than situations in which different choices might be best for different people (e.g., whether to use a supplement, whether to accept the risk of a beneficial product). Our approach extends the often-sophisticated methodology of these studies by considering the optimality of choices for individual consumers. It also formalizes the decision of whether a warning's inevitably imperfect performance is adequate given an agency's regulatory philosophy.

Although the FDA (1999a, b; 2002b, c) has issued guidance on some of the terms emerging from *Pearson v. Shalala* (1999), it recognizes the need to specify further the acceptability of consumer responses to structure and function claims and disclaimers (FDA 2003). That specification should accommodate the possibility that agencies do not hold labels responsible for consumers' failings. Our approach clarifies these choices by distinguishing among potential failings. Identification of the sources of problems with specific labels can rely on inferences from the general research literature or on dedicated studies, an approach to which we demonstrate herein.

A Behavioral Decision Research Approach for Evaluating Consumer Communications

The regulatory test for product communications is how they affect consumers' ability to make choices in their own best interest. A valid approach to such evaluations must reflect (1) the physical reality of products' effects, (2) the behavioral reality of consumers' information processing, and (3) the legal reality of an agency's enabling legislation and subsequent rulings. We offer an approach that is rooted in risk analysis and behavioral decision research (Fischhoff et al. 1998; Hastie and Dawes 2001; Morgan et al. 2001). Our approach adds the regulatory context to previous work, evaluating the effects of communications on lay decision making, in such domains as sexual assault (Fischhoff 1992), medical informed consent (Fischhoff 1999; Merz et al. 1993), waterborne parasites (Casman et al. 2000), and use of hazardous chemicals (Fischhoff 1999; Riley et al. 2001).

The approach begins with a normative analysis to identify the optimal choice for consumers drawn from the target distribution, given the consumers' values and the best-available scientific evidence, including the attendant uncertainties. It proceeds by successively weakening the assumptions made about the completeness of the information and the optimality of consumer information processing. At each step, we pose questions of regulatory philosophy that an agency must answer explicitly to apply the approach (and will answer implicitly, in any circumstance).

Step 1: Normative Analysis/Full Information

The first step is for an agency to characterize the decision for fully informed, rational consumers by estimating the effects of taking and avoiding a supplement on the outcomes that matter to consumers (e.g., relieving symptoms, saving money, avoiding side effects), on the basis of the best-available scientific evidence. The agency then applies an expected utility rule to that characterization to identify the consumers' best-interest choices, or the ones made by rational people taking full advantage of the information. These set a standard of comparison for choices made in more realistic conditions. If a product shows negative expected utility in this test, it can be argued that a communication that leads consumers to conclude otherwise is inherently misleading. An agency may be able to ban the communication even when it cannot ban the product.

Consumers may differ in their probability of experiencing the possible outcomes of using a product (e.g., sensitivity to side effects, ability to benefit). They may also differ in the utility that they assign to the effects (e.g., willingness to pay for symptomatic but not systemic relief). As a result, the expected utility of using (and avoiding) a product may vary across consumers. The variation creates a distribution of best-interest decisions over a consumer population. As a result, identification of best-interest decisions requires scientific understanding of both how products affect consumers and how consumers value the effects. The uncertainty in the science produces uncertainty in estimates of each consumer's expected utility from use and avoidance of the product.

Step 2: Normative Analysis/Incomplete Information

In the second step, the agency determines the decisions made by incompletely informed, rational consumers. The agency should make more realistic assumptions about the information available to consumers through communications such as product labeling, but it should still assume that consumers fully understand whatever product they have and use an expected utility rule to integrate it with their values in decision making. That is, the agency should rerun Step 1's decision-making model using actually available information instead of best-available information. Comparison of those choices with the best-interest choices (from Step 1) shows how a restricted information flow affects consumer welfare. That comparison can predict actual behavior only to the extent that consumers understand the available information and use it optimally. An agency might posit such rationality if it determined that producers bore no responsibility for protecting consumers from these human failings.

When the effect of omitting a fact is small, it has little practical value (for making these choices). As a result, such analyses enable agencies to set communication priorities. Merz and colleagues (1993) use this approach in the context of medical informed consent. In a case study, they found that information about only a few of the many possible side effects of a common surgical procedure (carotid endarterectomy) would affect the choices of many potential patients. They argue that whereas no information should be hidden, physicians bear a particular responsibility to make the few facts available (and comprehensible).

Step 3: Descriptive Analysis/Rational Choice, Nonoptimal Judgment

In the third step, the agency determines the decisions made by misinformed, rational consumers by identifying the choices of consumers who choose rationally but without fully understanding the available information. Such consumers might miss information because they are distracted or illiterate or because of poor label design. They might misinterpret information because it is confusingly presented or because they lack necessary background (Fischhoff 2000, in press). These consumers' choices are predicted by repeating the expected utility calculation (of Steps 1 and 2) with their beliefs rather than the information actually provided under a given informational regime. A comparison of these choices with choices made under the assumption of perfect comprehension produces a more behaviorally realistic prediction of a communication's effects. As in Step 2, regulators must decide whether the distribution of expected outcomes is acceptable.

