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Breaking Ground for Psychological Science: The U.S. Food and Drug Administration

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The U.S. Food and Drug Administration (FDA) regulates products accounting for 20% of U.S. consumer spending. Many of its actions depend on assumptions about behavior. Will people heed food recall notices? Will they follow medication schedules? Will they have realistic expectations regarding the benefits and risks of new products? Over time, FDA has increasingly made psychology integral to its processes for answering such questions. That progress has come when windows of opportunity have found psychologists with science relevant to FDA's needs, FDA with staff who can translate that research into agency terms, and a regulatory arena that can accommodate behavioral evidence. These experiences suggest opportunities and obstacles for psychologists hoping to apply their science to the public good.

Keywords: FDA, communication, policy, risk, translation

Effective government programs address public needs by either creating better options (e.g., limiting transfats, mandating fuel efficient vehicles) or helping people to choose among existing ones (e.g., financial product disclosures, EnergyStar labels). Psychology has a reservoir of knowledge for designing and evaluating such programs, whose potential was recognized in President Obama's recent executive order on behavioral science (The White House, Office of the Press Secretary, 2015) and creation of the Social and Behavioral Sciences Team within the National Science and Technology Council (https://sbst.gov/). To realize that potential, though, psychologists must find their way through the political, legal, bureaucratic, and budgetary mazes surrounding the programs that their science could inform.

That process can be relatively straightforward when a new agency includes psychology as a core discipline, as with the recently created Consumer Financial Protection Bureau and Center for Tobacco Products. It can be more difficult when psychological evidence is unwelcome, lest it challenge existing policies based on ad hoc behavioral assumptions. It can be more difficult still when agencies are dominated by staff who barely recognize psychology as a science (e.g., many natural scientists and engineers).

The present narrative traces my experience with attempting to increase psychology's role at one agency, the U.S. Food and Drug Administration (FDA). It suggests lessons for expanding psychology's role at other agencies, even ones as technically focused and politically scrutinized as FDA. The narrative includes failures as well as successes, both to show potential obstacles and to encourage perseverance when psychology is waylaid for reasons unrelated to its value. It is also incomplete, insofar as it reflects just what I have seen, heard, and inferred about complex processes with many players, none of whom have the full picture.

The Need for Psychological Science in FDA Regulation

FDA regulates products that account for 20% of U.S. consumer spending. Its success depends on its understanding of human behavior. Sometimes, success means encouraging choices, such as getting people to stop smoking, avoid tainted food, or use medications properly. At other times, success means helping people to make informed choices without taking a position on what those should be. For example, FDA may approve a prescription drug knowing that many patients will decide not to take it, once they understand its expected benefits and risks.

To do its job, FDA needs to understand both products and consumers. In the case of pharmaceuticals, FDA's analysis of the products involves examining raw data from clinical

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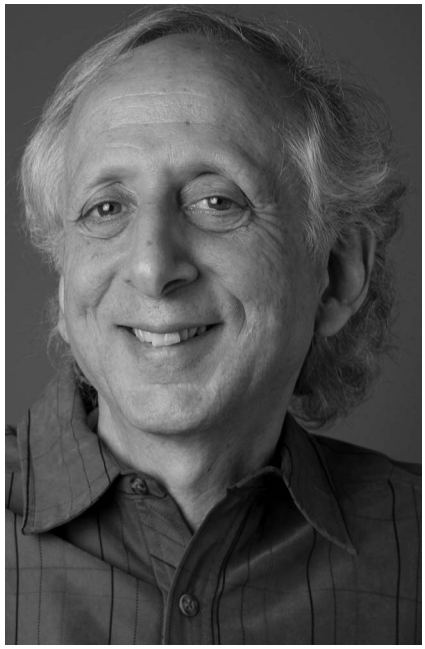

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and nonclinical trials, alongside producers' estimates of expected benefits and risks. That process typically takes months, as draft findings are revised in response to comments from colleagues, supervisors, and advisory panels. Before the advent of electronic submissions, a common sight at FDA's White Oak, Maryland, headquarters was staff members coming and going with rolling half-suitcases full of review documents.

FDA's analysis of behavior asks two questions. One is how actual patients might use a drug differently than patients in the trials (e.g., in terms of taking it as prescribed and noticing side effects). The second is how patients and their health care providers will view the tradeoffs that the drug entails (e.g., some chance of symptomatic relief vs. some chance of acute side effects). A drug's value is limited unless potential users receive and appreciate its expected benefits and risks.

