

Questions of Competence:

The Duty to Inform and the Limits to Choice

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Abstract

Many public policies embody assumptions about some individuals' competence to make some class of decisions. When that competence is underestimated, those individuals can be needlessly denied freedom of choice. When that competence is overestimated, those individuals can be denied needed protections. Questions of competence arise in policies as diverse as whether to make prescription drugs available over the counter, whether to declare martial law in an emergency, and whether to adjudicate adolescents as adults. We offer a general approach to assessing individuals' competence to make specific choices, under the conditions created by specific policies. Grounded in behavioral decision research, the approach characterizes policies by their ability to expand the envelope of competent individual decision making and reduce the need for paternalism.

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Introduction

Many of our decisions are shaped by government policies that reflect policy makers' beliefs about our competence to make those choices. For example, policies establishing disclosure requirements for investments and pharmaceuticals reflect beliefs about our competence to recruit and comprehend the relevant evidence. Policies regulating claims made about consumer products and political candidates reflect beliefs about our competence to evaluate them. Policies governing living wills reflect beliefs about our competence to anticipate personally unprecedented circumstances.

The stakes riding on these beliefs are high. If our competence is overestimated, then we may be denied needed protections. If our competence is underestimated, then we may be wrongly denied the right to choose. If ways to enhance our competence are underestimated, then we may lose chances for empowerment. If those opportunities are overestimated, then we may receive useless help (e.g., overly complex financial or medical disclosures) and be held responsible for its failure.

Assessments of decision-making competence are subject to known biases (Gilovich et al., 2002). *Outcome bias* leads to judging decisions by the outcomes that follow them, rather than by the thinking that goes into them. As a result, people facing

easy choices (e.g., among places to eat) seem more competent than people facing hard ones (e.g., among medical treatments). *Hindsight bias* leads to exaggerating the competence of people who experience good fortune and underestimating that of those who do not. *Defensive attribution* leads to deprecating the competence of people whom misery befalls, so that observers can feel less vulnerable to suffering a similar fate.

Beliefs about decision-making competence can also reflect motivated thinking (or even deliberate misrepresentation), when a policy's legitimacy depends on the perceived competence of those whose behavior it governs. For example, advocates of market-based policies want to see competent consumers (investors, patients, etc.), as do advocates of participatory policies (e.g., referenda, citizen advisory committees). Advocates of strong regulatory policies want to see incompetent consumers (investors, patients, etc.), needing that protection, as do advocates of policies that empower technocratic elites. Advocates of reproductive rights for adolescents make strong claims for teens' competence; opponents of adjudicating teens as adults make contrary claims (Scalia, 2005). Both cannot be right, at least without more discriminating accounts of the similarities and differences in these decisions and the teens making them (Parker & Fischhoff, 2005).

Sweeping generalizations about decision-making competence can stimulate useful public discourse, by encouraging partisans to assemble and defend examples supporting their positions. However, strategically chosen and interpreted examples are just that: things to consider, not systematic evidence. Sound policies require detailed analyses,

able to capture the heterogeneity in both the demands that decisions make and the skills of those making them (Bruine de Bruin et al., 2007).

An Approach to Competency-Based Policy Making

This chapter offers such a general approach to assessing and, where possible, improving, individuals' competence to make specific decisions, under the conditions created by specific policies. It illustrates the approach with risk-related decisions, in US policy contexts, chosen to suggest the variety of possible incentives and opportunities for implementing policies that enhance public decision-making competence. The examples vary in their topics (including drugs, pathogens, and contaminants), their policy-making locus (including regulators, courts, and emergency officials), and their decision makers (including teens, older men, hobbyists, and everyone). They are presented in roughly decreasing order of how explicit the decisions are, beginning with ones made at a clear point in time and ending with ones embedded in the flow of events.

Our approach follows the “traditional” behavioral decision research strategy (Edwards, 1954; vonWinterfeldt & Edwards, 1986):

(1) *Normative analysis*, identifying the best choices, using the available science to predict the outcomes of possible choices and decision makers' values to weight them.

(2) *Descriptive analysis*, predicting the choices that those individuals would actually make, under the conditions created by possible policies.

(3) *Prescriptive analysis*, characterizing the gap between the normative ideal and the descriptive reality, with each policy.

Determining the prescriptive implications of a normative-descriptive gap requires a value judgment. Among other things, policy makers must weigh the fates of different individuals. They might treat everyone equally or assign weights based on properties like age, health, pregnancy status, citizenship, or historical injustices (Fischhoff et al., 2007). Consider, for example, a choice between policies requiring just English or both English and Spanish on warning labels. Holding font size constant, the former allows more words, so that labels can address more problems or the same problems more thoroughly. However, that policy leaves Spanish-only speakers less protected. A third policy, reducing font size, could accommodate both languages, but lose users with limited vision (or aversion to fine print). A fourth policy, expanding warning label size, could allow more words or larger font, but crowd out benefit information. The prescriptive analysis makes these choices more explicit – which policy makers may or may not welcome.

The approach also allows clarifying the impacts of policies that honor procedural principles, like “freedom of choice,” “consumer protection,” “chances to learn from experience,” or “full disclosure.” For example, a First Amendment right to “commercial freedom of speech” has been invoked to expand the range of legal product claims. The result could be positive, if consumers can interpret the claims; negative, if not. “Full disclosure” has been advocated as a way to extract needed information from producers. The result could be positive, if consumers can extract the decision-relevant facts;

negative, if the clutter overwhelms them. The approach characterizes such policies by their effects on consumers' ability to make the choices that they govern.

Applying the approach requires contributions from multiple disciplines. Identifying the optimal choice requires decision analysis, informed by behavioral research (capturing individuals' values) and subject matter expertise (regarding expected outcomes). Predicting individuals' choices requires behavioral research, into how individuals interpret the choices that emerge under different policies. Evaluating the gap between the normative ideal and the descriptive reality requires expertise in law and philosophy. Choosing policies requires political judgment, informed by scientific assessments of impacts on outcomes that matter to policy makers.

Although described as sequential, these steps are inherently interdependent. Without knowing individuals' values, analysts cannot identify evidence relevant to their choices. Without knowing policy makers' values, analysts cannot properly disaggregate outcomes (e.g., by age, gender). Without knowing the sources of poor choices (e.g., lack of skills, facts, or motivation), policy makers cannot understand their options. And so on.

