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Authors

Catlin, Jesse R

Pechmann, Cornelia Connie

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An Investigation of Consumer and Doctor Regulatory Beliefs and Regulatory Knowledge about Pharmaceutical Drug Promotions

JESSE R. CATLIN AND CORNELIA (CONNIE) PECHMANN

ABSTRACT Pharmaceutical drug companies engage in numerous promotional activities—from advertising to sales calls. Yet little is known about whether consumers or doctors believe these activities are regulated by the Food and Drug Administration (FDA) or whether their beliefs are accurate. We refer to these constructs as regulatory beliefs and regulatory knowledge, and we introduce and partially test a conceptual model including them. Specifically, we surveyed 311 consumers and 104 doctors about 24 different marketing-type activities undertaken by pharmaceutical drug companies, and assessed their persuasion knowledge, regulatory beliefs, and regulatory knowledge. We found that both groups, but especially doctors, had high persuasion knowledge, whereas doctors had weaker regulatory beliefs about FDA oversight; on regulatory knowledge both groups manifested comparable and substantial deficits. This research contributes theoretically by introducing the constructs of regulatory beliefs and regulatory knowledge, and finding that expertise in this context influences regulatory beliefs but not knowledge.

Sales of pharmaceutical drugs in the United States totaled over \$360 billion in 2014, manifesting 13% growth compared to the prior year (Berkrot 2010). Pharmaceutical drug use has grown substantially for decades, with almost 60% of US consumers reporting use of at least one prescription drug in the past 30 days in a survey conducted in 2011–12 (Kantor et al. 2015). As a result, pharmaceutical drug company promotional activity has become a subject of much debate, as evidenced by the American Medical Association's recent call (2015) to ban direct-to-consumer (DTC) prescription drug advertising altogether.

While the advertising of drugs to consumers is a fairly straightforward illustration of promotional activity, pharmaceutical drug companies engage in a complex array of activities that may serve promotional goals, including sponsoring continuing education for doctors and posting messages about drugs on social media. Therefore, it is unclear whether consumers and/or doctors appreciate that these different activities may serve promotional goals, that is, what their levels of persuasion knowledge are (Friestad and Wright 1994, 1995). It is also unclear whether consumers and/or doctors believe that these various activities are regulated by the Food

and Drug Administration (FDA), that is, what their regulatory beliefs are. Moreover, it is unclear how accurate consumer and doctor regulatory beliefs are compared to actual FDA regulations, that is, what their levels of regulatory knowledge are.

In this research we surveyed 311 consumers and 104 doctors to assess their persuasion knowledge, regulatory beliefs, and regulatory knowledge about 24 different marketing-type activities engaged in by pharmaceutical companies. In addition to describing the current state of knowledge among consumers and doctors about pharmaceutical drug marketing and FDA regulation, we contribute to the persuasion knowledge literature by introducing two new constructs—regulatory beliefs and regulatory knowledge—that we believe hold promise for understanding how promotional information is evaluated. We present a conceptual model of these effects; on an empirical level, we find that both persuasion knowledge and regulatory beliefs are influenced by viewers' expertise (doctors vs. consumers), while regulatory knowledge is not. Specifically, we find that on persuasion knowledge doctors score higher than consumers, on regulatory beliefs about FDA oversight doctors score lower (i.e., are less likely

Jesse R. Catlin (jesse.catlin@csus.edu), assistant professor of marketing, California State University, Sacramento, 6000 J Street, Sacramento, CA 95819. Cornelia (Connie) Pechmann (cpechman@uci.edu), professor of marketing, University of California, Irvine, Irvine, CA 92697-3125. The authors contributed equally to this article. The authors gratefully acknowledge the input and feedback from former FDA officials Peter Rheinstein and Louis Morris. Cornelia Pechmann has served as an expert marketing witness for plaintiffs in cases involving Vioxx.

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to believe there is FDA oversight), and on regulatory knowledge both groups have comparable and objectively low levels of knowledge or accuracy.

BACKGROUND, CONCEPTUAL FRAMEWORK, AND HYPOTHESES

Regulatory Knowledge and Persuasion Knowledge

A key contribution of this research is that we introduce the constructs of regulatory beliefs and regulatory knowledge to the literature. We define regulatory beliefs as the degree to which a viewer believes that an activity is monitored or regulated by an outside regulatory authority, such as a government agency (e.g., the FDA). We define regulatory knowledge as the objective accuracy of a regulatory belief when compared to current laws and regulations. Regulatory beliefs and regulatory knowledge are distinct from the construct of persuasion knowledge, which refers to the ability “to recognize, analyze, interpret, evaluate, and remember persuasion attempts and to select and execute coping tactics believed to be effective and appropriate” (Friestad and Wright 1994, 3). Persuasion knowledge involves awareness of an activity’s persuasive or promotional nature, while regulatory beliefs and regulatory knowledge involve awareness of regulatory oversight. Conceptually, we argue that regulatory beliefs and regulatory knowledge can function as moderators that can amplify or dampen the impact of persuasion knowledge on product evaluations, as will be discussed subsequently (see fig. 1).

Effects of Persuasion Knowledge on Product Evaluations. Our conceptual model is grounded on the persuasion knowledge model, which posits that persuasion knowledge affects evaluations of promoted products (Friestad and Wright 1994, 1995). If an activity is viewed as manipulative or promotional in nature, persuasion knowledge is activated, causing viewers to be more cautious or skeptical of the promotional claims (Campbell and Kirmani 2000) and lowering their evaluations of the promoted product. For instance, one study found that revealing that a radio program received promotional sponsorship from a brand that was described positively during the program activated persuasion knowledge and lowered brand evaluations (Wei, Fischer, and Main 2008). In a medical context, Wei and Delbaere (2015) found that when doctors prescribing a drug had a promotional item for that drug in their offices, this activated consumers’ persuasion knowledge, lowered their evaluations of the doctor and drug, and increased their in-

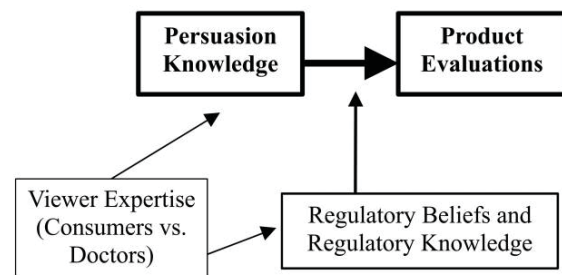


Figure 1. Conceptual model.

terest in alternative treatments such as generic drugs or herbal therapies.