Potentially relevant cognitive barriers have been widely studied. For example, people may have difficulty inferring the size of verbally described quantities (e.g., "rare" side effects, "good" evidence), underestimate how quickly risks mount up over repeated exposures, exaggerate the extent of their own understanding, and have difficulty aggregating different kinds of information (e.g., regarding general tendencies and specific cases) (Gilovich, Griffin, and Kahneman 2002; Kahneman, Slovic, and Tversky 1982). Such tendencies may undermine the value of information that would

be adequate for sophisticated consumers (e.g., detailed package inserts). Whether consumers undermine the value of information is an empirical question to be informed by basic research and dedicated studies. It is also possible that consumers successfully read between the lines of reduced communications and draw on other beliefs to create a fuller mental model of the problem they face (Fischhoff, Bostrom, and Quadrel 2002; Gentner and Stevens 1983).

Step 4: Descriptive Analysis/Nonrational Choice

In the fourth step, the agency determines the decisions made by heuristic consumers by relaxing the assumption that consumers make choices by rationally integrating their beliefs and values. Instead, consumers have limited mental computational capacity, which forces them to rely on heuristic decision rules (Simon 1957). Even when consumers have the necessary information-processing capacity, they may not know or choose to use the expected utility rule required for rational choice (Hastie and Dawes 2001). Heuristic decision rules can approximate rational choices, but they can also produce biases. People can apply heuristic decision rules to perfectly understood situations (a variant of Steps 1 or 2) or to ones that they misunderstand (a variant of Step 3). The impact of these imperfections on the optimality of consumers' choices is an empirical question; the acceptability of this impact is a policy question.

As with Step 3, the effects of imperfections can be assessed directly or inferred from previous research. A source of predictive guidance is studies of lay theories, which show intuitively plausible decision rules in a particular domain (Furnham 1988). Another source is studies of contingent decision rules, which show how people simplify complex environments (Payne, Bettman, and Johnson 1993). Another source is studies of simple linear models, which show how well the models predict people's choices when it is known which features attract their attention (Dawes 1979).

Summary

Steps 1 and 2 reflect differences in the situations consumers face, namely, the information available. Steps 3 and 4 reflect differences in the consumers who face the situations, namely, how adequately they process information about products' risks and benefits (Step 3) and how rationally they integrate those beliefs with their values (Step 4). Such imperfect behavior is called "nonrational" rather than "irrational" to reflect its orderliness and to avoid the negative connotations of the latter term. Unreasoning behavior is certainly possible and can be analyzed by adding a fifth step to this approach. Research into emotion and cognition provides an empirical and theoretical basis for that extension (Loewenstein and Lerner 2003; Mellers, Schwartz, and Ritov 1999). Whether producers and regulators should consider irrationality is a larger policy question.

Thus, each step predicts the choices made by a class of consumers in a type of situation. Table 1 summarizes the contrasts between the optimal choices of Step 1 and the potentially suboptimal choices of Steps 2–4. The columns in Table 1 reflect whether a product should be consumed, as is determined by a normative analysis (Step 1). The rows in Table 1 reflect whether a product would be consumed, under the increasingly imperfect conditions of Steps 2–4. Ideally, all choices would fall on the diagonal, despite imperfections in information provision and human behavior. Off-diagonal choices reflect consumers acting against their best interest, that is, inadvisably consuming or avoiding a product.

Table 1. Possible Outcomes of Best-Interest Analysis of Consumer Choices

	Optimal Choice (Step 1)	
Actual Choice (Step 2–4)	**Should Consume**	**Should Not Consume**
Would consume	Optimal choice	Type I decision error
Would not consume	Type II decision error	Optimal choice

Regulatory policy involves two choices. The first is which step (1–4) makes the appropriate behavioral assumptions. The second is whether the distribution of consumers over the cells is acceptable. Regulators can then create policies that reflect agency policy for the relative importance of good and bad choices. Producers can design labels, marketing systems, or even products and create more acceptable choices.

Application of this approach requires specification of (1) a product in terms of its benefits, costs, and risks, each of which is known with some precision; (2) an informational regime in terms of the accessibility and comprehensibility of its choice-relevant facts; and (3) a consumer population in terms of the distribution of potential consumers' responses, personal values, and cognitive capabilities. The analysis samples individual consumers from the target population, characterizing each in the following terms: They may be actual consumers who are characterized empirically (e.g., using interviews or medical records) or hypothetical consumers who are characterized statistically (e.g., using Monte Carlo methods to sample values from a posited distribution; Merz et al. 1993). When each consumer has been characterized, Step 1's best-interest analysis is performed with complete product information. The analysis is then repeated, and more realistic assumptions are made about the information available and its cognitive processing (Steps 2–4). The results of each reanalysis enable the researcher to assign the consumer to one cell in Table 1. Aggregation of the individual analyses produces a distribution of outcomes.

There is only one Step 1 analysis, which makes best use of all available information; however, there are many possible versions of Steps 2–4, depending on how information provision and processing are specified. That specification should consider both performance capability and execution. How good can an informational regime be if it is diligently executed, and how good is it likely to be? How efficient can a cognitive heuristic be, and how well is it likely to perform (e.g., for harassed consumers, under typical shopping conditions)? Some strategies degrade more gracefully than others (Hastie and Dawes 2001; von Winterfeldt and Edwards 1986).

When the inputs to an analysis are uncertain, assignment of consumers to the cells of Table 1 may be only proba-

bilistic. For example, the best-interest (Step 1) analysis may yield a probability distribution for the expected utility of product consumption, with 70% of its mass on positive values. If so, there is a 70% chance that consumption is the best-interest choice (and a 30% chance that it is not). The same logic applies to assigning the potentially suboptimal choices of Steps 2–4 to rows of Table 1. When assignment to the cells is uncertain, the potential outcomes should be weighted by their likelihood and by their impact on consumer welfare. For example, less damage is done if consumers fail to consume a product that might be in their best interest than one that is definitely in their best interest.