Although dominated by natural scientists, physicians, and lawyers, FDA has long had some psychologists on its staff, in position to recruit outside researchers and instruct them in the ways of the agency. Over time, these engagements have expanded psychology's role at FDA, including participation in perhaps its most visible activity: deciding whether drugs can go on the market.

Patient Package Inserts

Late in the Carter Administration, FDA staff invited Paul Slovic, Sarah Lichtenstein, and me to comment on a proposal for revising the patient package inserts (PPIs) that then accompanied a few select prescription drugs (e.g., oral contraceptives, hormone replacement therapy). As psychologists, we quickly saw that the PPIs violated basic principles of effective communication. They were dense, jargon laden, and obscurely organized, so much so that a patient might reasonably take one look at a PPI and discard it as useless. Moreover, when we reviewed the content of PPIs, we found that even patients who read them in their entirety might not find the information needed to decide whether to take a drug. Critical facts were missing entirely or hidden in plain sight, buried in irrelevant details. Indeed, even physicians could struggle to find the quantitative estimates of risks, benefits, and uncertainties essential to informed decision making.

We were eager to apply our science, behavioral decision research, to improving the PPIs (Edwards, 1954; Edwards & von Winterfeldt, 1986; Fischhoff & Kadvany, 2011; Yates, 1989). That would entail *formal analysis*, identifying the facts critical to patients' decisions; *empirical research*, identifying gaps between what patients need to know and their existing beliefs; and *interventions*, closing those gaps. We were optimistic about getting a chance to contribute, because the psychologists who approached us were trusted insiders, ready to guide our work, thereby providing FDA *absorptive capacity* for psychological science (Cohen & Levinthal, 1990). However, the PPI reform initiative faded after the 1980 election, a casualty, I assumed, of the incoming administration's distrust of regulation—even when promoting consumer information that efficient markets need.

Consumer Medication Information

Late in the first Clinton Administration, a related window opened, when FDA asked Michael Wogalter (NC State) and me for advice on the consumer medication information (CMI) sheets meant to accompany prescriptions (with information provided and distributed by independent publishers). FDA even asked us to become special government employees, so that it could vet us for conflicts of interest.

Developed over the intervening 15 years, CMIs appeared to be more readable than the PPIs. However, as vital as sound information is to patients' welfare, there was relatively little evidence regarding CMIs' effectiveness. One barrier to collecting such evidence was the requirement that any survey or questionnaire administered by FDA (or other federal agency) secure Office of Management and Budget (OMB) approval under the Paperwork Reduction Act (PRA) of 1980 (revised in 1995). As interpreted by OMB, the Act applies not just to Internal Revenue Service forms (and the like), but also to behavioral research that involves completing forms (broadly defined). Demonstrating that a study does not impose an unreasonable paperwork burden on the American people can mean a 2-year process of announcing its design in the *Federal Register*, opening a docket for

comments, posting responses, offering a revised design, and so on.

In parallel, the U.S. Pharmacopeial Convention had developed 81 pictograms related to drug use (http://www.usp.org/usp-healthcare-professionals/related-topics-resources/usp-pictograms). Unbounded by the PRA, it subjected each pictogram to 50 think-aloud pretests (Ericsson & Simon, 1994; Merton, 1987), in which lay respondents reported their thoughts as they inferred its meaning. As reported at a hearing on CMIs, one troubling finding was that some people interpreted a red circle with a slash over a pregnant woman as meaning that the product was a contraceptive, whereas others thought that pregnant women should avoid it. The pictogram studies, coming from outside the regulatory process, had little apparent impact within it, showing a limit to the strategy of creating tools, hoping that they will, somehow, be adopted.

Although I had nothing to hide, I declined the invitation to become a special government employee given the paperwork involved. Mike Wogalter accepted, but was never called. Eventually, FDA chose not to undertake the laborious, uncertain process of conducting systematic empirical evaluation of CMIs' impact on patient and provider understanding, relying instead on extensive consultation, leading to something like the CMIs used today.

Mandatory Disclaimers

Early in the first G. W. Bush Administration, FDA asked us to conduct a study (not subject to the PRA) evaluating a court-mandated disclaimer for dietary supplement labels. The U.S. Court of Appeals (in *Pearson v. Shalala*, 1999), ruling on grounds of commercial freedom of speech, had allowed supplement manufacturers great latitude in their claims, as long as product labels also stated that "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease" (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.93). The second sentence allows claims regarding benefits to bodily structure and function (e.g., "it will make you stronger," "smarter," or "more virile").