The following case studies illustrate the approach with risk-related policies. Other applications include avian flu (Fischhoff et al., 2006), sexual assault (Fischhoff, 1992), nuclear energy sources in space (Maharik & Fischhoff, 1993), nuclear weapons (Florig & Fischhoff, 2007), and sexually transmitted infections (Downs et al., 2004).

The core of each application is a normative model informed by descriptive and prescriptive research. How deeply each component is pursued depends on the policy context. For some applications, rough normative models suffice; for others, quantitative solutions are needed. Some require dedicated behavioral research; others can rely on existing results, showing general tendencies. Some allow testing prescriptive interventions; others barely invite suggestions for change. Because each example responded to a perceived opportunity (and, sometimes, an actual invitation) to influence policy, they do not represent a well-defined universe of policy choices that depend on assessments of competence. Rather, they illustrate the variety of possible applications and their, sometimes surprising, policy implications.

Applications

Saw Palmetto: Consumers' Competence to Make Decisions Created by Commercial Freedom of Speech

Policy Context. In the US, dietary supplements are a \$14 billion industry, with over half of Americans consuming at least one of the 29,000 products (FDA 2000a). Currently, the law treats supplements as “reasonably expected to be safe, unless adulterated.” FDA bears the burden of proof for demonstrating harm and for ensuring that label information is “truthful, non-misleading, and sufficient to communicate any risk.” Labels can make non-medical claims without FDA approval, but must be withdrawn, if FDA demonstrates that they are *potentially misleading* to a *reasonable*

consumer (FDA 2002b) (emphasis added). Thus, the policy rests on whether consumer behavior meets a normative standard.

Some supplement manufacturers and consumer advocacy groups have argued that consumers are competent to evaluate such claims. In *Pearson v. Shalala* (1999), 164 F.3d 650 (D.C. Cir.), the US Court of Appeals accepted this argument, ruling that consumers might benefit from an unverified claim, if they knew that they had to evaluate it and could do so. One commentator praised the ruling as ending “FDA’s paternalistic approach... based on the counterintuitive notion [that] consumers lack the sophistication necessary to evaluate truthful and non-misleading health information” (Emord 2000, p. 140). If FDA’s “counterintuitive notion” is accurate, though, the ruling denies consumers needed protection.

Eggers & Fischhoff (2004) analyzed this question for a supplement central to the litigation: saw palmetto (SP), a dietary supplement that might relieve lower urinary tract symptoms of benign prostatic hyperplasia (BPH), a chronic problem common among older men.

Step 1: Normative Analysis. Figure 1 shows the decision facing men with those symptoms. The options (the square *choice* node) are (a) consume the recommended saw palmetto dose, (b) consult a physician (seek MD), and (c) do nothing. One uncertain *outcome* (triangular node) is the change in BPH-related symptoms. Others are the health effects of prostate cancer and other conditions with similar symptoms. The circular

chance nodes capture the associated uncertainties. The probability of the other conditions should not depend on whether men self-treat with saw palmetto. However, it might take longer to discover those conditions, perhaps long enough to affect the chances of effective treatment (Coley et al., 1997).

The scientific evidence on saw palmetto (Marks et al., 2000; Schulz et al., 2002; Wilt et al., 1998) allowed creating a relatively simple decision tree. The tree omits side effects because they are too small to affect choices. It omits costs, because they, too, are small (\$10/month). It has a single dose option (the recommended one) because taking more has no known (positive or negative) effects (Ernst, 2002). A “take less” option could be added; it would have less chance of symptom relief and, hence, greater chance of having other problems diagnosed in time. Eggers and Fischhoff (2004) summarize that evidence in decision-relevant terms, taking outcome probabilities from medical evidence and values from studies of utilities for health states (Tengs & Wallace, 2000). The message emerging from the normative analysis is “Saw palmetto might be worth a try, but don’t neglect other possible sources of your symptoms.” The behavioral analysis asks, in effect, how well men can extract this, easily understood, message from the information available to them.

Step 2: Descriptive Analysis. The Court allowed any product claim, short of preventing or treating specific diseases, if accompanied by the 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” (FDA, 2002a). Mason and

Scammon (2000) found that people often ignore the disclaimer, hence might believe that FDA had approved the claim. Consumers who notice the disclaimer still might not understand its implications, perhaps assuming that FDA can regulate dietary supplements as stringently as food (GAO, 2000).

Whether such problems are severe enough to undermine men's competency to make these choices is an empirical question. Eggers and Fischhoff (2004) addressed it by asking older men to think aloud as they read, in turn, four labels with increasing detail: (a) *no health claim*, beyond what was inferred from the product name on a green background; (b) an *unqualified claim* of "improving prostate health"; (c) the same health claim, *qualified* by the Court-mandated disclaimer; and (d) *full information*, summarizing decision-relevant evidence in a drug fact box (Schwartz et al., 2009; Woloshin et al., 2008). After reading each label, respondents said whether they would use the product, if they had BPH symptoms, and for how long, if symptoms persisted. Given respondents' extensive study of the materials, we treated their choices after reading the fact box as the ones that they should make. For 55%, that choice was to take saw palmetto.

The interview transcripts provide rich qualitative detail regarding respondents' beliefs about supplements, labeling, and regulation. Most saw the health claim as advertising and the disclaimer as perfunctory (e.g., "for liability protection"). Many interpreted "prostate health" as referring to prostate cancer or sexual function. The (unqualified) health claim prompted many to offer higher estimates of positive effects than with full information. Adding the disclaimer decreased the product's perceived

efficacy for some respondents, while increasing it for others, who gave explanations like, “FDA doesn’t believe in alternative medicine.” The full information label sometimes increased judged side effects, sometimes reduced them. Almost all respondents said that they would check with their physicians, should symptoms persist. Gades et al. (2005) found that about 50% of men with lower urinary tract symptoms seek medical treatment.

Step 3: Prescriptive Analysis. Table 1 compares whether respondents *should use* saw palmetto with whether they said that they *would use* it, after reading each label. With No Claim, all those for whom the optimal choice is taking saw palmetto would miss its potential benefits (row 2). With the Unqualified Claim, most of them would use it (44% in row 1 vs. 11% in row 2), as would some for whom it was inappropriate (row 3). Adding the Disclaimer to the Unqualified Claim reduces appropriate choices, by discouraging some men who should try saw palmetto (row 1).