In terms of these methodological choices, the following case study of saw palmetto (1) characterizes individual consumers empirically by interviewing them, (2) assesses the potential effectiveness of several informational regimes in favored conditions by having consumers study them, and (3) ignores uncertainty by assigning consumers categorically to the choice (consume/not consume) that is most likely to be in their best interests.

Case Study: Normative Analysis/Full Information (Step 1)

Saw Palmetto and Benign Prostatic Hyperplasia

Saw palmetto (*Serenoa repens*) is an herbal extract advocated for short-term symptomatic treatment of benign prostatic hyperplasia (BPH), a noncancerous enlargement of the prostate that causes urinary tract problems. Common among older men, BPH has symptoms that include irritation, nocturia, incontinence, and weak urinary flow. Other treatments include pharmaceutical and phytotherapeutical options, surgical procedures, and in extreme cases prostatectomy. Saw palmetto producers have petitioned the FDA to approve structure and function claims and disclaimers such as the following:

> Claim: Recently, a review of the efficacy and safety of saw palmetto supplementation in men with prostate problems revealed that about 80%–90% of men treated with saw palmetto in 18 randomized clinical studies showed a positive correlation between saw palmetto and prostate health.
>
> Disclaimer: The FDA has not evaluated this claim. This product is not intended to diagnose, treat, cure, or prevent any disease.

The FDA (2000a) denied this claim, arguing that it "is clearly aimed at correcting an existing abnormal physiological function—namely, urinary abnormalities caused by BPH" and thus should "be classified as drug claims rather than health claims." The court held that the FDA could deny the claim only if it could classify it as either inherently or potentially misleading. After a review criticized for both coverage and conclusions, Wilt and colleagues (1998) argued that the claim is not demonstrably false. If the courts sustained Wilt and colleagues' opinion, the FDA would need to demonstrate that the claim is potentially misleading in order to deny it.

Analytical Assumptions

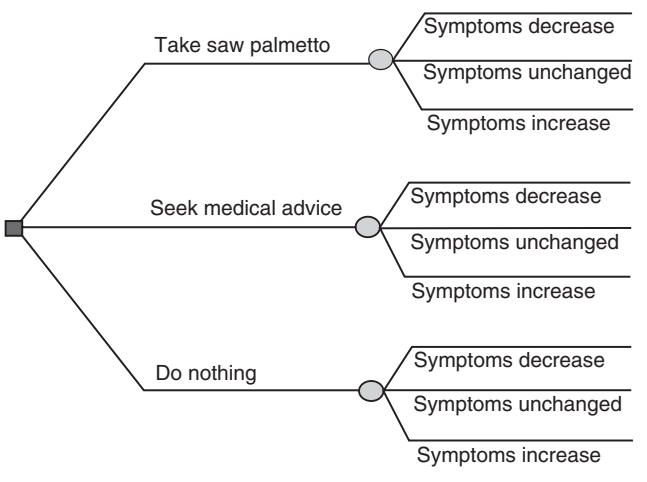
At the time of this writing, saw palmetto labeling was subject to intense litigation, as was the claim that it is a dietary supplement and not a drug. We have no intent to resolve these issues; rather, we hope to clarify the choices faced by the FDA (and the courts). To this end, we consider possible implementations of three informational regimes: (1) health claim and accompanying disclaimer (as we mentioned previously), (2) health claim and no disclaimer, and (3) no health claim. We also examine two conceptualizations of the decision consumers face: a static choice, in which consumers consider the effects of taking or rejecting saw palmetto for an indeterminate period, and a dynamic choice, in which they also consider the effects of taking saw palmetto on consulting a physician about prostate problems.

Any binding implementation of the approach requires a procedure for determining the estimates to use as model inputs (as well as the informational regimes, consumers, outcome weightings, and so on). For the purposes of this demonstration, we use several recent summaries and ignore the associated controversies. According to Wilt and colleagues (1998), saw palmetto is superior to a placebo and comparable to pharmaceuticals in improving peak urine flow, and the duration of resultant symptom reduction varies. Saw palmetto's long-term efficacy in preventing BPH complications is unknown. It does not reduce prostate size (Marks et al. 2000), and its known side effects are minimal, as are any drug–herb interactions (Ernst 2002). An indirect risk of saw palmetto is that it provides symptomatic relief without actually curing the disease, thereby delaying medical treatment and increasing the chances of secondary complications (e.g., urinary tract infection, renal damage). A related risk is that it may relieve or mask symptoms of more serious conditions. The American Urological Association (2000) notes that BPH's symptoms are also those of life-threatening prostate and bladder cancer. These cancers can rarely be cured after they have spread beyond the primary organ, which makes early detection essential. These risks depend on the length of the delay, though we estimate their magnitude only roughly.

Static Decisions

Figure 1 depicts the decisions of a man concerned about two outcomes: urinary symptoms and curing BPH. (We treat

Figure 1. Decision Tree for Saw Palmetto Consumption (Step 1)



concern for prostate cancer in the next section.) Monetary costs are low ($10 per month); we ignore them here for simplicity. His options (indicated by a square choice node) are (1) to consume the recommended saw palmetto dosage, (2) to talk to a doctor about his condition, and (3) to do nothing. Consumption of larger doses has no known effects (Ernst 2002); thus, we do not consider it an option. In the absence of side effects and without the chance of curing BPH, the only noteworthy outcome is symptom relief. We can directly assess the utility of that health state or take it from published studies if their context seems sufficiently similar (Tengs and Wallace 2000, Table 2). The expected utility of an option depends on the probability of each outcome (multiplied by its utility), which is indicated by circular event nodes in Figure 1. For saw palmetto, the probabilities depend on the consumer's initial health state (Wilt et al. 1998).