The Moderating Role of Regulatory Beliefs and Knowledge. Our conceptual model extends the persuasion knowledge model by positing that the effects of persuasion knowledge on product evaluations may be moderated by regulatory beliefs, that is, beliefs regarding whether a promotional activity is regulated by an outside regulatory or government agency (see fig. 1). For example, Wei and Delbaere (2015) found that when consumers’ persuasion knowledge was activated because of a visible drug promotion, this lowered product evaluations; however, we posit that the impact of persuasion knowledge on product evaluations may depend on whether the promotion is believed to be regulated or not. If consumers’ regulatory belief is that there is no FDA regulation, they may show heightened vigilance toward the promotion, amplifying the well-established negative effect of persuasion knowledge on evaluations. On the other hand, if consumers’ regulatory belief is that there is FDA regulation, they may show reduced vigilance toward the promotion, dampening the negative effect of persuasion knowledge on evaluations. In other words, our model posits that differences in regulatory beliefs may heighten or weaken the negative effects of persuasion knowledge on product evaluations.

We furthermore argue that the accuracy of consumer and doctor regulatory beliefs, or their regulatory knowledge, is also important in evaluating effects on decision making and well-being. If regulation is overestimated (i.e., it is wrongly believed an activity is regulated when it is not), the effects of persuasion knowledge on evaluations may be unduly dampened, resulting in less scrutiny than is optimal. If regulation is underestimated (i.e., it is wrongly believed an activity is unregulated when it is regulated), the effects of persuasion

knowledge on evaluations may be unnecessarily heightened, leading to more scrutiny than is optimal.

The Role of Expertise. Finally, our conceptual model posits that viewers' level of relevant expertise may affect their persuasion knowledge, regulatory beliefs, and regulatory knowledge (see fig. 1). Because consumers and doctors alike are heavily exposed to pharmaceutical drug promotions in the United States including DTC television ads, we reasoned that they should exhibit substantial persuasion knowledge. However, we posited that doctors should manifest even greater persuasion knowledge than consumers, due to their exposure to both doctor-targeted and consumer-targeted promotions. In contrast, we did not expect consumers or doctors to have extensive regulatory knowledge, because FDA regulations are not widely publicized or well-known and sometimes change. Nonetheless we expected that doctors should exhibit more regulatory knowledge than consumers, because doctors have more exposure to FDA regulations (e.g., in their practices and continuing education). Thus we tested the following hypotheses:

H1: Both doctors and consumers will have substantial persuasion knowledge of pharmaceutical drug companies' marketing-type activities due to their high exposure to such activities, but doctors will have even more persuasion knowledge due to greater exposure.

H2: Both doctors and consumers will have limited regulatory knowledge of whether the FDA regulates pharmaceutical drug companies' marketing-type activities due to their low exposure to FDA regulation, but doctors will have more regulatory knowledge due to greater exposure.

PHARMACEUTICAL COMPANY PROMOTIONAL ACTIVITIES, FDA REGULATION, AND REGULATORY KNOWLEDGE

Medical, public health, and marketing literatures have identified a myriad of ways in which pharmaceutical drug companies can leverage various activities to achieve their promotional goals (Steinman et al. 2006). Based on these literatures, we identified 24 common marketing-type activities, and we grouped these activities into five general categories: (1) advertising, publicity, and social media, (2) sales communications to doctors, (3) continuing education for

doctors, (4) public relations about a disease, and (5) marketing research and strategy. Each activity has been identified in the literature as being promotional in nature or as having the potential to be used for promotional purposes by pharmaceutical marketers, as will be discussed in the next sections. We will first briefly describe each activity, and then we will go into detail about the FDA regulation of each activity and relate the FDA regulations to our focal constructs of regulatory beliefs and regulatory knowledge.

Advertising, Publicity, and Social Media

Three common activities that are used to promote pharmaceutical drugs are advertising, publicity, and social media. Pharmaceutical companies in the United States promote their drugs via DTC advertising to consumers (Donohue, Cevasco, and Rosenthal 2007), advertising to doctors (Gonul et al. 2001; Bala and Bhardwaj 2010), and seeking publicity for their drugs (Anderson 2001). Drugs are also promoted through social media (Greene and Kesselheim 2010) such as paying celebrities to post drug endorsements (Greene and Kesselheim 2015). Current FDA regulations regarding each activity and what this means for regulatory beliefs and regulatory knowledge are discussed in the subsections that follow.

Advertising. The FDA regulates pharmaceutical drug advertising to both consumers and doctors (21 USC 352 (n)). Therefore, a key component of regulatory knowledge is knowledge that the FDA monitors advertising to both groups. The FDA's Office of Prescription Drug Promotion oversees drug advertising as well as promotional labeling, with the assistance of its two divisions: the Division of Professional Promotion for doctors, and the Division of Direct-to-Consumer Promotion for consumers (Arnold 2011). Advertising is defined by the relevant FDA regulation as "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems" (21 CFR 202.1(l)(1)).

The FDA requires companies to submit their advertising to the agency "at the time of initial publication or dissemination" using form FDA 2253 (21 CFR 314.81(b) (3) (i); 21 CFR 601.12(f) (4)), which lists 43 possible submission types (FDA 2010a). The FDA selectively reviews a subset of the submissions based on perceived reach and impact (US Government Accountability Office 2006; Schwartz et al. 2009). If a violation is found, the drug is considered "misbranded"

(21 CFR 321(n)), and the FDA sends a cease and desist letter (Palumbo and Mullins 2002; US Government Accountability Office 2006). A notice of violation letter is for a nonserious violation, while a warning letter is for a serious violation and requires a response and follow-up (*Lancet* 2006). The FDA can also impose monetary fines (Lurie 2009; Schwartz et al. 2009). For instance, under the Federal False Claims Act, the government can seek to recover financial damages for funds expended by federally funded healthcare programs to purchase drugs prescribed for unapproved uses that were promoted in violation of the FDA Act (Morris 2009). Some limited industry guidelines for pharmaceutical advertising also exist, which generally mirror the FDA regulations. Details about all of the FDA regulations and all of the relevant industry guidelines are provided in appendix table A1 (appendix and tables A1–A4 available online).

Publicity. The FDA regulates publicity materials for specific drugs, and so regulatory knowledge involves knowing this as well. Publicity materials include press releases and video news releases, which are listed on FDA form 2253 (FDA 2010a), and these must be submitted to the FDA upon first use. The FDA considers these materials to be promotional labeling, which it broadly defines as a “variety of written, printed, or graphic matter that bears a textual relationship with a drug” (2004, 2). It is not necessary for the promotional label to be physically attached to the drug (FDA 2004). The FDA criteria for reviewing promotional labeling are virtually the same as for reviewing advertising (2010b).

Social Media. The FDA partially regulates social media posts about pharmaceutical drugs and therefore regulatory knowledge involves relatively nuanced information in this case. Specifically, the FDA regulates companies’ posts on their own social media websites and on other websites in which they actively participate (2015a). The FDA also regulates social media posts that companies pay others to make, including paid spokespeople or celebrities (2015a). The FDA even regulates social media posts with character space limitations such as on Twitter (2015b) and requires such posts to be accurate and balanced. However, the FDA does not monitor companies’ posts to correct independent third-party misinformation and does not require companies to correct misinformative third-party posts (2015c).