Policy Analysis. Table 1 predicts the distributions of outcomes with three policies, each embodied by a different label. The policy choice should depend on the weight that regulators assign to each cell. If they weight all cells equally, then they should prefer the Unqualified Claim, which produces the most appropriate choices (row 1+ row 4). They should prefer No Claim, if mistakenly taking the product (row 3) is much worse than missing its potential benefits (row 2). They should never add the Disclaimer, which is worse than the (somewhat misleading) Unqualified Claim.

Consumers are competent to make a decision, if the distribution of outcomes, under a policy, falls within regulators' tolerances. Here, although the Unqualified Claim label dominated the Claim+Disclaimer label, its outcomes would be acceptable only if the 77% correct choices (row 1+ row 4) outweighed the 22% incorrect ones (row 2 + row 3). Having 11% take saw palmetto inappropriately seems of little consequence, given that almost all respondents said that they would see a doctor, if symptom persisted, reducing the opportunity costs of trying saw palmetto. Given its limited efficacy, not much is lost by having another 11% fail to give it a warranted try. By the same logic, even the confusing disclaimer might allow competent choices, with this benign product and such moderately engaged, informed, and skeptical consumers.

A product that might produce similar conclusions is black cohosh, a supplement that might reduce menopausal symptoms. Its decision tree resembles that of Figure 1, with the only major risks arising from delayed treatment. Behavioral research might reveal similar consumer competence, perhaps reflecting heuristics like "Supplements are worth a try, but not for too long, if they're not working" and "Tell your doctors what you're taking, even if you expect them to be skeptical." With other products, though, the disclaimer might exact a high price, if (as seen here) consumers ignore it, brush it off as perfunctory, or have it remind them about the possibilities of alternative medicine. With most dietary supplements, the risks and benefits are unknown. Saw palmetto and black cohosh are unusual, in having been studied enough to be able to estimate their effects.

Even if a label produces acceptable outcomes, policy makers need not accept it. Schwartz et al. (2009) found that most people can understand fact boxes, summarizing the risks and benefits of possible treatments, like that used in the Full Information label. Consumers are better served by policies that require providing the facts needed to make sound choices, rather than just claims and disclaimers that “work well enough” in forgiving situations. Developing such messages requires analytical and empirical research. It should not be left to intuition, even that of well-intended jurists.

Plan B Morning-After Pill: Adolescents’ Competence to Make Reproductive Decisions

Policy Context. Plan B is an emergency contraceptive (EC) pill that reduces the probability of pregnancy, if two doses are taken within 72-120 hours of unprotected sex (von Hertzen et al., 2002). In August 2000, US FDA approved OTC sale of EC to women aged 18 and over, in outlets that have accredited pharmacies and avoid selling it to younger women. In 2003, the drug’s manufacturer, Barr Pharmaceuticals, petitioned FDA to approve OTC status for all women, in less restricted outlets. Such approval requires demonstrating the drug’s safety and efficacy without physician supervision (Pub. L. No. 82-215, 65 Stat. 648, 1951). The producer submitted clinical trial data, along with behavioral evidence regarding label comprehension and use, under simulated OTC conditions. An advisory panel (Sherman, 2004) recommended OTC status, by a vote of 23 to 4 (FDA, 2003). However, FDA’s Center for Drug Evaluation and Research (CDER), which governs prescription-to-OTC switches, denied approval (FDA, 2004). In

his explanatory note, CDER's acting director objected to extrapolating behavioral data from older adolescents to ones under 16, who might exhibit "impulsive behavior, without the cognitive ability to understand the etiology of their behavior (GAO, 2005, p. 46)." He also expressed concern about "the potential impacts that the OTC marketing of Plan B would have on the propensity for younger adolescents to engage in unsafe sexual behaviors due to their possible lack of cognitive maturing compared to older adolescents (GAO, 2005, p. 5)."

The parties to this rulemaking invoked opposing theories of teen decision-making competence. Critics of OTC status predicted that making Plan B more available would encourage unprotected intercourse, with teens knowing that they can still prevent pregnancy – so that Plan B becomes Plan A. Sexually transmitted infections (STIs) would then increase, even if unplanned pregnancies did not. Some critics worried about increased intercourse among unmarried teens per se, an outcome with no status under the law (FDA, 2003). In contrast, proponents of OTC status argued that teens were sufficiently competent as decision makers that they would not only maintain their current contraceptive practices, but make better choices given the additional option. These advocates also predicted that reducing unintended pregnancies would reduce abortions.

Step 1: Normative Analysis. The deliberations over Plan B addressed two decisions within FDA's statutory public health mission: how adolescents choose to protect themselves against (a) unwanted pregnancy and (b) STIs. Some panel members seemingly considered decisions outside the statutes: whether adolescents have sex and

abortions. Figure 3 analyzes one decision whose options and outcomes clearly fall within FDA's mandate: whether women use Plan B after suspected contraceptive failure. Krishnamurti et al. (2007) provide additional details on this choice and two others: whether women have sex and what protection they use, if they do.

Predicting the outcomes in these normative analyses is generally straightforward, as the health outcomes are often well studied. Evaluating the outcomes is more difficult. Some outcomes are valued similarly by most women, hence might be assessed with standard utility measures; others depend on the woman facing them. Some women, in some life situations, find unplanned pregnancies enormously disruptive; others take them in stride. Some women view pregnancies avoided by Plan B as abortion; others do not. Teen (or unmarried) sex is acceptable to some people, sinful to others. These normative analyses used the values of the women making them. Decisions optimal for them might be unacceptable to people with different values (e.g., regarding the morality of extramarital sex or various birth control options).

Step 2: Descriptive Analysis. Krishnamurti et al. conducted semi-structured, open-ended interviews with 30 adolescents from high-risk populations, whose ages straddled 16 years old (critical to FDA's decision). The interviews followed a mental-models protocol (Morgan et al., 2001), which directs respondents increasingly toward issues in the normative analysis. Such interviews have the statistical power to reveal large group differences. Their results guide the design of structured surveys suited to larger samples (which confirmed the results reported here).