Using best estimates for the probability and utility values taken from these sources, we conducted consumer best-interest analyses for hypothetical men with different levels of initial symptoms (i.e., mild, moderate, and severe), as determined by the International Prostate Symptom Score (Wilt et al. 1998). The model defines a best-interest outcome as the probability that initial symptoms will improve to a less-severe symptom level (e.g., from severe to moderate). The results show that for men who experience mild BPH symptoms, taking saw palmetto initially has higher expected utility than does visiting a physician. The opposite is true for men who experience moderate and severe initial symptoms. Because best estimates of saw palmetto's efficacy in relieving symptoms vary widely (Marks et al. 2000; Schulz et al. 2002; Wilt et al. 1998), we conducted sensitivity analyses using a rectangular probability distribution over the range of estimates. We found that for men with moderate initial symptoms, the best-interest choice is sensitive to the estimate used. Choice of the values to use in a sensitivity analysis depends on how the regulatory agency defines terms such as "significant scientific evidence."

Dynamic Decisions

For many products, this basic model would capture consumers' decisions. Incorporation of side effects or drug–herb interactions, should they be an issue, is straightforward. A multiattribute model can accommodate other outcomes (e.g., monetary costs, social status, stigma); however, the basic model neglects indirect effects, such as use of saw palmetto modifying other health behaviors. Both the FDA and the American Urological Association have expressed concern about self-medication with saw palmetto leading to untreated BPH and undetected prostate cancer.

Figure 2 considers how the consumption decision affects the *time* until a man informs his physician about his symptoms and supplement use. It shows three choices, one of which is to first consult with a physician. If cancer is detected, appropriate actions are taken. If the symptoms are attributed to BPH, the situation follows its natural course, and the desired treatment may or may not include saw palmetto in conjunction with another medical treatment. Another option is to self-medicate with saw palmetto. The course of the disease affects the probability of the user continuing or discontinuing the supplement and seeking medical advice. Finally, the consumer can do nothing immediately, but he can delay his choice until he observes how his symptoms develop.

These are logical, if complex, dependencies. Computation of the model requires estimates of probabilities and specification of the thresholds for transitions. For example, the model will be different for a man who would always check with his physician and one who would inform his physician about severe lower-urinary-tract symptoms but not about mild or moderate ones. Some probabilities may be path independent, such as the outcomes of prostate cancer detection at a particular stage (given our assumption of optimal treatment in all cases); others may vary by path. For example, a man who takes saw palmetto because he believes that it treats the underlying condition may be less able to recognize the risk of undetected prostate cancer. Although estimation of the parameters may be daunting, doing so merely renders explicit a choice that would otherwise be buried in a rule authorizing or proscribing a label.

Case Study: Descriptive Analysis

The next section outlines the set of issues that need to be addressed in applying the approach to a regulatory context. In our evaluation of four labels for saw palmetto that represent informational regimes that differ in their degree of detail, we illustrate the kinds of results that might be observed.