The FDA considers a company’s own social media websites and its social media posts to be promotional labeling

and so it requires each company to “submit in its entirety all sites for which it is responsible on Form FDA 2253” (2015a, 6). Thereafter each month, the company must “submit an updated listing of all nonrestricted sites for which it is responsible or in which it remains an active participant and that include interactive or real-time communications” and in addition, for any restricted-access site, the company must “submit all content related to the [user-generated] discussion” (6–7).

Sales Communications to Doctors

Another common class of activity used to promote pharmaceutical drugs is sales communications to doctors. Pharmaceutical companies provide doctors with handouts and brochures about their drugs (Mello 2009) and distribute reprints of published studies about their drugs’ FDA-approved uses (Mitka 2008). Companies also promote their products through salespeople or detailers who present preplanned or scripted and other information to doctors during office visits (Applbaum 2009; Kappe and Stremersch, forthcoming). In addition, companies send out mass mailings about their drugs, and they send preplanned and other information to individual doctors in response to their drug queries (Mello 2009).

Brochures and Handouts. The FDA regulates the brochures, handouts, and other detailing aids that pharmaceutical sales representatives show to doctors when detailing their drugs. Therefore, regulatory knowledge involves knowing that the FDA monitors such aids. The FDA’s definition of promotional labeling (see FD&C Act 502(a); also 21 CFR 352 (a)) expressly includes “brochures, booklets, mailing pieces, [and] detailing pieces” (21 CFR 202.1(l) (2)). Companies must submit these materials to the FDA at the time of their initial use using the 2253 form. While the FDA reviews the detailing aids that sales representatives use, it does not try to monitor what sales representatives say when using these aids, as will be discussed subsequently.

Drug Studies of FDA-Approved Uses. The FDA regulates the provision of drug studies to doctors about FDA-approved uses, and so this is another component of regulatory knowledge. Drug studies are included under promotional labeling; they are referred to as “reprints” (21 CFR 202.1(l) (2)), and they must be submitted to the FDA upon dissemination to doctors using the 2253 form (21 CFR 99.101 (a) (2) (i)). Moreover, if a reprint has a monetary value over \$5, it must

be included in the annual report to the US government of company payments to individual doctors (Physician Payments Sunshine Act, 42 USC 1301 1128(h)).

Presenting Preplanned Drug Information to Doctors.

The FDA does not monitor the verbal information that pharmaceutical drug sales representatives present to doctors when detailing their drugs (2010b). Therefore, regulatory knowledge involves knowing that this type of verbal information is not FDA monitored. The FDA does not ask companies to submit preplanned messages or training materials such as sales scripts, talking points, sales bulletins, or sales training videos that are provided to sales representatives for their study and use in preparing their presentations to doctors. FDA form 2253 shows that a “script for telephone calls” and “professional or consumer slide presentations” must be submitted to the agency for review. However, the FDA does not require submission of the preplanned messages and training materials that guide detailing visits (2010a).

Sending Preplanned Drug Information to Doctors. The FDA only partially monitors the sending of preplanned drug information to doctors; so, in this case, regulatory knowledge requires more nuanced understanding of the FDA. When a company sends a mass mailing piece to doctors, that mailing piece must be submitted to the FDA using the 2253 form. In fact, the definition of promotional labeling includes “mailing piece” (21 CFR 202.1(l) (2)).

However, when doctors submit unsolicited drug queries to pharmaceutical companies, (e.g., about approved or unapproved drug uses or adverse drug effects), there is no FDA monitoring of the company replies. Typically, these queries are handled by a company’s medical affairs office whose staff often utilize pre-prepared responses that reside in the company database (e.g., they send preplanned summaries of studies on a topic). Therefore, if thousands of doctors make a similar query, thousands of similar replies may be sent out. However, the FDA does not require submission of this pre-prepared response text (FDA 2011).

Continuing Education for Doctors

Pharmaceutical drug companies also use continuing education for doctors for promotional purposes, that is, education that is required by the US states for doctors to maintain their licenses. For instance, companies may sponsor or provide funding for continuing education events, and pro-

mote their drugs at those events (Wazana 2000; Relman 2001). Also, company sales representatives may provide meals to doctors at their offices when they discuss their companies’ drugs (Wazana 2000; Grande 2010). Companies may pay influential doctors to give presentations related to their drugs (Sah and Fugh-Berman 2013) and/or pay doctors to write, or pay someone to help doctors write, about their drug studies (Ross et al. 2008; Lacasse and Leo 2010; Sismondo and Doucet 2010). Pharmaceutical companies refer to the payments for writing as publication planning, and many even employ third-party communication companies to identify, contract with, and pay the writers (Healy and Cattell 2003; Sismondo and Nicholson 2009). In addition, pharmaceutical companies may distribute studies about unapproved off-label drug uses to doctors (Mitka 2008; Stafford 2008).

Funding Continuing Education. The FDA does not regulate funding for, or virtually any other aspect of, continuing education for doctors, that is, education to maintain medical licenses. Consequently, regulatory knowledge requires knowing that no FDA regulation exists in this area. Instead of providing direct oversight, the FDA works with the pharmaceutical drug industry and with the organizations that accredit continuing medical education to try to ensure that educational programs are independent from commercial influence (US Department of Health and Human Services 1997). To address the issue of independence, the pharmaceutical industry’s code of conduct states that companies can only provide funding through independent continuing medical education (CME) providers (Pharmaceutical Research and Manufacturers of America 2009). Furthermore, the accrediting organizations’ guidelines state that these providers must ensure that all major decisions, including the topics covered and the featured speakers, are free from commercial interest (Accreditation Council for Continuing Medical Education 2014; American Osteopathic Association 2014).

Pharmaceutical drug companies are, however, allowed to sponsor continuing education events, publicize that they are a sponsor, subsidize meals and receptions, set up and staff drug information booths and exhibits, and display their advertisements and promotions at such events. Additionally, if the FDA determines that a pharmaceutical drug company has funded a continuing medical education program that has violated the industry guidelines and in fact is not independent from commercial influence, then the

Agency has the authority to regulate that program as drug labeling (US Department of Health and Human Services 1997).

Paying Doctors to Present. The FDA does not monitor payments to doctors to present at continuing medical education events or other events, and so regulatory knowledge requires knowing this. However, the pharmaceutical industry code of conduct states that company sponsors of accredited continuing education events should not influence the choice of topics or presenters (Pharmaceutical Research and Manufacturers of America 2009). The industry code of conduct does permit drug companies to pay doctors to speak at their own company-hosted, nonaccredited, events. The code states, though, that these payments should not be used as inducements to encourage doctors to prescribe the companies' drugs. Such payments must be included in the annual report to the US government of company payments to individual doctors (Physician Payments Sunshine Act, 42 USC 1301 1128(h)).