As with any other study, the results of these interviews should be interpreted in the context of general scientific knowledge. In this case, a broad summary (Fischhoff, 2008; Reyna & Farley, 2006) might be that, by the mid-teen years, most adolescents have roughly the cognitive decision-making skills of adults. GAO (2005) noted that FDA's Plan B decision departed from earlier rulings that had found it "scientifically appropriate to extrapolate data from older to younger adolescents"(p.5), consistent with the research.

Whatever their skills, teens' knowledge of a topic depends on their opportunities to learn about it, through exposure to information (e.g., instruction, media, word-of-mouth) and experience. Krishnamurti et al. found that their respondents generally said that they (a) knew about Plan B; (b) would not use it as their primary birth-control method (usually citing discomfort or cost); (c) would consider it, if they suspected an unplanned pregnancy; (d) saw barriers to access that expanded OTC status would reduce; and (e) had considered whether Plan B constituted abortion. Based on these accounts, Krishnamurti et al. concluded that expanded OTC status would not affect sexual behavior or the choice of primary birth control method; however, it would increase Plan B use when needed. They also found considerable confusion about the timing of usage, with more teens underestimating the effective period. The only observed difference between teens over and under 16 was that younger teens saw greater costs and less benefits to Plan B, hence were less likely to use it.

Step 3: Prescriptive Analysis. Based on these interviews, expanded OTC availability would affect only one decision: Plan B use after unprotected sex. There, it would allow some young women to achieve a desired end that is currently infeasible. Although the teens' decision-making processes were thoughtful, they were not always well-informed, particularly regarding Plan B's effective period. Women who underestimate effectiveness will not receive full benefit from greater availability. Those who overestimate it will not receive the benefits that they expect.

Policy Analysis. In terms of the health outcomes in FDA's regulatory mandate, these results suggest that expanded OTC availability dominated limited availability: There should be fewer unplanned pregnancies, with no changes in other health effects. The largest gap in teens' knowledge, the period of EC effectiveness, should not be hard to close, with a suitable communication channel. Emotion might, in principle, undermine the cognitive competencies seen here (and in other studies). In practice, though, it seems that OTC availability should reduce emotional pressure in the one decision where EC seems to play a role: dealing with unplanned unprotected sex.

Going beyond FDA's mandate allows considering abortion-related issues. In the study, most respondents who were opposed to abortion thought that Plan B was used too soon after intercourse to constitute abortion. For them, expanded availability would allow more optimal choices. That conclusion should be rejected by individuals who oppose abortion and place conception at intercourse. They should fault such teens' beliefs (about how Plan B works), but not their cognitive abilities.

Carotid Endarterectomy: Medical Informed Consent

Policy Context. In the US, roughly half of the states hold physicians to a *materiality* standard, when securing informed consent. That is, they must ensure that patients understand all facts material to their decisions. (The other states have a *professional* standard, requiring adherence to common practice.) That standard implies a normative analysis, ordering information by its materiality, signaling when physicians can stop communicating, because they have conveyed all that patients need to know. Having that standard should provide some protection against unfair legal judgments, when things go wrong and patients claim that they were not adequately informed. Merz et al. (1993) offer an approach to formalizing the materiality standard, which they illustrate with a common surgical procedure whose large risks and benefits have engendered extensive research on expected outcomes.

Carotid endarterectomy, scraping out the artery to the brain, can reduce stroke risk for patients with atherosclerosis. However, many things can go wrong, ranging from death and iatrogenic strokes to headaches and broken teeth. Some risks are specific to the procedure; others are part of major surgery. The full list is a lot to consider, when facing difficult tradeoffs between these risks and the expected benefits of treating a life-threatening illness. “Informed consent” is a vague policy without specifying what patients need to know.

Step 1: Normative Analysis. The method creates hypothetical patients, for whom surgery would be the optimal choice were there no risks (and were money no object). These “patients” vary in their physical condition, represented by probability distributions over possible outcomes, and in their personal values, represented by utility distributions over the outcomes. Patients are created by sampling values from these distributions (with the simplifying assumption of independence, in this application). The expected utility of surgery is calculated for each such patient, ignoring all risks. It is positive, given how because the population is created. Expected utility is then recalculated, incorporating knowledge of each possible side effect. A side effect’s materiality is defined as how often it gives the surgery negative expected utility, so that it is no longer recommended.

Merz et al. found that only three side effects should matter to many of these simulated patients: About 15% should decline surgery, if told the risk of immediate death; another 5%, if told the risk of iatrogenic stroke; and 3% more, if told the risk of facial paralysis. Learning about other risks would tip the scales for very few patients.

Step 2: Descriptive Analysis. Because few candidates for this surgery have faced it before, they cannot be expected to have authoritative risk information. As a result, Merz et al. (1993) conducted no behavioral research, assuming that all information would have to be conveyed. This strategy would be flawed, if patients held strong beliefs about other risks that communications about the three focal risks would ignore (Downs et al., 2008). In cases where there are many material facts, assessing current beliefs allows identifying those that go without saying – and can be skipped in favor of new ones.

Step 3: Prescriptive Analysis. Thus, effectively conveying the three major side effects would keep 15-20% of these potential patients from undergoing surgery that is suboptimal for them (because its risks outweigh its benefits). Based on risk-communication research (Fischhoff, 2009; Woloshin et al., 2008), that task seems manageable. Each critical side effect involves a fairly familiar event (death, stroke, facial paralysis), with a fairly large probability (not, say, 1/46,000). Thus, it should be possible to afford patients the knowledge needed for competent decision making. A greater prescriptive challenge may be helping patients to be rational enough to take advantage of that information. The empirical-analytical question is how sensitive these choices are to imperfect information integration (vonWinterfeldt & Edwards, 1986).

Policy Analysis. If the materiality standard is implemented in this way, the duty to inform is fulfilled once the three critical side effects are communicated. Doing so absolves physicians of responsibility for suboptimal choices that reflect poor information integration, rather than poor understanding. Focusing communication on the most material facts should improve patients' information integration by protecting them from "full disclosure" practices that drown them in immaterial facts. Full disclosure is needed to perform the analyses that identify the critical risks (and to ensure that nothing is hidden). However, forcing patients to sort through all the details can undermine their competence.

Materiality analysis can also help to implement research-funding policies, by assessing the value of potential results for patient decision making. Those analyses could help patients decide whether to wait for clinical trial outcomes.