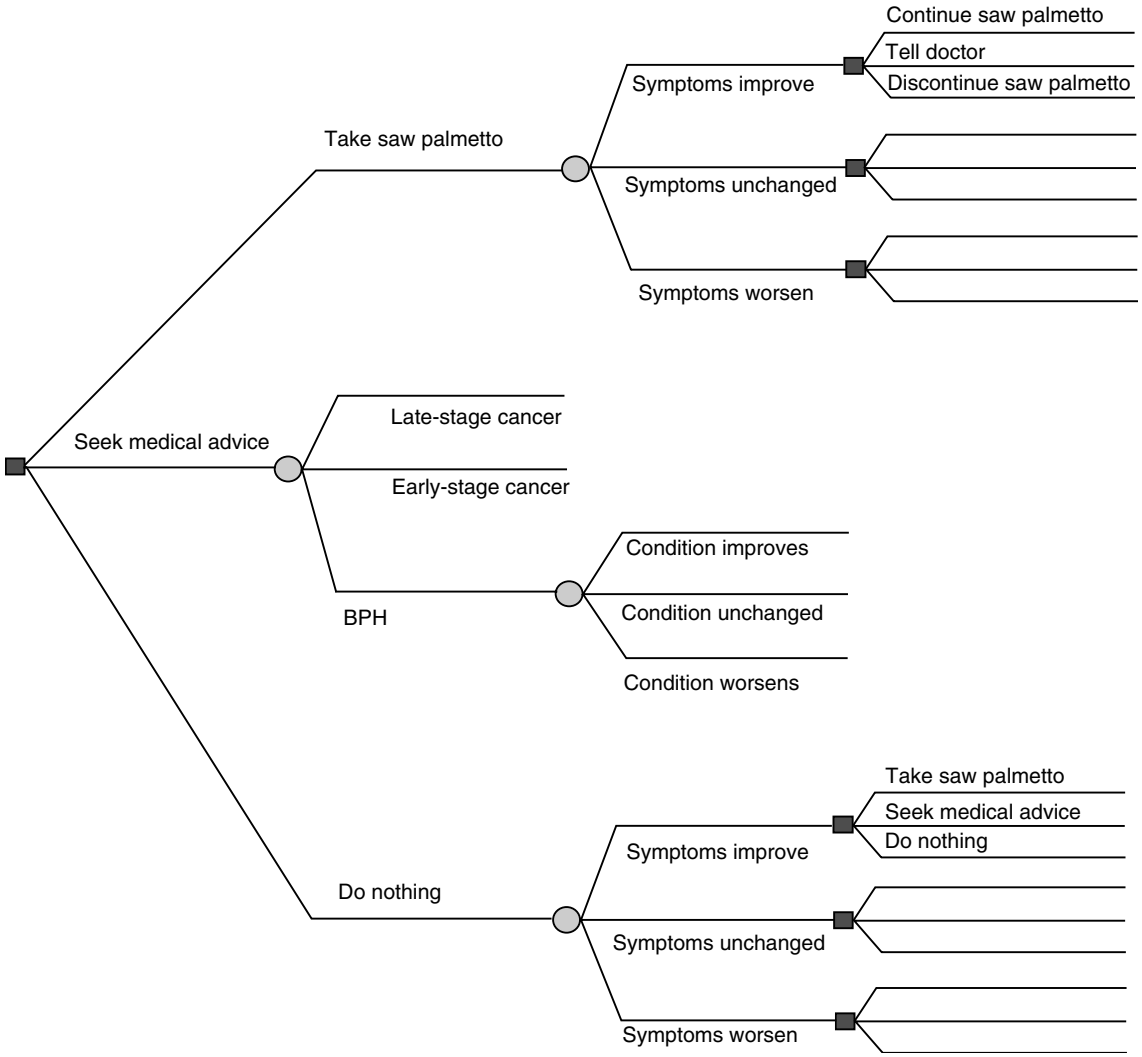
Method

Procedure

We used a structured interview with open-ended responses (following Morgan et al. 2001) and a self-administered survey to elicit respondents' beliefs about the elements of the decision trees in Figures 1 and 2 and about their health state and preferences. Respondents received up to four labels that had increasing amounts of information: (1) no health claim, (2) an unqualified health claim, (3) a health claim and disclaimer, and (4) full information.

For each label, the open-ended portion of the interview protocol prompted respondents to address each element of the tree, but it did not exert pressure that might hint at correct responses or compromise the interview's conversational tone. We elicited several parameter estimates explicitly: (1) the number of men (of 100) who would experience relief from taking saw palmetto; (2) the relief experienced by men who it helped, compared with their initial health state (on a 0%–100% scale); (3) the number of men (of 100) who would experience negative side effects from taking it; and (4) the severity of the side effects, on a scale anchored at 1 = "very mild" and 7 = "very severe." Parallel questions addressed product benefits, risks, and overall attractiveness. After reading the labels, respondents were asked which they preferred. At the end, a self-administered survey elicited their history of dietary-supplement use, related health history, current BPH symptoms (which we adapted from Barry et al. 2002), and (dis)utility for any current BPH symptoms (which we adapted from Wimisberg et al. 2002). We did not define terms such as "relief," "side effects," and "initial health state."

Figure 2. Dynamic Decision Tree



Pretests showed that lay respondents typically found our initial design too demanding. It elicited judgments for all elements of the decision tree after completion of the semi-structured protocol that probed for qualitative responses to labels that represented the different informational regimes. As a result, we could not elicit all the judgments we needed to perform Step 1 analyses for each participant. Because our goal was to demonstrate the approach rather than offer definitive results (which would require policy guidance of the sort we summarize in the section "Policy Questions"), we adopted a compromise method. Namely, as a proxy for respondents' best-interest decision, we used the choice of the respondents given full information after an hour or so of dealing with the topic.

Stimuli

The unqualified health claim we used was the one we mentioned in the section "Saw Palmetto and Benign Prostatic Hyperplasia." The associated front label also contained the following: "Herbal Good™/Concentrated Saw Palmetto/Supports Prostate Health/60 capsules 500mg/All natural plant extracts." The back label read: "Directions: As a dietary supplement, take one to three capsules; Concentrated Saw Palmetto." A supplement facts panel, patterned after the FDA's Nutrition Facts panel, listed serving size, servings per container, amount per serving (percentage of daily value), and ingredients (saw palmetto berries [*Serenoa repens*] [500mg]). The label also listed other ingredients, storage instructions, and a warning ("Keep out of reach of children"). In the health claim and disclaimer condition, we added the disclaimer provided in the section "Saw Palmetto and Benign Prostatic Hyperplasia." The full information label we used appears in Table 2. The estimates were adapted from Health Dialog Inc. (Barry et al. 1995) and Wilt and colleagues (1999), and the design follows that of Woloshin and Schwartz (1999).

Respondents

In this demonstration, we included men who represented a diversity of age, concern, and education of potential consumers to reveal the ranges of beliefs and preferences. To that end, we recruited a Pittsburgh-area convenience sample of 16 men aged 40 and older. Participants ranged from age 47 to age 80 (mean = 58) and reported BPH symptoms that ranged from none to severe. None of the participants currently used saw palmetto; few had heard of it. Because preferences and expectations vary across a population that has relevant heterogeneity, as do the distributions of optimal and predicted decisions, actual policy analyses should sample the relevant population, as specified by regulators.