Providing Meals during Meetings. The FDA does not regulate the provision of meals, entertainment, gifts, or other items to doctors during meetings about drugs or at other times. Thus regulatory knowledge involves knowing that these activities are not FDA monitored. However, the pharmaceutical drug industry has weighed in on this issue (Pharmaceutical Research and Manufacturers of America 2009). The industry code of conduct allows drug companies to provide meals to doctors during informational drug presentations, but does not allow companies to provide entertainment, gifts, or items that doctors can use in their practices such as note pads (only drug samples are permissible). In addition, the US government requires that companies report their aggregate annual payments to individual doctors, excluding meals or gifts valued at under \$5 (Physician Payments Sunshine Act, 42 USC 1301 1128(h)). Finally, some US states require companies to disclose or limit meals and/or gifts to doctors (Grande 2010).

Paying a Doctor to Write about a Study or Paying for Writing Help. The FDA does not monitor pharmaceutical drug company payments to doctors to write about drug studies or company payments to others to help doctors do this type of writing. Therefore, regulatory knowledge involves knowing that FDA oversight does not exist in this area. Most major medical journals require authors to report

conflicts of interest and seek to avoid guest writers (prominent authors who are paid to write but have minimal research involvement) and ghost writers (undisclosed authors who may be paid or employed by drug companies). However, experts opine that journal policies and enforcement are not yet fully uniform or adequate (Healy and Cattell 2003; Sismondo 2007; Ross et al. 2008; Sismondo and Nicholson 2009).

Giving out a Drug Study before FDA Approval. The FDA (2009) regulates and expressly allows companies to give doctors published studies of unapproved off-label drug uses. Hence, regulatory knowledge involves knowing that this one education-related area is FDA regulated. Specifically, the FDA requires that the drug be FDA approved for another use, and the study must also be published in an independent peer-reviewed journal. The FDA furthermore requires that the study reprint that is disseminated to doctors be free from any markings. There can be no accompanying promotion, the approved drug label must be provided, and a disclosure must be included that states that the studied use is not FDA approved. The company must submit the study reprint at the time it is disseminated to doctors using FDA 2253 form.

Public Relations about a Disease

It is also common for pharmaceutical drug companies to mount promotional campaigns to increase public awareness of the diseases that their drugs treat. Pharmaceutical drug companies may run ads about or otherwise seek publicity for a disease (Moynihan and Henry 2006) and/or may provide financial grants to organizations that provide advocacy, education, and support related to the disease and those afflicted with it (Rose 2013).

Advertising or Seeking Publicity about a Disease. The FDA does not regulate advertising or publicity to enhance disease awareness. Consequently, regulatory knowledge requires knowing this is something the FDA does not monitor. The FDA's authority to regulate drug advertisements and promotional labeling is based on its authority to prevent the misbranding of specific drugs. If no specific drug is identified either explicitly or implicitly, the FDA lacks regulatory authority. For instance, if a communication merely advises consumers to "see your doctor" or advises doctors to "look for signs" related to a disease, the FDA has no over-

sight because this “constitutes neither [drug] labeling nor advertising” (FDA 2004, 3).

Providing Grants to Disease-Related Organizations. Likewise, the FDA does not regulate pharmaceutical drug company grants to disease-related organizations; knowing this is another component of regulatory knowledge. Many non-profit patient advocacy organizations seek to raise awareness of specific diseases and treatment options, and many also try to promote or even fund disease-related research (Rothman et al. 2011; Rose 2013). Many of these organizations receive funding from pharmaceutical companies, especially if their diseases are treatable with the companies’ drugs (Rose 2013). Moreover, many of these organizations do not fully disclose their funding sources or any potential conflicts of interest (Rothman et al. 2011; Rose 2013). However, the FDA has expressed no interest in overseeing grants to disease-related organizations, and no industry group has either.

Marketing Research and Strategy

A final area of pharmaceutical drug company promotional activity involves engaging in marketing research and marketing strategizing. Market research is often conducted to study consumer and/or doctor comprehension of prescription drug advertising, promotional labeling, and warnings (Grande 2007; Greene 2007; Applbaum 2009). In addition, most pharmaceutical companies purchase prescription databases to analyze the prescribing behaviors of individual doctors (Greene 2007) and to customize their promotional materials and sales calls accordingly (e.g., to target doctors who are most interested in their branded drugs) (Steinman et al. 2006; Applbaum 2009; Spielmans and Parry 2010; Kesselheim, Mello, and Studdert 2011).

Reviewing Consumer Surveys. The FDA does not monitor pharmaceutical drug companies’ consumer research, so regulatory knowledge involves knowing that this area lacks FDA oversight. Consumer research may be conducted internally by the company itself or by one or more of its agents (e.g., its advertising or public relations agency). Other research may be conducted by third-party marketing research firms, some of whom issue syndicated reports that any company or entity may purchase. In particular, copy-tests are often used to determine what messages are conveyed in DTC television ads, promotional labels, and warnings. However, the FDA does not ask companies to submit their consumer

research findings or their purchased research reports to the agency. In fact, under the current law, the FDA is expressly prohibited from obtaining internal company research data, other than data related to new drugs (21 USC 374).

Reviewing Doctor Surveys. The FDA may, on occasion when it has a specific concern, review syndicated marketing research reports about doctors from third-party marketing research firms such as IMS Health (Dr. Peter Rheinstein, former FDA official, personal communication, December 18, 2015). IMS and other firms pay panels of doctors to complete surveys about the promotional messages they recall hearing during sales representatives’ detailing visits, including their verbatim recall of specific drug messages. These data are then compiled into syndicated reports that are sold to pharmaceutical companies and others. If the FDA becomes aware of a possible promotional violation, the agency may decide to purchase such a report. The FDA is permitted to review this type of data because it is provided by a third-party marketing research firm, and it is available for purchase; it is not internal drug company research data.

Purchasing Doctor Prescription Databases. The FDA purchases and monitors doctor prescription drug databases that indicate what specific drugs US doctors have prescribed, based on pharmacy records (Dr. Peter Rheinstein, former FDA official, personal communication, December 18, 2015). Therefore, knowledge of FDA oversight involves knowing that the agency monitors doctor prescription databases. These databases, which are compiled by third-party marketing research firms like IMS, identify the doctors, prescribed drugs, and prescription fill dates. Patient identifiers are stripped to protect patient confidentiality. The FDA uses these databases primarily to determine drug usage rates as a baseline for estimating adverse drug event rates. Companies use the databases for the same purpose and also for marketing purposes such as to develop sales goals, estimate sales trends, and monitor and direct sales representatives or detailers. While the FDA monitors doctor prescription databases, it does not regulate data collection or storage or try to protect doctor confidentiality or rights. However, the pharmaceutical industry’s code of conduct states that doctors should be allowed to opt out of such databases (Pharmaceutical Research and Manufacturers of America 2009). Accordingly, the American Medical Association’s Physician Data Restriction Program offers doctors the opportunity to opt out (American Medical Association 2016).