FDA wondered whether the court's intuitions about consumers' psychology were valid, meaning that the disclaimer would eliminate any unwarranted expectations about supplements' benefits and risks. In response, we developed a general approach to evaluating disclaimers, which we then applied to saw palmetto, one of the few supplements with evidence regarding health effects (Eggers & Fischhoff, 2004). At the time, saw palmetto appeared to have some promise for helping men with benign prostatic hyperplasia and to have minimal side effects.

Following the behavioral decision research strategy, we began with a formal analysis of the decision facing men with benign prostatic hyperplasia (see Figure 1). That analysis identified little risk from taking saw palmetto, except for men with conditions that require prompt medical attention. Our empirical research, using think-aloud protocols, found that men often interpreted the disclaimer differently than the court had intended. Some dismissed it as irrelevant, with comments to the effect that "Of course, FDA hasn't evaluated the statement; FDA doesn't believe in alternative medicine." Others felt that "If a product needs a warning, then it must be strong enough to have an effect." Nonetheless, despite being misinterpreted, the label appeared to do no harm. Few men had enough faith in saw palmetto to self-medicate for long, if their symptoms persisted. As a result, the flawed disclaimer would not affect their decisions. Formal analysis of black cohosh, an herbal treatment for menopausal symptoms, revealed a similar decision tree: some chance of benefit, with risks for users with serious conditions who self-medicated too long. Thus, decisions about black cohosh, too, should be insensitive to the disclaimer's failings. However, for supplements with other benefit-risk profiles, a poor disclaimer might be worse than none at all.

Unfortunately, by the time our study was done, FDA had decided to challenge saw palmetto's status as a dietary supplement, rendering our research not only irrelevant, but awkward. The court-mandated label is still in use (Kesselheim, Connolly, Rogers, & Avorn, 2015), posing the threat to consumers' well-being that comes with relying on intuition, rather than evidence.

Drug Facts Boxes

During the second Clinton Administration, researchers at what is now the Dartmouth Institute for Health Policy and Clinical Practice began developing a *drug facts box*, akin to the familiar nutrition facts box (Schwartz & Woloshin, 2013). The box's design (see Figure 2) reflects several behavioral decision research principles: It focuses on the issues critical to users' decisions, so that they can easily find the facts that they need. It expresses those facts in numerical terms, so that users need not guess at the meaning of verbal quantifiers (e.g., "rare" side effect, "positive" results; Fischhoff, 1994; O'Hagan et al., 2006). It presents both risks and benefits, so that the tradeoffs are clear. It shows alternatives, so that users can compare their options. It describes the quality of the evidence (under "Study Findings" and "How long has the drug been in use?"), so that users have some idea about how much to trust the estimates.

The drug facts box might seem too difficult for lay users. It presents technical information, about more than one option, in quantitative terms, and with explicit acknowledgment of uncertainty. Nonetheless, studies with nationally representative samples have found that most people can find the information that they need in such boxes (Schwartz & Woloshin, 2013). That success reflects both the behavioral