Representative Results

The interviews provide rich qualitative results on consumers' attitudes and beliefs about dietary supplements, labeling, and government regulation. The results can guide both the design of communications by suggesting terms and formulations that resonate with consumers and the design of structured surveys for estimating the population prevalence of beliefs and attitudes (Morgan et al. 2001). The present demonstration focuses on suggestive results. Three general patterns from this sample seem to have particular regulatory importance. First, most respondents regarded the health claim as advertising and the disclaimer as a mandatory statement (or "for liability protection"). Second, respondents often assumed that the term "prostate health" referred to prostate cancer. Third, all respondents stated that they would either consult their doctor before or inform their doctor after taking the supplement.

Table 3 shows four quantitative estimates for Respondent A after he received each successive level of information. Even with no information (no claim), Respondent A believed that the supplement must have been somewhat

Table 2. Full-Information Condition Display

	Facts About Saw Palmetto
What is saw palmetto?	Saw palmetto (*Serenoa repens*) is a dwarf palm found in the southeastern United States and West Indies. Extract from saw palmetto berries has traditionally been used to treat **BPH**.
What is BPH?	After the age of 40, the prostate gland may become a source of problems for men. More than half of men older than age 60 have BPH, a noncancerous enlargement of the prostate. This tissue growth may eventually obstruct the bladder outlet, causing difficulties with urination. The chance of developing BPH increases with age. Nearly 80% of men over age 80 have enlarged prostates. The **symptoms** of BPH vary in severity. They include difficulty urinating, incomplete emptying of the bladder, incontinence, frequent urge to urinate, weak urinary stream, frequent nighttime urination, and inability to urinate.
Why would someone take saw palmetto?	A review of studies has found that the berries of the **saw palmetto** plant may reduce moderate BPH symptoms. Saw palmetto has not been found to reduce the size of the prostate.
What are other treatments to consider?	There are several other **treatment options** for BPH. They include: 1. "Watchful waiting" means monitoring the condition to see if and how it changes. It is for men with mild symptoms. 2. Two drug treatments are alpha blockers and finasteride. Alpha blockers relax the muscles of the bladder neck and prostate, helping to increase the flow of urine. Finasteride shrinks the prostate. 3. Surgery can remove all or a part of the prostate. It is an alternative for men with more bothersome symptoms. A transurethral resection of the prostate shaves away a part of the prostate to improve urine flow. Open prostatectomy removes the prostate, and is rarely used to treat BPH. Your doctor can explain these options to you.
What do you need to do when taking saw palmetto?	There are two risks from self-medicating with saw palmetto to treat BPH. Saw palmetto does not reduce the size of the prostate and the condition can worsen if untreated. Second, although BPH is *not* cancer and does not lead to cancer, a man could have both BPH and prostate cancer. Often they have similar symptoms. Men who use saw palmetto without informing their doctor may slightly increase their risk of undetected prostate cancer. Anyone who takes saw palmetto should tell his doctor, who can properly deal with the underlying condition, as well as perform the proper screen for prostate cancer.
Supplement health claim[a]	A recent review of studies found that about 80%–90% of men who took saw palmetto in 18 randomized clinical studies reported an improvement in their prostate health.
FDA approval status	The FDA does not approve this claim. The FDA does not permit claims suggesting that a dietary supplement is intended to treat, prevent, or cure a disease.

Table 2. Continued

Saw Palmetto Review Facts					
Who was studied?	A total of 2939 men between the ages of 40 and 90 participated in the 18 studies. On average, participants experienced moderate urinary tract symptoms associated with BPH.				
	Summary of Review		**Studies of Treatments[b]**		
	Men Who Took Placebo	**Men Who Took Saw Palmetto**	**Alpha Blocker[c] (Drug)**	**Finasteride (Drug)**	**Transurethral Resection of the Prostate (Surgery)**
How drug might help					
Number of men (of 100) who report relief	51	74	74	67	88
Average degree of relief	29%	37%	48%	32%	85%
Percentage of men who stopped treatment	7%	9%	15%	11%	N.A.
Side effects due to treatment					
Death	0%	0%	?	?	Less than 1%
Infection	0%	0%	?	?	16%
Incontinence	0%	0%	?	?	3%
Erectile dysfunction	.7%	1.1%	0%	3%	14%
Other sexual problems	?	?	6%	?	73%

[a]Source: Wilt et al. 1998.
[b]Source: Foundation of Informed Medical Decision Making and Health Dialog 2002 (www.healthdialog.com).
[c]Alpha blockers include Tamsulosin, Doxazosin, and Terazosin.
Notes: N.A. = not applicable; ? = unknown or nonspecified.

Table 3. Parameter Estimates from Respondent A

	Information Regime			
Parameter	**No Claim**	**Claim**	**Claim and Disclaimer**	**Full Information**
Number of men (of 100) reporting positive effect	20	50	20	20
Average reduction of symptoms from initial condition	20%	40%	20%	20%
Number of men (of 100) reporting side effects	20	10	10	10
Average severity of side effects (1 = "very mild," 7 = "very severe")	2	2	2	2
Would you try saw palmetto for free?	No	Yes	Yes	Yes

effective to be on the market. With the claim, Respondent A believed the supplement to be even more effective. The disclaimer tempered that evaluation, but full information had no further effect. Row 2 of Table 3 shows that Respondent A's estimate of the product's effectiveness, when it worked, paralleled his estimates of the chances that it would work. Rows 3 and 4 show that more knowledge about the product reduced the estimated prevalence of side effects, the intensity of which remained low in all circumstances.