Creating Strategic Goals Related to Consumers or Doctors. Finally, the FDA does not monitor pharmaceutical drug companies' strategic communications goals or sales goals. Therefore, FDA regulatory knowledge involves knowing the agency provides no oversight in these areas. Most companies prepare strategic plans, typically on an annual basis, that state their marketing communications and sales goals (e.g., to convey to consumers and/or doctors that a drug provides a certain benefit to improve sales). The FDA does not review these strategic plans or sales goals because the agency is currently prohibited by law from obtaining "financial data, sales data . . . or pricing data" (21 USC 374) from pharmaceutical drug companies.

SURVEY OF CONSUMER AND DOCTOR PERSUASION KNOWLEDGE, REGULATORY BELIEFS, AND REGULATORY KNOWLEDGE

Survey Research Aims

One main aim of our quantitative research was to assess consumers' and doctors' persuasion knowledge of pharmaceutical drug company marketing and to compare their relative persuasion knowledge to test hypothesis 1. A second aim was to assess consumers' and doctors' regulatory beliefs and regulatory knowledge about FDA oversight and to compare their relative regulatory knowledge to test hypothesis 2.

Participants

A general population sample of 311 adults participated in our consumer survey (mean age = 47.1, 66.2% female, 33.6% with bachelor's degree or higher, 46.9% with household income greater than \$50,000). In addition, 104 licensed physicians participated in our doctor survey (mean age = 46.5, 36.5% female, 63.5% with 10+ years of practice experience). Survey participants were recruited from Qualtrics panels in exchange for monetary compensation during a weeklong period in September 2015. To ensure broad geographic representation, we specified quotas for the consumer and doctor samples from each region of the United States (West, Midwest, Northeast, South), with added quotas for age and ethnicity in the consumer sample. All quotas were based on the US Census population statistics. Full sample characteristics are in table 1.

Procedures

In each survey, we told participants they would be asked questions regarding the possible activities of US prescription drug companies and the US Food and Drug Administra-

tion (FDA). Then we asked about the 24 different pharmaceutical marketing-type activities that were drawn from the literature as outlined previously. We first asked if each activity was promotional in nature and then if it was monitored by the FDA. A supplementary section asked about desire for FDA oversight of each activity.

Measures

Persuasion Knowledge. To assess persuasion knowledge, participants were asked whether they believed that each of the 24 activities was a "promotional activity, i.e., an activity that promotes a drug." The response options were "1 = Definitely not a promotional activity, 2 = Probably not a promotional activity, 3 = Not sure if a promotional activity, 4 = Probably a promotional activity, and 5 = Definitely a promotional activity." Persuasion knowledge was recorded if the mean response was significantly higher than "not sure" (i.e., probably or definitely a promotional activity).

Regulatory Beliefs and Knowledge. To assess regulatory beliefs, participants were asked whether they believed the "FDA tries to track or monitor" each of the 24 activities. The response options were "1 = Definitely does not try to track; 2 = Probably does not try to track; 3 = Not sure; 4 = Probably tries to track; 5 = Definitely tries to track." A regulatory belief was recorded if the mean response was significantly higher than "not sure" (i.e., the FDA probably or definitely tries to track or monitor). We then assessed regulatory knowledge by comparing regulatory beliefs to actual FDA regulations.

Desire for FDA Oversight. To assess desire for FDA oversight, participants were asked whether they believed the "FDA should try to track or monitor" each of the 24 activities. The response options were "1 = Definitely should not track; 2 = Probably should not track; 3 = Not sure; 4 = Probably should track; 5 = Definitely should track." Desire was recorded if the mean response was significantly higher than "not sure" (i.e., the FDA probably or definitely should track or monitor).

Analyses

Factor Analyses of Scale Items. First we conducted a factor analysis of the 24 items that assessed persuasion knowledge about the activities being promotional. The purpose of the factor analysis was to verify that these items measured our general promotional categories of (1) advertising,

Table 1. Sample Characteristics

Variable	Consumers (<i>n</i> = 311)		Doctors (<i>n</i> = 104)	
	Frequency	%	Frequency	%
Sex				
Male	105	33.8	66	63.5
Female	206	66.2	38	36.5
Ethnicity				
White (non-Hispanic)	234	75.2	78	75.0
Black (African American)	31	10.0	3	2.9
Hispanic/Latino	31	10.0	6	5.8
Asian	11	3.5	16	15.4
Other	4	1.3	1	1.0
Region				
West	72	23.2	24	23.1
Midwest	68	21.9	23	22.1
Northeast	57	18.3	19	18.3
South	114	36.7	38	36.5
Education				
Some high school or less	7	2.3		
High school graduate	83	26.7		
Some college	76	24.4		
Associate degree	41	13.2		
Bachelor's degree (4 year)	72	23.2		
Master's degree	26	8.4		
Professional degree	3	1.0		
Doctorate degree	3	1.0		
Marital status				
Married or living with sig. other	184	59.2		
Single, never married	72	23.2		
Divorced or separated	36	11.6		
Widowed	19	6.1		
Employment status				
Employed full-time	126	40.5		
Employed part-time	39	12.5		
Unemployed	21	6.8		
Student	8	2.6		
Home-maker	44	14.1		
Retired	73	23.5		
Annual household income				
Less than 25 k	63	20.3		
25 to 50 k	102	32.8		
50 to 75 k	71	22.8		
75 to 100 k	41	13.2		
100 to 150 k	22	7.1		
150 to 200 k	6	1.9		
More than 200 k	6	1.9		
Years of experience as a doctor				
0 to 9 years			38	36.5
10 to 19 years			22	21.2
20 to 29 years			30	28.8
30 years or more			14	13.5

Table 1. (Continued)

Variable	Consumers (<i>n</i> = 311)		Doctors (<i>n</i> = 104)	
	Frequency	%	Frequency	%
Practice area				
Primary care			37	35.6
Specialist			67	64.4
Practice size				
Sole practitioner			16	15.4
2 to 4 doctors			24	23.1
5 to 10 doctors			18	17.3
11 or more doctors			46	44.2

Note.—Consumers: mean age = 47.1 years, SD = 17.4. Doctors: mean age = 46.5 years, SD = 13.2. Percentages may not add up to 100 due to rounding.

publicity, and social media; (2) sales communications to doctors; (3) continuing education for doctors; (4) public relations about a disease; and (5) marketing research and strategy. Aggregating across the consumer and doctor responses to the persuasion knowledge items, and using principal components analysis with varimax rotation and eigenvalue cutoffs greater than one, we extracted the five expected factors and verified that the individual items loaded on these factors as anticipated. Appendix table A2 provides a full list of factors, items, and item loadings, and appendix tables A3 and A4 provide the inter-item correlations for consumers and doctors, respectively.