Methylene Chloride-Based Paint Stripper: Consumer Competence to Make Decisions Created by Voluntary Self-Regulation:

Policy Context. In the mid-1990s, the International Agency for Research on Cancer declared the solvent methylene chloride a probable carcinogen. Methylene chloride also gives off carbon monoxide, which can cause heart attacks in confined spaces. One use of the solvent with no clear substitute is stripping paint. Although industrial users might be required to take protective measures (e.g., ventilating hoods, respirators), home users must protect themselves. If they can, then it is safe to leave paint stripper on the market. That depends on their competence to make decisions about how to use the product and about whether it has acceptable risks relative to its benefits.

Step 1: Normative Analysis. Riley et al. (2001) characterized consumers' health risks with an analysis sensitive to their usage patterns. It predicted consumer exposures based on physical principles (e.g., air circulation, chemistry), whose interactions had been calibrated under laboratory conditions, and on the effects of actions that users might decide to take (e.g., open windows, wait in corner while stripper is curing). The analysis created a *supply curve*, ordering the actions by decreasing marginal effectiveness for reducing exposure. That order is the logical one for adopting risk-control measures

(assuming similar costs). The analysis found that, for many jobs (varying in room size, duration, etc.), consumers could greatly reduce their risks by deciding to implement two simple actions: opening a window and having a fan blow outward.

Step 2: Descriptive Analysis. Interviews with paint stripper users found that they (a) were motivated to use control measures, (b) could easily understand the two key measures, and (c) seemed realistic about their ability to execute them (e.g., “I’m not going to open a window in the winter, however bad the fumes”). However, those actions were sufficiently unintuitive that consumers needed to have them explained. For example, without instruction, many would have fans blow inward, in order to feel the airflow, not realizing that internal circulation left concentrations unchanged. Many also reported choosing actions whose ineffectiveness could be easily explained (e.g., gloves get ruined because the solvent dissolves them; fumes diffuse, so don’t bother crossing the room while the solvent cures). Thus, users appeared competent to make sound choices, if provided the relevant information.

Step 3: Prescriptive Analysis. In lieu of in-home observation of consumers’ usage decisions, Riley et al. (2001) estimated exposures for users who understood and conscientiously followed everything they read, but had different labels and reading patterns (e.g., just the instructions, just the warnings, just the bolded material, just the first five items). The analyses found wide variation in exposures, across labels and reading patterns. Some labels provided useful information, whatever the reading strategy; some had no information on reducing exposures anywhere. Thus, consumers

are competent to make sound usage decisions, if they receive relevant information about how to use the product. Without that information, they cannot know what risks they are taking or whether to use the product. Predictions of actual label-reading behavior, and resultant risk levels, could use direct observation or general patterns (Wogalter, 2006).

Policy Analysis. Flawed communications limit otherwise competent consumers' ability to make effective choices. As a result, they may purchase unduly risky products and use them in needlessly risky ways. Or, consumers may forego useful products and take needless precautions. When a product's risks and benefit depend on how it is used, its label is as much a part of the product as are its physical constituents. Regulators should want to know what consumers take away from labels, so that they can ensure proper protections. Producers should want the same knowledge, so that they can help consumers get the greatest value from their products – and defend themselves against charges of failing to fulfill their duty to inform. Individual firms produced the labels in this study. The great variation in the value of the information that they provided (and the associated risks) suggests that such voluntary self-regulation was inadequate.

Cryptosporidium: Consumer Competence to Cope with Contamination Emergency

Policy Context. *Cryptosporidium* is a common protozoan parasite, with mammalian hosts, that can infect public water supplies, typically through uncontrolled sewage discharges and fecally contaminated runoff after heavy storms (e.g., from feedlots, deer). Typical water treatment systems cannot fully remove or deactivate it.

Symptoms, appearing after 1-7 days, include nausea, vomiting, diarrhea, cramps, and low fever. Although cryptosporidiosis has no medical cure, most infected individuals recover, many without exhibiting symptoms. However, the disease, which attacks the liver, can be fatal to immunocompromised individuals (e.g., those with AIDS). Water and public health authorities have a duty to inform consumers so that they can make competent water-usage decisions, namely when and how to use boiled or bottled water.

Step 1: Normative Analysis. Casman et al. (2000) created a model predicting the health effects of a *Cryptosporidium* intrusion. The model includes inputs from microbiology (dose-response relationships), civil engineering (filtration, testing), ecology (upstream land use), communication research (dissemination of “boil water” notices), and psychology (perceived risk, actual response). It allows assessing when consumers are competent to make water-usage decisions, under the conditions created by different intrusion scenarios. Among other things, it examines how quickly they receive messages, how adequately they boil water, and how much they rely on personal testing (which has little value).

Step 2: Descriptive Analysis. The model uses estimates from observational studies of consumers’ water-use decisions in past intrusions, which have found that people often use improperly treated water. New interviews found that the main sources of these poor decisions were ignorance (about how to boil water well enough to destroy the parasite) and suspicion (about how seriously to take warnings). Both the procedures and the context are simple enough that it should be possible to explain them well enough

to allow most people make competent choices. As a result, the competence of consumer choices depends on whether they get sound messages in time to act.

Step 3: Prescriptive Analysis. The model was used to predict health effects under the conditions created by plausible intrusion scenarios – varying, for example, in how long it took to detect and repair problems. One set of simulations examined the effects of ensuring that all consumers received sound messages, as soon as an intrusion was established. Such communication was found to have no effect, a result that was traced to *Cryptosporidium* testing being too slow for messages to arrive in time to prevent exposures. As a result, relying on “boil water” notices ensures suboptimal choices, by individuals who could be competent, given the right information.

Policy Analysis. In this case, the analysis revealed an inherent flaw in a standard policy, relying on consumer decision making to manage risks – a faith that deflected attention from other possible policies. One other possibility is improving the speed of detection, so that officials can provide timely warning. Another possibility is reducing the risk, through better land use or water purification. A third possibility is routinely providing highly vulnerable populations with safe water. Repeated with contaminants allowing rapid detection (e.g., some *E. coli* strains), the analysis might reveal that timely, comprehensible warnings would allow effective consumer decision making. Consumers should not be blamed for negative outcomes, when they cannot help themselves.