As is shown in Row 5 of Table 3, after receiving full information, Respondent A would take saw palmetto. Treating this as his best-interest choice (the Step 1 equivalent), we can evaluate the optimality of his choices with less information. In the no-claim condition, he did not intend to take saw palmetto, which means that his a priori beliefs about a generic supplement would have served him poorly. In the claim and claim and disclaimer conditions, he would have taken saw palmetto. Thus, even if the information were fragmentary and imperfectly understood, it would have been sufficient to produce the correct choice.

Table 4 shows another commonly observed pattern. With full information, Respondent B reached the same decision as Respondent A and made similar judgments about saw palmetto's efficacy. However, he made different choices in the no-claim and claim and disclaimer conditions. Here, the disclaimer reduced saw palmetto's attractiveness enough for

Table 4. Parameter Estimates from Respondent B

Parameter	Information Regime			
	No Claim	Claim	Claim and Disclaimer	Full Information
Number of men (of 100) reporting positive effect	60	60	90 (20)	80
Average reduction of symptoms from initial condition	50%	60%	80% (10%)	40
Number of men (of 100) reporting side effects	15	5	5	1
Average severity of side effects (1 = "very mild," 7 = "very severe")	2	2	2	1
Would you try saw palmetto for free?	No	Yes	No	Yes

Notes: Values in parentheses indicate subject response with discounting for the placebo effect.

Respondent B to forgo a supplement that was attractive when he was most fully informed. When asked to explain increasing his efficacy estimate after receiving the disclaimer, Respondent B said that he was accounting for a placebo effect, which would have inflated the supplement's apparent efficacy for people who believed in the claim, stating "90% would say they found [saw palmetto] effective, but deep down 20% [actually] would." Every subject who mentioned placebo effects also reported being personally unaffected by them. If broadly shared, this belief would cause systematic underestimation of personal benefits (because some people must be subject to placebo effects for them to exist).

Table 5 aggregates estimates across respondents. Although the sample is too small for reliable statistic tests, it implies possible patterns. First, addition of the claim increased the estimated number of men reporting positive effects, addition of the disclaimer reduced the number, and provision of full information partially restored it. Second, the expected degree of symptom reduction was independent of the label content. Perhaps respondents had a general notion of how effective supplements are, if they work. Third, anticipated side effects showed a converse pattern: Respondents' reading the claim about positive effects reduced estimates of side effects. For some reason, claims of effects suggested safety rather than the product being physiologically active enough to have side effects. Addition of the disclaimer increased that estimate, even though it revealed nothing about side effects except that the FDA had not tested the product. Perhaps respondents believed that efficacy testing would reveal problems. Full information decreased the side effects estimate (to the number provided in the label). Finally, the estimated intensity of side effects was independent of their expected prevalence, which parallels estimates of the intensity of positive effects.

Table 6 aggregates label-impact analyses across respondents. As we mentioned previously, respondents' choices with full information are taken as their best-interest deci-

Table 5. Mean Estimates of Benefits and Risks of Saw Palmetto Consumption

Parameter	Information Regime			
	No Claim	Claim	Claim and Disclaimer	Full Information
Number of men reporting effect	40.5 (28.9)	66.1 (17.2)	53.6 (23.7)	60.5 (22.2)
Average reduction of symptoms	39.0 (28.8)	52.5 (23.3)	48.6 (24.5)	35.0 (13.2)
Number of men reporting side effects	20.6 (26.3)	20.4 (26.0)	23.3 (23.3)	9.3 (13.8)
Average severity of side effects (1 = "very mild," 7 = "very severe")	2.8 (1.1)	2.8 (1.0)	2.8 (1.3)	2.5 (1.14)

Notes: Standard deviations are in parentheses.

Table 6. Aggregate Best-Interest Analysis

Result of Best-Interest Analysis		Information Regime		
Should Take (Step 1)	Would Take (Steps 2–4)	No Claim (N = 11)	Claim (N = 9)	Claim and Disclaimer (N = 15)
Yes	Yes	0%	44%	27%
No	**Yes (Type I error)**	**0**	**11**	**13**
Yes	**No (Type II error)**	**55**	**11**	**27**
No	No	45	33	33

Notes: Boldface indicates choices that are contrary to the consumer's best interest.

sions (Step 1). With full information, 55% of respondents would use the product. With no claim, none of the respondents intended to try the product, which means that 55% needed some information to make the right choice. With the health claim alone, 22% made choices against their best interest. However, addition of the disclaimer led to 40% of respondents making suboptimal choices. If we were to obtain these results in a larger sample, we would show that the disclaimer undermines consumer decision making. Presumably, the disclaimer created unwarranted suspicions about saw palmetto's efficacy and side effects, ones not substantiated by consumers reading the full information. As a respondent reported: "The [disclaimer] killed any good intention that I would want to buy [saw palmetto]. This statement is telling me the product is not intended to treat even.… I can understand it is not there for a cure or to prevent a disease, but surely if I am taking a dietary supplement for prostate health that is a form of treatment…. They are telling me 'no it's not.'... [E]vidently they have to put that in there and that would cause me to not even take it for free."