Analyses Involving Persuasion Knowledge and Oversight Desire. For the persuasion knowledge items, we compared the mean response to the scale midpoint, separately for consumers and doctors, using *t*-tests. If the mean response was significantly higher than the scale midpoint, this indicated persuasion knowledge. In other words, the average respondent believed the activity was probably or definitely a promotional activity. Then we compared the doctor versus consumer mean response to each item, using unequal variance *t*-tests. If the mean doctor response was significantly higher than the mean consumer response, we concluded doctors had higher persuasion knowledge. We analyzed the items about desire for FDA oversight similarly.

Analyses Involving Regulatory Beliefs and Regulatory Knowledge. For the regulatory knowledge items, we again compared each mean response to the scale midpoint, sepa-

rately for consumers and doctors, using *t*-tests. If the mean response was significantly higher than the scale midpoint, this indicated a regulatory belief. In other words, the average respondent believed the activity was probably or definitely FDA regulated.

We then assessed regulatory knowledge. If the mean regulatory belief matched actual FDA regulation, we coded this as accurate regulatory knowledge. If the mean response indicated a regulatory belief but there was no regulation, or if the mean response indicated no regulatory belief but there was regulation, this was coded as inaccurate regulatory knowledge. If the FDA partially regulated an activity, any mean response was coded as partially accurate.

Finally, we compared doctor versus consumer regulatory knowledge. If both groups demonstrated accurate regulatory knowledge about an activity, or if both groups demonstrated inaccurate regulatory knowledge, we concluded their regulatory knowledge was comparable. If one group demonstrated accurate regulatory knowledge while the other did not, we concluded the first group had higher regulatory knowledge.

Results

Persuasion Knowledge. Table 2 summarizes the results for persuasion knowledge. Consistent with hypothesis 1, both consumers and doctors demonstrated considerable persuasion knowledge, with consumers recognizing the promotional nature of 20 of the 24 activities (83%) and doctors recognizing the promotional nature of 21 of the 24 activities (88%). The average consumer and doctor believed that all activities related to advertising, publicity, and social me-

Table 2. Persuasion Knowledge of Consumers and Doctors

Activity category and items	Consumer mean (SD)	Consumer knowledgeable (>midpoint)	Doctor mean (SD)	Doctor knowledgeable (>midpoint)	Doctor > consumer on persuasion knowledge
Advertising, publicity, and social media (overall)	4.42 (.73)	Yes	4.70 (.48)	Yes	Yes ($t = 4.54, p < .001$)
Advertising a drug to consumers	4.50 (.91)	Yes	4.80 (.55)	Yes	Yes ($t = 4.03, p < .001$)
Advertising a drug to doctors	4.41 (.96)	Yes	4.55 (.79)	Yes	No ($t = 1.48, p = .140$)
Seeking publicity for a drug	4.40 (.89)	Yes	4.57 (.75)	Yes	No ($t = 1.89, p = .060$)
Posting about a drug on social media	4.27 (1.01)	Yes	4.74 (.65)	Yes	Yes ($t = 5.46, p < .001$)
Paying celebrities to post on social media	4.50 (.95)	Yes	4.86 (.55)	Yes	Yes ($t = 4.62, p < .001$)
Sales communications to doctors (overall)	3.92 (.95)	Yes	3.92 (1.00)	Yes	No ($t = .01, p = .996$)
Showing a drug brochure or handout to doctors	4.25 (1.01)	Yes	4.32 (.95)	Yes	No ($t = .64, p = .524$)
Giving out a drug study after FDA approval to doctors	3.89 (1.15)	Yes	3.66 (1.20)	Yes	No ($t = -1.71, p = .089$)
Presenting preplanned drug information to doctors	3.80 (1.24)	Yes	3.79 (1.24)	Yes	No ($t = -.06, p = .949$)
Sending preplanned drug information to doctors	3.75 (1.22)	Yes	3.91 (1.18)	Yes	No ($t = 1.24, p = .217$)
Continuing education for doctors (overall)	4.01 (.87)	Yes	4.24 (.68)	Yes	Yes ($t = 2.80, p = .006$)
Funding continuing education for doctors	3.85 (1.20)	Yes	3.94 (1.00)	Yes	No ($t = .78, p = .435$)
Paying a doctor to present about a drug	4.35 (1.02)	Yes	4.65 (.79)	Yes	Yes ($t = 3.11, p = .002$)
Paying a doctor to present about a disease	4.11 (1.05)	Yes	4.16 (1.06)	Yes	No ($t = .48, p = .633$)
Providing meals to doctors during meetings	3.90 (1.28)	Yes	4.24 (1.05)	Yes	Yes ($t = 2.68, p = .008$)
Paying a doctor to write about a drug study	4.13 (1.16)	Yes	4.39 (.89)	Yes	Yes ($t = 2.41, p = .017$)
Paying someone to help a doctor write about a drug study	4.08 (1.17)	Yes	4.28 (.97)	Yes	No ($t = 1.71, p = .088$)
Giving out a drug study before FDA approval	3.64 (1.26)	Yes	4.01 (1.08)	Yes	Yes ($t = 2.89, p = .004$)
Public relations about a disease (overall)	3.07 (1.06)	No	3.13 (.99)	No	No ($t = .58, p = .562$)
Advertising about a disease	2.87 (1.28)	No	3.32 (1.12)	Yes	Yes ($t = 3.37, p = .001$)
Seeking publicity for a disease	3.09 (1.33)	No	3.11 (1.10)	No	No ($t = .14, p = .885$)
Providing grants to disease-related organizations	3.24 (1.32)	Yes	2.98 (1.27)	No	No ($t = -1.82, p = .071$)
Marketing research and strategy (overall)	3.38 (.94)	Yes	3.70 (.87)	Yes	Yes ($t = 3.17, p = .002$)
Reviewing consumer surveys	2.97 (1.29)	No	3.28 (1.25)	Yes	Yes ($t = 2.18, p = .031$)
Reviewing doctor surveys	2.97 (1.31)	No	3.20 (1.20)	No	No ($t = 1.63, p = .104$)
Purchasing doctor prescription databases	3.18 (1.27)	Yes	3.51 (1.20)	Yes	Yes ($t = 2.41, p = .017$)
Creating strategic goals about consumers	3.89 (1.09)	Yes	4.23 (.95)	Yes	Yes ($t = 3.05, p = .003$)
Creating strategic goals about doctors	3.91 (1.11)	Yes	4.29 (.90)	Yes	Yes ($t = 3.50, p = .001$)

Note.—Comparisons to scale midpoint of 3, $p < .05$. Doctor versus consumer comparisons calculated using unequal variance t -tests.

dia, sales communications to doctors, and continuing medical education were promotional. However, consumers did not believe that advertising about a disease or seeking publicity for a disease were promotional, while doctors believed the advertising to be promotional but not publicity. Consumers believed that providing grants to disease-related organizations was promotional; doctors did not. Both consumers and doctors believed that many of the marketing research and strategy activities were promotional, except reviewing consumer surveys (not promotional according to consumers) and reviewing doctor surveys (not promotional according to consumers and doctors). In sum, persuasion knowledge was high among both groups.