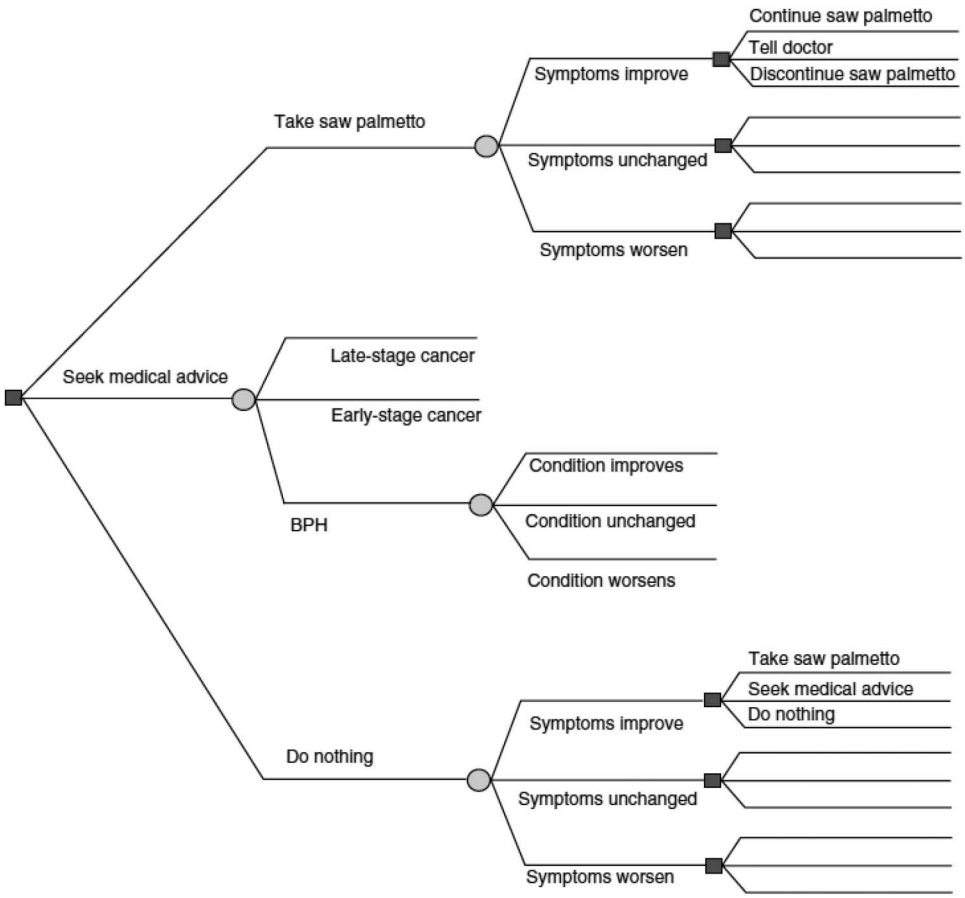


Figure 1. A formal analysis of the decision facing men considering using saw palmetto for benign prostatic hyperplasia. Square nodes indicate decision points. Circular nodes indicate uncertain events. From "A Defensible Claim? Behaviorally Realistic Evaluation Standards," by S. L. Eggers & B. Fischhoff, 2004, *Journal of Public Policy and Marketing, 23*(1). Copyright 2004 by the American Marketing Association. Reprinted with permission.

principles underlying the box's design and its extensive testing with potential users (Woloshin, Schwartz, & Welch, 2008).

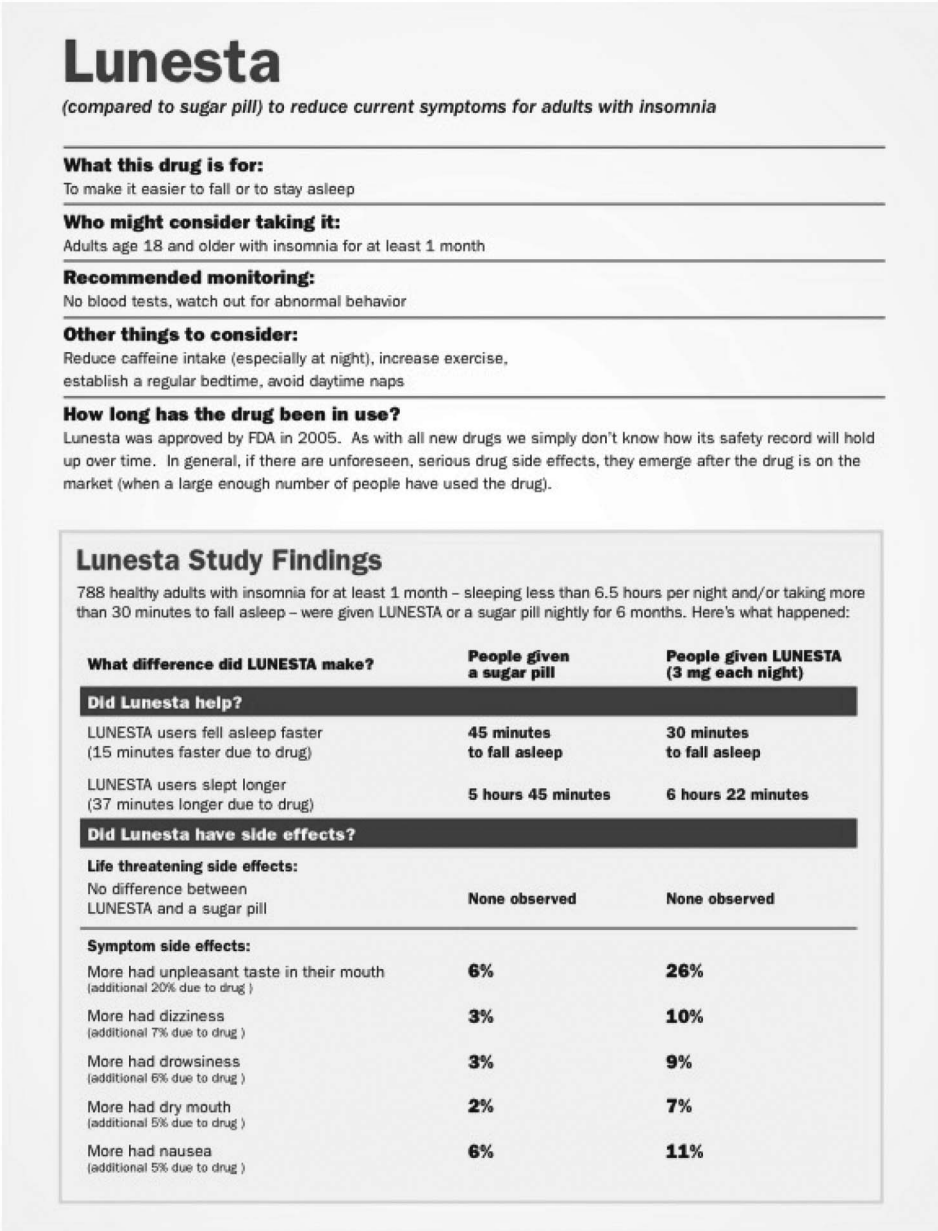
Thus, the drug facts box was ready when an opportunity arose for FDA to consider it as a replacement for the disappointing CMIs (Winterstein, Linden, Lee, Fernandez, & Kimberlin, 2010). Indeed, during the G. W. Bush Administration, FDA supported creation of a guide for translating its clinical reviews into fact box terms. Eventually, though, FDA chose not to undertake the regulatory ordeal of evaluating and securing approval for a new label. The drug facts box initiative is still proceeding, but outside of FDA, drawing on estimates that determined experts can find in FDA's rulings, but which ordinary patients and physicians cannot readily find anywhere.