Emergency Evacuation: Citizen Competence to Make Voluntary Decisions

Policy Context. Mass emergencies can be defining moments for a society (Boin et al., 2005), in which leaders' decision-making competence will be examined intensely. One aspect of that examination will be how their actions affected their citizens' decision making. Were citizens afforded the information needed to make effective choices? Did they have the resources needed to act on that information? Were they treated like competent adults? Was martial law imposed when they could have managed without it?

Emergency plans must make some assumptions about the public's decision-making competence under stressful conditions. One such class of hazards is terror attacks with contaminating materials, like radioactive dispersion devices (RDDs), or "dirty bombs." RDDs use ordinary explosives to spread radioactive materials, causing immediate casualties from the blast, long-term casualties from radiation poisoning, and potentially great social and economic costs. The extent of that disruption will depend on their leaders' perceive competence. That will depend, in turn, on how well those leaders assess their public's competence. If they expect too much, then the public will be denied needed protection. If they expect too little, the public will be denied deserved freedom.

Step 1: Normative Analysis. Dombroski et al. (2006a, b) developed a general model for predicting the health effects of RDD attacks, with one predictor being citizens' decisions about evacuating or sheltering in place. The model incorporates features from research into explosive impacts, aerosol dispersion, traffic flows, dose-response relations, and so on. Choosing values for model parameters (e.g., location, time of day, explosive

force, contaminant, weather) produces attack scenarios specific enough to predict morbidity and mortality (from which economic and social effects might be predicted). For public health officials, the optimal response minimizes those health effects. One key decision is whether to recommend evacuation or sheltering in place. For individual citizens, the optimal response minimizes those risks, subject to other concerns (e.g., protecting family members, helping co-workers, demonstrating resilience). For them, one key decision is whether to follow that recommendation.

Step 2: Descriptive Analysis. Estimates for most model parameters were taken from the research literature. However, although there are many studies of emergency behavior, they are rarely in model-ready form. Therefore, judgments of the model's behavioral parameters were elicited from ten social science experts and 36 local disaster specialists. These experts predicted behavior for variants of a scenario involving a 10-kilo Cs-137 RDD, exploded at Pittsburgh's USX Tower, at 10am on a summer weekday. Their judgments included the percentages of citizens complying with instructions to evacuate or shelter in place, when at home and at work. These experts generally agreed about citizens' decisions. Consistent with historical experience, although not with popular myth (Tierney, 2005; Wessely, 2005), the experts expected no panic. Rather, they expected most people to follow instructions, with higher rates for sheltering at home and evacuating from work.

Step 3: Prescriptive Analysis. Incorporating the experts' judgments in the model revealed that, for this scenario, the predicted rates of compliance with official instructions

(60-80%) are good enough to minimize health effects. Enough people would shelter in place to keep the roads open enough to allow first responders to treat those injured in the blast, while not trapping evacuees in a radioactive cloud. Little would be gained by making the recommendation compulsory.

Policy Analysis. These results suggest that citizens are competent enough to make choices that achieve generally optimal outcomes. Thus, voluntary compliance should satisfy a consequentialist regulatory philosophy. It should have additional procedural value for demonstrating faith in the public, compared to compulsory policies, like martial law. That value underlies the commitment to, “Keep the public fully informed -- tell what we know, tell what we don’t know, and tell it often. ... Maintain credibility and public trust, by providing accurate, science-based information.” (DHHS, 2006) Producing and disseminating useful information is one way to earn trust.

Strategies for Competence Assessment

Reprise

More or less the same kinds of (ordinary) people, with more or less the same general decision-making skills, were involved in each of these examples. Yet, their competence emerges differently in each, depending on the difficulty of the choice and the adequacy of others’ attempts to fulfill a duty to inform. Normative, descriptive, and

prescriptive analyses allowed evaluating proposed policies, in terms of how well they fit the competence that individuals bring to them and to design better ones.

According to these analyses:

With saw palmetto, the policy of allowing any non-health claim, if accompanied by a court-mandated disclaimer, created decisions that consumers were competent to make. That occurred despite the disclaimer's flaws, as a result of the product being benign and consumers being skeptical. Taking saw palmetto should not hurt them or lead them to delay medical care too long. The disclaimer's main impact is leading some consumers to forgo a product that might help them. With other products and consumers, the policy might have much worse effects.

With Plan B, young women should be competent to make the decisions created by the policy of expanded OTC availability. It should help them to avoid unwanted pregnancies, without violating their abortion views. Expanded availability should not affect their decisions about sexual behavior or contraceptives.

With carotid endarterectomy, most patients should be competent to make the decisions created by a policy of focusing patient briefings on the most material facts. In states with a materiality standard, conveying those few, simple facts might allow physicians to claim to have secured informed consent.

With methylene chloride paint stripper, most consumers would not be competent to make the decisions created by the current policy of allowing producers to design their own labels. However, the critical facts are simple: decide to use the product only if you can have a fan blow outward through an open window. Thus, a policy that mandated labels with that information should allow competent choices.

With *Cryptosporidium*, consumers are not competent to make water usage decisions, under the conditions created by a policy of relying on them to protect themselves – because critical information will not arrive in time. In effect, such a policy asks consumers to do the impossible, whatever their decision-making skills. It might allow them to make competent choices about contaminants with faster testing.

With the radioactive dispersion device scenario, citizens are competent to decide whether to obey recommendations to evacuate or shelter in place. Trusting that competence should enhance citizens' trust in their authorities. Thus, a policy of making clear recommendations should dominate draconian policies, like martial law.

Organizing for Assessing (and Improving) Decision-Making Competence

Sweeping claims about decision-making competence cannot do justice to the diversity of decisions and decision makers. Blanket claims of competence leave some people without needed protections. Blanket claims of incompetence deprive some of deserved freedoms. Blanket claims create the temptation of working backward from

desired policies to behavioral assumptions that justify them. An incompetent public suits those who favor strong regulations and technocratic management. An incompetent public suits those who favor free markets and participatory processes. A disciplined approach, combining empirical and analytical research, is needed to determine the legitimacy of such policies.

Executing this approach to assessing (and improving) decision-making competence requires an interdisciplinary team, with

a. *Subject-matter experts*, able to identify the decision options and characterize the processes determining their effects;

b. *Decision analysts*, able to estimate the risks and benefits of those options, showing the facts most relevant to decision making – and competence;

c. *Social scientists*, able to assess decision makers' beliefs and values, guide attempts to enhance competence, and evaluate their success; and

d. *Designers*, able to implement measures that achieve theoretically possible competence .