Nevertheless, consistent with hypothesis 1, doctors showed even more persuasion knowledge than consumers. On 12 of the 24 activities, doctors were significantly more likely than consumers to indicate that the activities were promotional in nature. These included three advertising, publicity, and social media activities, four continuing education activities, four marketing research and strategy activities, and one activity involving public relations about a disease (table 2).

Regulatory Beliefs. Table 3 summarizes the results on consumer and doctor regulatory beliefs. Consumers had strong regulatory beliefs, in that they believed that 19 of the 24 activities (79%) were FDA monitored. Consumers believed that all of the advertising, publicity, and social media activities were FDA monitored, as well as most of the sales communication activities (except showing a drug brochure or handout to doctors). Consumers also believed the FDA monitored most continuing education activities (except providing meals to doctors during meetings), and most marketing research and strategy activities (except reviewing consumer surveys and doctor surveys). However, consumers did not believe that advertising about a disease or seeking publicity for a disease were FDA monitored, though they believed that providing grants to disease-related organizations was FDA monitored.

Doctors had far weaker regulatory beliefs than consumers, in that they believed that just 11 of the 24 activities (46%) were FDA monitored. Doctors believed the FDA monitored many of the advertising, publicity, and social media activities (except posting about a drug on social media). Doctors also believed the FDA monitored many of the continuing education activities (except giving out a drug study before FDA approval). However, doctors did not believe the FDA monitored any of the sales communication activities, or

any of the marketing research and strategy activities. Moreover, doctors did not believe advertising about a disease or seeking publicity for a disease were FDA monitored, although they believed providing grants to disease-related organizations was FDA monitored, as did consumers.

Regulatory Knowledge. Table 3 also summarizes the results on consumer and doctor regulatory knowledge (i.e., comparing regulatory beliefs to actual FDA regulatory actions). Consistent with hypothesis 2, both consumers and doctors demonstrated limited regulatory knowledge of how the FDA regulates pharmaceutical drug marketing. Consumers were accurate for 11 of the 24 activities (46%). Consumers were most accurate about the advertising, publicity, and social media activities, correctly believing the FDA monitored virtually all of these activities. Consumers were also quite accurate about activities involving public relations about a disease, accurately believing the FDA did not monitor most of these activities. Otherwise consumers manifested weak regulatory knowledge, especially about continuing education for doctors, virtually always because consumers believed there was FDA monitoring when there was not (i.e., they overestimated the level of FDA oversight).

A comparison of doctors to consumers did not support hypothesis 2. Doctors' level of regulatory knowledge was roughly on par with that of consumers, rather than being superior. Doctors manifested accurate regulatory knowledge for just 10 of the 24 activities (42%), similar to consumers' 46% accuracy rate. Specifically, consumers and doctors showed comparable regulatory knowledge on 17 of the 24 activities (71%), doctors showed more knowledge on three (13%), and consumers showed more knowledge on four (17%).

Doctors, like consumers, had the greatest regulatory knowledge about advertising, publicity, and social media activities, and then about activities involving public relations about a disease. Doctors manifested inaccuracies with respect to sales communication activities, and marketing research and strategy activities, because they believed the FDA did not monitor these activities even when it does. Just like consumers, doctors were least accurate in their regulatory knowledge about continuing education for doctors, virtually always because they believed there was FDA monitoring when there was not. In fact, doctors were inaccurate about every one of the continuing education activities, and thus they performed worse than consumers.

Table 3. Regulatory Knowledge of Consumers and Doctors

Activity category and items	Consumer mean (SD)	Consumer has regulatory belief (>midpoint)	Consumer has regulatory knowledge (belief = FDA action)	Doctor mean (SD)	Doctor has regulatory belief (>midpoint)	Doctor has regulatory knowledge (belief = FDA action)	Doctor vs. consumer on regulatory knowledge
Advertising, publicity, and social media (overall)	3.50 (.91)	Yes	Part accurate	3.41 (.84)	Yes	Part accurate	Comparable
Advertising a drug to consumers	3.59 (1.14)	Yes	Accurate	3.77 (1.08)	Yes	Accurate	Comparable
Advertising a drug to doctors	3.54 (1.17)	Yes	Accurate	3.68 (1.07)	Yes	Accurate	Comparable
Seeking publicity for a drug	3.55 (1.15)	Yes	Accurate	3.26 (1.14)	Yes	Accurate	Comparable
Posting about a drug on social media	3.33 (1.22)	Yes	Part accurate	3.02 (1.17)	No	Part accurate	Comparable
Paying celebrities to post on social media	3.52 (1.30)	Yes	Accurate	3.32 (1.33)	Yes	Accurate	Comparable
Sales communications to doctors (overall)	3.17 (1.03)	Yes	Part accurate	2.86 (1.07)	No	Part accurate	Comparable
Showing a drug brochure or handout to doctors	2.90 (1.30)	No	Inaccurate	2.82 (1.28)	No	Inaccurate	Comparable
Giving out a drug study after FDA approval to doctors	3.35 (1.26)	Yes	Accurate	2.88 (1.21)	No	Inaccurate	Doctor < consumer
Presenting preplanned drug information to doctors	3.22 (1.19)	Yes	Inaccurate	2.88 (1.21)	No	Accurate	Doctor > consumer
Sending preplanned drug information to doctors	3.21 (1.20)	Yes	Part accurate	2.88 (1.20)	No	Part accurate	Comparable
Continuing education for doctors (overall)	3.51 (.94)	Yes	Part accurate	3.67 (.90)	Yes	Inaccurate	Comparable
Funding continuing education for doctors	3.47 (1.18)	Yes	Inaccurate	3.56 (1.06)	Yes	Inaccurate	Comparable
Paying a doctor to present about a drug	3.71 (1.22)	Yes	Inaccurate	3.93 (1.13)	Yes	Inaccurate	Comparable
Paying a doctor to present about a disease	3.63 (1.19)	Yes	Inaccurate	3.77 (1.12)	Yes	Inaccurate	Comparable

Providing meals to doctors during meetings	2.90 (1.34)	No	Accurate	3.55 (1.24)	Yes	Inaccurate	Doctor < consumer
Paying a doctor to write about a drug study	3.76 (1.17)	Yes	Inaccurate	4.02 (1.02)	Yes	Inaccurate	Comparable
Paying someone to help a doctor write about a drug study	3.63 (1.18)	Yes	Inaccurate	3.76 (1.19)	Yes	Inaccurate	Comparable
Giving out a drug study before FDA approval	3.48 (1.25)	Yes	Accurate	3.09 (1.28)	No	Inaccurate	Doctor < consumer
Public relations about a disease (overall)	3.20 (.96)	Yes	Part accurate	3.00 (.93)	No	Part accurate	Comparable
Advertising about a disease	3.03 (1.16)	No	Accurate	2.89 (1.06)	No	Accurate	Comparable
Seeking publicity for a disease	3.14 (1.24)	No	Accurate	2.80 (1.06)	No	Accurate	Comparable
Providing grants to disease-related organizations	3.43 (1.19)	Yes	Inaccurate	3.31 (1.25)	Yes	Inaccurate	Comparable
Marketing research and strategy (overall)	3.26 (.95)	Yes	Part accurate	2.66 (.96)	No	Part accurate	Comparable
Reviewing consumer surveys	3.14 (1.21)	No	Accurate	2.41 (1.13)	No	Accurate	Comparable
Reviewing doctor surveys	3.17 (1.22)	Yes	Part accurate	2.38 (1.11)	No	Part accurate	Comparable
Purchasing doctor prescription databases	3.65 (1.17)	Yes	Accurate	3.23 (1.24)	No	Inaccurate	Doctor < consumer
Creating strategic goals about consumers	3.17 (1.23)	Yes	Inaccurate	2.63 (1.04)	No	Accurate	Doctor > consumer
Creating strategic goals about doctors	3.15 (1.22)	Yes	Inaccurate	2.63 (1.07)	No	Accurate	Doctor > consumer