Risk Communication Advisory Committee

In 2006, the Institute of Medicine (2006) recommended changes in how FDA manages risks. FDA's response included creating a Risk Communication Advisory Committee (RCAC), which became a statutory committee under the FDA Amendments Act of 2007. I was chair for the first 4-year term. Ellen Peters (Ohio State) and William Hallman (Rutgers) have succeeded me.

A low point in my tenure as chair was a meeting in which the committee tried to advise FDA on how to evaluate direct-to-consumer advertising for prescription drugs (a practice that only the United States and New Zealand allow). The committee proposed a series of studies, each building on its predecessors' results, only to learn that such research was effectively impossible, given the lengthy approval process that OMB requires under the PRA. As a result, the committee could only make some general suggestions and complain about the threat to public health (and the pharmaceutical industry) created when red tape restricts science.

A high point in my tenure was the committee's adoption of recommendations on several questions raised by FDA



Lunesta

(compared to sugar pill) to reduce current symptoms for adults with insomnia

What this drug is for:
To make it easier to fall or to stay asleep

Who might consider taking it:
Adults age 18 and older with insomnia for at least 1 month

Recommended monitoring:
No blood tests, watch out for abnormal behavior

Other things to consider:
Reduce caffeine intake (especially at night), increase exercise, establish a regular bedtime, avoid daytime naps

How long has the drug been in use?
Lunesta was approved by FDA in 2005. As with all new drugs we simply don't know how its safety record will hold up over time. In general, if there are unforeseen, serious drug side effects, they emerge after the drug is on the market (when a large enough number of people have used the drug).

Lunesta Study Findings

788 healthy adults with insomnia for at least 1 month – sleeping less than 6.5 hours per night and/or taking more than 30 minutes to fall asleep – were given LUNESTA or a sugar pill nightly for 6 months. Here's what happened:

What difference did LUNESTA make?	People given a sugar pill	People given LUNESTA (3 mg each night)
Did Lunesta help?		
LUNESTA users fell asleep faster (15 minutes faster due to drug)	45 minutes to fall asleep	30 minutes to fall asleep
LUNESTA users slept longer (37 minutes longer due to drug)	5 hours 45 minutes	6 hours 22 minutes
Did Lunesta have side effects?		
Life threatening side effects: No difference between LUNESTA and a sugar pill	None observed	None observed
Symptom side effects:		
More had unpleasant taste in their mouth (additional 20% due to drug)	6%	26%
More had dizziness (additional 7% due to drug)	3%	10%
More had drowsiness (additional 6% due to drug)	3%	9%
More had dry mouth (additional 5% due to drug)	2%	7%
More had nausea (additional 5% due to drug)	6%	11%

Figure 2. A drug fact box. Copyright 2006 by Steven Woloshin and Lisa Schwartz. Reprinted with permission.

staff. Table 1 shows our recommendations for dealing with "emerging events," such as anecdotal reports of foodborne illnesses, ineffective drugs, or contaminated dietary supplements. In such cases, if FDA responds too early, it can cause needless concern and be accused of alarmism. If it responds too late, it can cause needless risks and be accused of a cover-up. A second high point in my tenure was the committee's consultation with the nascent Center for Tobacco Products on how to make psychological science central to its work. A third was a meeting on CMIs, where David Moxley (Wayne State/Oklahoma), a former member, described how the drug facts box might help homeless individuals communicate better with physicians serving them.

Hoping to make behavioral research more accessible, FDA commissioned a guide to the science of communication (Fischhoff, Brewer, & Downs, 2011). Each chapter summarizes research on a topic (e.g., readability, affect, media), offers practical suggestions, and describes ways to evaluate communications for no money at all, a little money, or resources commensurate with the health, economic and political stakes riding on effective communication. Two special issues of the *Proceedings of the National Academy of Sciences*, following

Table 1
FDA Risk Communication Advisory Committee Recommendations for Addressing Emerging Events

Have a consistent policy in all domains
Provide useful, timely information
Address risks, benefits, and uncertainty, for both personal actions and FDA actions
Let audience needs drive agency analyses
Use standard formats; evaluate routinely
Consider needs of diverse populations

Source: http://www.fda.gov/advisorycommittees/committeesmeetingmaterials/riskcommunicationadvisorycommittee/default.htm.

Sackler Colloquia on the Science of Science Communication, continue the effort to make psychological research available to other professions (Fischhoff & Scheufele, 2013, 2014).

Benefit–Risk Framework

As an outgrowth of the RCAC's work, I was invited to join a staff-led project in FDA's Center for Drug Evaluation and Research (CDER), aimed at improving its process for deciding whether to approve drugs. FDA faced internal pressure, from its staff, to improve communication among reviewers. It faced external pressure, from the industry and patient groups, to make its decisions more transparent. The resulting benefit–risk framework (FDA, 2013) is intended as a centerpiece of FDA's review process; while fulfilling a commitment under the fifth Prescription Drug Users Fee Act, the law that gives FDA the authority to collect fees from producers who submit drugs for marketing approval. As seen in Figure 3, the framework reflects all three aspects of behavioral decision research: analysis, description, and intervention.

Analytically, the framework's rows address the five topics central to FDA's decisions: the condition being treated, the current treatment options, the product's expected benefits, its estimated risks, and the steps proposed for managing those risks, should it be approved. The columns distinguish scientific judgments, regarding evidence and uncertainty (on the left), from policy judgments, regarding conclusions and reasons (on the right). The framework acknowledges that all evidence has uncertainty (on the left) and requires interpretation in terms of FDA's regulatory mandate (on the right).

Descriptively, the framework embodies behavioral principles in its design. The columns separate scientific and policy judgments, by giving explicit expression to each. The first row spells out the medical condition, to create shared understanding (e.g., "The constipation associated with irritable bowel syndrome is worse than anything that anyone who has not suffered it can imagine"). The second row does the same for existing products (e.g., "Nothing on the market allows patients to lead normal lives"). Posing benefits and risks separately (Rows 3 and 4) highlights the (sometimes hard) tradeoffs. The risk management options (Row 5) include ways to make products with acceptable tradeoffs even better (e.g., through patient registries, training programs).

As an intervention, the framework was subjected to iterative testing with multiple review teams. Their feedback led to its final form, which represents a compromise between a structured narrative (as previously used) and formal elicitation of tradeoffs and uncertainties (Drummond, Sculpher, Torrance, O'Brien, & Stoddart, 2005; Keeney & Raiffa, 1976). Treating the product evaluation process as a form of behavioral decision research, the framework seeks to elicit judgments that are explicit as possible without forcing FDA experts to lose their intuitive feel for the work (Fischhoff, 2012; Morgan, 2014; O'Hagan et al., 2006). CDER has now incorporated the framework in the templates used by its reviewers and in the reporting of its approval decisions. The Center for Biologics Evaluation and Research is using it as well (e.g., for coagulation products).