Assembling such a team requires leadership. Often, policy-making organizations are dominated by experts from one field, with little interest in collaborating with others. They may want to avoid sharing scarce resources. They may not recognize the limits to their own expertise. When such organizations expand, they face the challenge of evaluating unfamiliar expertise. If they cannot tell “what good is” and select poor representatives of another field, they may both get poor advice and devalue that field.

Once present, these experts must be coordinated. A strong team will accept ideas from anyone. However, it must assign responsibility for each task to the appropriate experts. Subject-matter experts can best predict that outcomes that concern decision makers, but social scientists are needed to assess what those outcomes are. Subject-matter experts will know which facts are central to their professional community, but decision analysis are needed to determine their relevance. System designers will know how to get messages out, but social scientists are needed to determine how well their content is absorbed. Social scientists will know how difficult tasks are, but decision analysts are needed to assess how sensitive decisions are to those effects.

Once assembled and coordinated, the competence-assessment team must be integrated into the policy-making process. Figure 4 shows an organizational model with that goal. Taken from the quasi-governmental Canadian Standards Association (1997), it is consistent with recommendations from HM Treasury (2005), National Research Council (1996), and the Presidential/Congressional Commission on Risk (1997), among other bodies. The center of the figure depicts a standard policy-making process, unusual only in evaluating each stage, before proceeding to the next (with the implicit possibility of never finishing). Notably, each stage requires two-way risk communication. For example, the Initiation stage entails experts learning which issues matter to those whom a policy affects and telling them how those issues will be addressed. These communications might be direct or indirect, with social researcher soliciting views and conveying results.

Such a process allows considering decision-making competence early enough to shape the design of policies and mid-course corrections. It invites recruiting the kinds of expertise needed to make the work *behaviorally realistic*, in its assumptions about individuals' ability to secure, comprehend, and use information, and *analytically sound*, in its sensitivity to the heterogeneity in people's abilities and decisions. Without such integrated expertise, it is impossible to do justice to individuals' needs and limitations, and create policies that afford them as much autonomy as they want and can handle.

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Table 1. Predicted optimality of consumer choices with alternative saw palmetto labels

| Normative Decision | Predicted Decision | Label | | |
|--------------------|--------------------|-----------|-------------------|------------------|
| | | No Claim | Unqualified Claim | Claim+Disclaimer |
| Should Use | Would Use | | | |
| Yes | Yes | 0% | 44% | 27% |
| Yes | No | 55 | 11 | 27 |
| No | Yes | 0 | 11 | 13 |
| No | No | 45 | 33 | 33 |

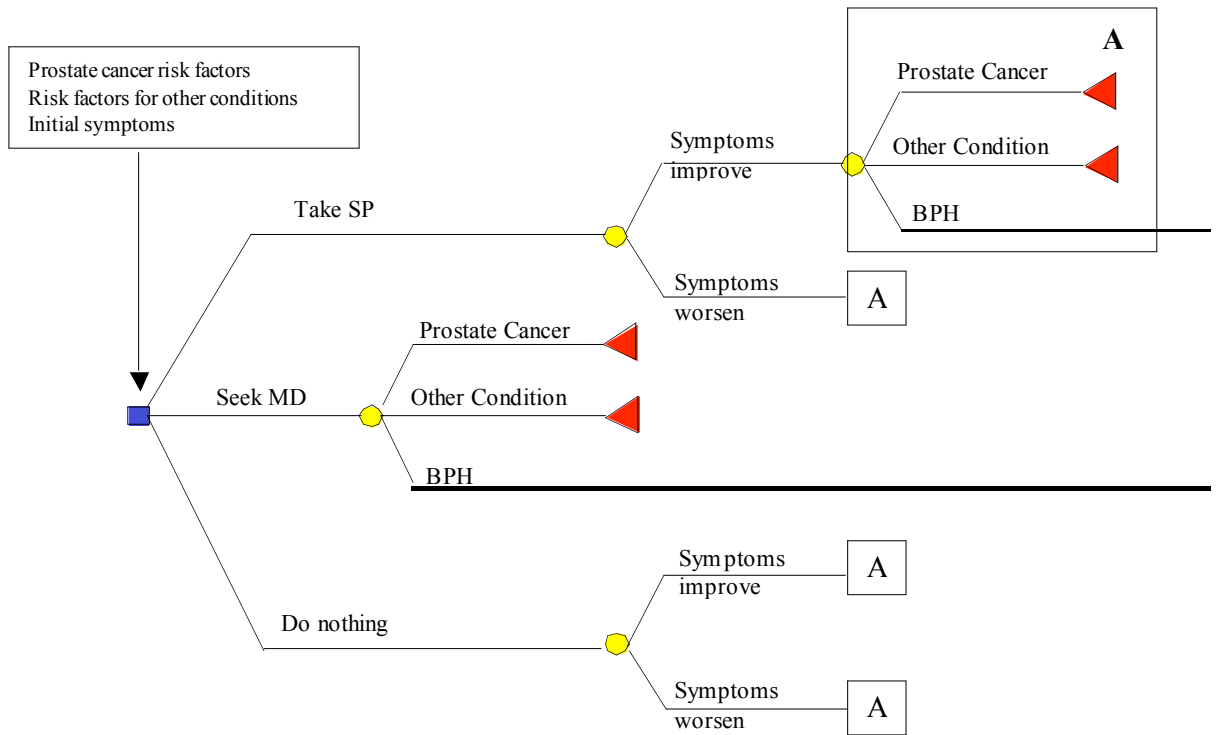
Note: The optimal decision (should consume) reflects the choices of respondents who studied the full disclosure label. Bold indicates appropriate decisions. See Eggers & Fischhoff (2004) for details.