Policy Questions

Results such as the ones we obtained describe the impacts of specific informational regimes for presentation of a specific product to members of a target population. The results do not prescribe a policy. Such a prescription requires definition of the acceptable level of misunderstanding, in terms of Table 1. Thus, in the example, the acceptability of an FDA-mandated disclaimer would depend on the relative importance assigned to inappropriately taking and forgoing saw palmetto. In general, respondents who received only the health claim made the correct decision, partly because all said that they would consult their doctor, which eliminates the risk of delayed treatment. Addition of the disclaimer increased the rate of Type II errors but did not reduce Type I errors. Without the claim, there was a high rate of Type I errors. Suppression of this claim would mean holding that the disutility of Type II errors outweighs the combined disutility of Type I errors and the forgone utility of increased appropriate use.

As we mentioned previously, our results are meant to demonstrate the method, not to resolve thorny regulatory issues. Were the method adopted for evaluating a particular label, the regulatory agency would need to specify the appropriate summaries of scientific evidence and the conditions for collection of the behavioral evidence. That specification should include the following:

- *Sample size, which indicates the degree of precision needed*: A sample of 20 has approximately an even chance of identifying any pattern that characterizes 5% of the population. That percentage might be adequate, or regulatory purposes might require identifying less common patterns (and thus a larger sample).
- *Target population, which indicates the consumers who need protection*: We attempted to find a range of men who might initiate saw palmetto use. Regulatory policy might emphasize current users, older men, men with prostate cancer risk factors, or people who have difficulty comprehending labels.
- *Sample weighting, which indicates the relative importance of consumer groups*: Table 6 weights sample members equally. If regulators cared more about some groups, effects on those groups could receive extra weight. They might also be sampled more heavily to improve the estimates.
- *Relevant outcomes, which indicate the extent of regulatory concerns*: Probabilities and utilities are needed only for outcomes within an agency's mandate. We ignored monetary costs herein, and an agency might consider them irrelevant in principle. It may or may not have the authority to control for indirect effects, such as any opportunity costs of treating oneself rather than consulting a physician (such that Figure1 would define the best-interest analysis).
- *Sources of nonoptimal choices, which indicate regulatory responsibility*: Our research focused on the impacts of alternative information regimes (Step 2). By accepting respondents' full-information choices as representative of their best interest, we treated them as rational actors who understood what they read (thereby taking positions of Steps 3 and 4). However, the interviews revealed misunderstanding (e.g., about placebo effects, about unwarranted inferences from claims and disclaimers), which echoes effects found elsewhere in the research literature. If an agency cares about the source of imperfect decisions, more intensive probing is needed.

Assumptions about the quality of consumers' information processing take a stand in the controversy between the law and economics movement (which assumes rationality as a guide to legal opinions) and its behavioral law and economics counterpart (which argues for more behaviorally realistic assumptions) (Hanson and Keysar 1999; Jolls, Sunstein, and Thaler 1998). An agency might invoke inherent limits to consumers' information processing in arguing for label restrictions, which disclaimers cannot overcome, or it might exonerate producers from responsibility for consumer failings.

Our approach is intended to clarify, not to resolve, such issues of regulatory policy. Whether a label should be approved depends on the situation (e.g., supplement, consumers) and regulatory philosophy (e.g., weighting outcomes and consumers, responsibility for indirect effects, assumptions about consumer rationality). Working through the approach should clarify the legal and scientific issues that require greatest attention by casting them in common analytical terms that can improve both communication among the parties and comparisons across regulatory proceedings.

Initial applications are likely to be labor intensive, though they still might reduce costs of regulation and litigation. However, many issues recur across applications, just as we could draw on existing research on related judgment and decision-making processes. Recurrent modeling issues (Step 1) include structuring choices and creating meta-analytical summaries of health effects. Recurrent behavioral issues include (1) the impacts of advertising and lay beliefs about supplements, (2) comprehension problems (e.g., ambiguous terms), (3) utilities for health states (widely studied in health economics), and (4) assumptions about regulatory procedures (e.g., who tests what for side effects and efficacy?). Whatever the costs, they may be justified if they reduce agencies' legal costs, producers' uncertainties, and consumers' suboptimal choices. If the approach proved tractable for dietary supplements, it might be carried over to drugs and other contexts, with further economies of scope, thus creating a general approach to risk-based regulation.

How regulatory bodies accommodate strengths and weaknesses of consumers' decision making has broader

implications as well. Each regulatory decision has consequences for producers (as they lose or gain sales), for consumers (as they receive good or bad answers about products), and for regulators (as they gain or lose the power to define the public interest). Cumulatively, these decisions determine the roles of each group in society. The face of civil society depends on the extent to which citizens are treated either as idiots, unable to fend for themselves, or as sophisticates, able to cope with whatever choices face them. If consumers' abilities are overestimated, they may face bewildering messages that overflow with information, or they may face ostensibly simple messages that are couched in terms understood only by technical specialists. If consumers' abilities are underestimated, they may face unduly simple messages that limit their opportunity to make personally relevant choices. Consumers might even be denied freedom of choice if they are not trusted to exercise it effectively. As a result, products might be needlessly withdrawn from the market or restricted to supervised usage. The roles of governments and markets depend on similar considerations. As a result, people concerned with larger issues may weigh in on specific regulatory battles. The broader stakes may even create a willingness to sacrifice the good of a "minor" product or a "small" consumer population for the greater good of shaping the overall regulatory system in a desired way. These political considerations will necessarily be expressed in terms of whatever issues have legal standing. As a result, risk and benefit arguments may become hostage to strategic posturing motivated by other issues. This can further obscure the value trade-offs embodied in regulatory rulings. Systematic incorporation of behavior research is part of achieving balanced, responsible policies.

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