In ongoing work related to the framework, FDA is conducting "Voice of the Patient" workshops (FDA, 2015), designed to inform its understanding of complex conditions (e.g., sickle cell disease, chronic fatigue syndrome, breast

Decision Factor	Evidence and Uncertainties	Conclusions and Reasons
Analysis of Condition		
Current Treatment Options		
Benefit		
Risk		
Risk Management		
Benefit-Risk Summary Assessment		

Figure 3. U.S. Food and Drug Administration's benefit–risk framework. Reproduced from FDA (2013).

cancer), so as to put product risks and benefits in perspective. FDA is also examining how to capture and communicate uncertainty (Institute of Medicine, 2014), how to evaluate the framework's impact, and how to address current political interest in "patient-focused drug development." In keeping with the behavioral principles underlying the framework, though, there are no plans to translate estimates of benefits and risks into a common measure (e.g., quality-adjusted life years, monetary equivalents). Rather, each outcome is listed separately so that patients can make their own tradeoffs.

Conclusions

Psychology has now a firm presence at FDA, as seen in its RCAC, communication guide, *Strategic Plan for Risk Communication* (FDA, 2009), benefit–risk framework, and Center for Tobacco Products, as well as active programs in the Center for Food Safety and Applied Nutrition, Office of Prescription Drug Products, and elsewhere. That presence includes roles in helping FDA both to change behavior (e.g., food safety, smoking) and to inform decisions (e.g., drugs, medical devices). It provides FDA staff with a place to turn for advice, when psychological issues arise. For example, after consulting with the RCAC, FDA adopted a standard format for food recall notices and a protocol for testing them (using think-aloud interviews with FDA staff, who, as federal employees, do not fall under the PRA).

These experiences, including the early false starts, suggest three conditions for expanding the range of psychological science. (A related account for intelligence agencies appears in National Research Council, 2011.)

An External Catalyst

A 2006 Institute of Medicine report cited behavioral issues as one cause of widely publicized safety problems. It empowered psychology's internal advocates at FDA to identify opportunities to expand its role. They found support from FDA leadership, including Commissioners Andrew von Eschenbach and Margaret Hamburg (in the G. W. Bush and Obama Administrations, respectively) and CDER Director Janet Woodcock.

Resident Expertise

A few core professions dominate most agencies. At FDA, they are physicians, biomedical researchers, and attorneys. However, FDA has long realized that its decisions rest on behavioral assumptions. As a result, FDA has long had psychologists on staff to answer calls for evidence. These trusted insiders were in a position to identify the relevant science and scientists, and weave them into the agency's work.

Engaged Behavioral Scientists

FDA's continuing efforts to involve psychologists created a cadre of researchers familiar with its complex internal and external environment. Those researchers have then been ready when opportunities arose, whether for evaluating products, providing safety information, setting food inspection priorities, or dissuading teens from smoking.

Other agencies' ability to follow FDA's example may depend on whether these conditions are met. Does some external event provide a catalyst for action? Is there the absorptive capacity for identifying and incorporating needed help? Are there psychologists able and willing to work on these applied problems? To create those conditions, other agencies might adapt FDA initiatives, such as its science advisory committee, strategic communication plan, and framework for more transparent decision making. The academic community can help that process along by rewarding its members for time spent getting to know an agency, nurture relationships with its staff, and undertake applications. The return on that investment can be measured in our impact on agency programs, jobs for our students, and publications inspired by these problems.

In our own research program, these engagements have prompted studies on how to identify the facts that patients and consumers most need to know regarding regulated products, from among all the facts that it would be nice to know; on how to evaluate communications, in terms of how well they have fulfilled their duty to inform; and on how to characterize uncertainty in terms that decision makers can use and experts can assess (Fischhoff, 2013; Fischhoff & Davis, 2014; Krishnamurti, Eggers, & Fischhoff, 2008; Riley, Fischhoff, Small, & Fischbeck, 2001). Other researchers would doubtless find other opportunities, whether for *applied basic* research, seeing how useful our theories prove in real-world settings or *basic applied* research, pursuing new questions that arise from them, so that theory and practice support one another (Baddeley, 1979).

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