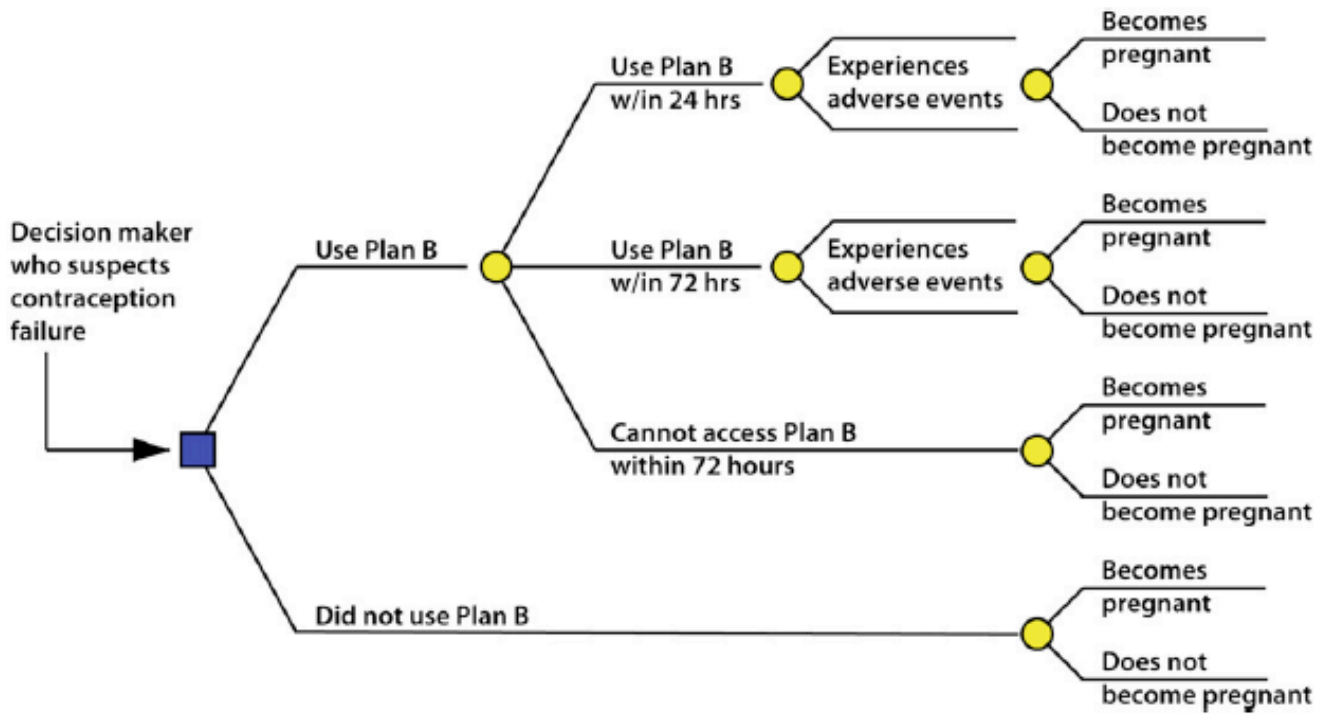
Figure Captions

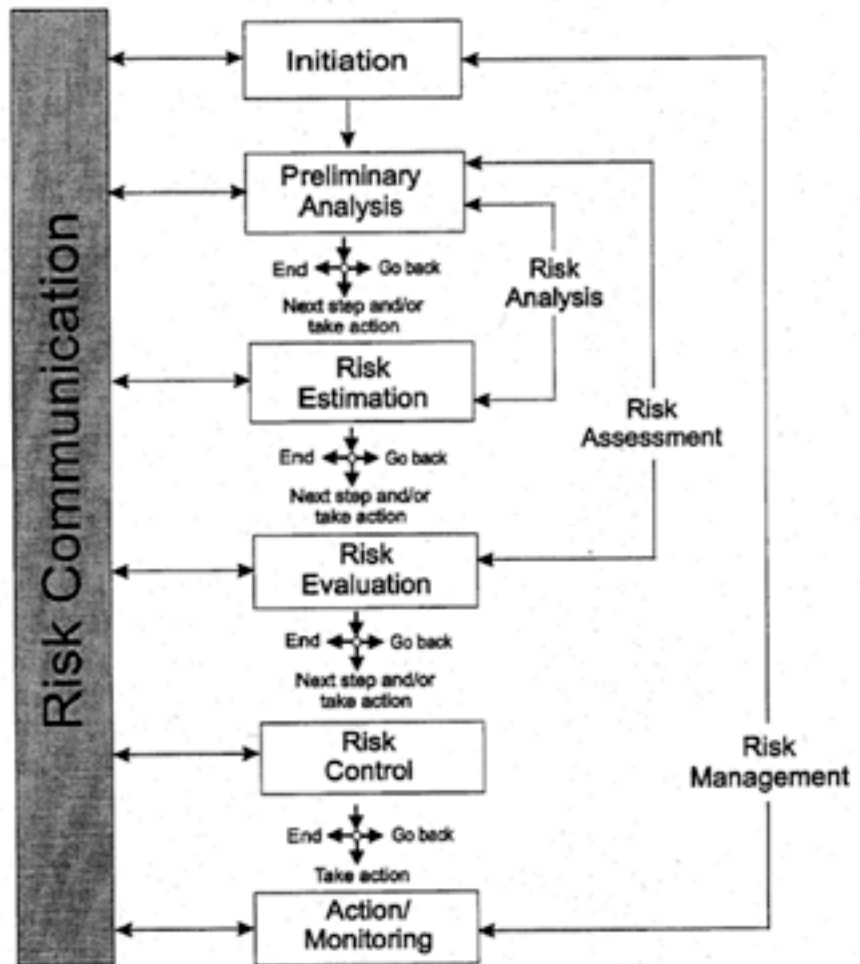
Figure 1. Decision tree for men considering saw palmetto (SP) as a treatment for lower urinary track problems. Other decision options (square node) are getting medical help (Seek MD) and doing nothing. The primary uncertainty (circular node) for Take SP and Do Nothing is how symptoms will respond. For Seek MD, it is whether the diagnosis is benign prostatic hyperplasia (BPH), prostate cancer, or some other conditions. The outcomes (triangles) depend on the underlying condition and how it responds to treatments, which will depend on how soon it is diagnosed. Box A reflects outcomes with delayed diagnosis. Source: Eggers & Fischhoff (2004)

Figure 2. Decision tree for women considering the use of emergency contraception, contingent on suspecting failure of contraceptive method. Source: Krishnamurti, Eggers & Fischhoff (2008)

Figure 3. Source: Canadian Standards Association (1997)







Note: Risk communication with stakeholders is an important part of each step in the decision process.

Figure 2
Steps in the Q850 Risk Management Decision-Making
Process — Simple Model