Note.—Comparisons to scale midpoint of 3, $p < .05$. Consumer versus doctor regulatory beliefs differed significantly for: Seeking publicity for a drug ($t = -2.22$, $p = .028$), Posting about a drug on social media ($t = -2.31$, $p = .022$), Sales communications to doctors (overall) ($t = -2.58$, $p = .011$), Giving out a drug study after FDA approval to doctors ($t = -3.45$, $p = .001$), Presenting preplanned drug information to doctors ($t = -2.52$, $p = .013$), Sending preplanned drug information to doctors ($t = -2.41$, $p = .017$), Providing meals to doctors during meetings ($t = 4.51$, $p < .001$), Paying a doctor to write about a drug study before FDA approval ($t = -2.75$, $p = .007$), Seeking publicity for a disease ($t = -2.72$, $p = .007$), Marketing research and strategy (overall) ($t = -5.54$, $p < .001$), Reviewing consumer surveys ($t = -5.54$, $p < .001$), Reviewing doctor surveys ($t = -6.20$, $p < .001$), Purchasing doctor prescription databases ($t = -3.04$, $p = .003$), creating strategic goals about consumers ($t = -4.33$, $p < .001$), and creating strategic goals about doctors ($t = -4.18$, $p < .001$).

Desire for FDA Oversight. Table 4 summarizes our additional descriptive results on consumer and doctor desire for FDA oversight. Consumers desired FDA oversight for all 24 activities (100%). Doctors were far more selective; they desired FDA oversight for just 11 of the 24 activities (46%). Doctors desired FDA oversight of all advertising, publicity, and social media activities, most activities involving continuing education for doctors, but just one of the five activities involving marketing research and strategy (purchasing doctor prescription databases), and none of the activities involving sales communications to doctors or public relations about a disease.

These findings indicate that desire for FDA oversight is not strongly related to persuasion knowledge in this context; these seem to be relatively independent constructs. For instance, while doctors believed 88% of the activities to be promotional reflecting persuasion knowledge, they desired FDA oversight of just 46% of them. Consumers believed 83% of the activities to be promotional but desired FDA oversight of 100%. The correlations among persuasion knowledge, regulatory beliefs, and desire for oversight are provided in appendix tables A3 and A4.

GENERAL DISCUSSION

Findings, Contributions, and Future Research

In this research, we introduced two novel constructs to the literature: regulatory beliefs or beliefs about regulatory oversight, and regulatory knowledge or regulatory belief accuracy. We empirically demonstrated that these constructs are distinct from but complementary to persuasion knowledge or knowledge of marketers' persuasive attempts (Friestad and Wright 1994, 1995). We also showed how to measure both regulatory knowledge and regulatory beliefs and we developed and partially tested a conceptual model with these constructs.

More specifically, in our empirical research, we assessed consumer and doctor persuasion knowledge about whether different pharmaceutical company activities were promotional, their regulatory beliefs about whether these activities were FDA monitored, and their regulatory knowledge or belief accuracy. We studied 24 different marketing-type activities related to advertising, publicity, and social media; sales communications to doctors; continuing education for doctors; public relations about a disease; and marketing research and strategy. We found that among both consumers and doctors, persuasion knowledge was quite high, in that both groups recognized the promotional nature of these activities, but doctors scored somewhat higher than consum-

ers. In contrast, doctors had weaker regulatory beliefs than consumers, that is, doctors were less likely to believe these activities were FDA regulated. Furthermore, both consumers and doctors had comparable and low regulatory knowledge, manifesting substantial knowledge deficits. Overall, our findings suggest that regulatory beliefs and regulatory knowledge merit additional study because they are distinct constructs from persuasion knowledge, and they could have important downstream consequences on evaluations of promotions, decision making, and well-being.

Our research also describes the current state of affairs regarding doctor and consumer regulatory beliefs and regulatory knowledge about FDA oversight of pharmaceutical drug company activities. Our findings indicate that consumers have relatively strong regulatory beliefs in that they believe the FDA monitors a large number of these activities. However, consumers lack regulatory knowledge because the FDA does not actually monitor many of these activities. Doctors have weaker regulatory beliefs than consumers, in that they believe many of the activities are not FDA monitored. Nevertheless, doctors also lack regulatory knowledge because the FDA monitors some activities doctors believe to be unmonitored, and the FDA does not monitor some activities doctors believe to be monitored.

We find that the largest gap in both consumer and doctor regulatory knowledge relates to continuing education for doctors, because both groups believe the FDA monitors virtually all of these activities when in fact the FDA does not monitor virtually any of them. Industry groups have guidelines or codes of conduct for continuing education for doctors, but this is fundamentally different from FDA monitoring, for example, in terms of the level of scrutiny and the costs of noncompliance. Doctors may have been aware of the industry guidelines and could have confused these with actual FDA regulation. Nevertheless, if doctors inaccurately believe continuing education for doctors is FDA monitored, they could potentially scrutinize it less carefully than they otherwise might. This is an issue that should be examined in future research.

We also measured consumer and doctor desire for FDA oversight, and we found that persuasion knowledge about an activity being promotional was not very highly correlated with desire for FDA oversight. Doctors had high persuasion knowledge and yet relatively low desire for FDA oversight. Consumers had somewhat lower persuasion knowledge but nonetheless desired FDA oversight of all activities. Future studies may want to examine why consumers desire FDA oversight while doctors often do not.

Table 4. Desire for FDA Oversight by Consumers and Doctors

Activity category and items	Consumer mean (SD)	(>Midpoint)	Doctor mean (SD)	Doctor oversight desire (>midpoint)	Consumer > doctor on oversight desire
Advertising, publicity, and social media (overall)	3.98 (.86)	Yes	3.75 (1.00)	Yes	Yes ($t = -2.04, p = .043$)
Advertising a drug to consumers	4.16 (1.05)	Yes	4.21 (1.06)	Yes	No ($t = .42, p = .672$)
Advertising a drug to doctors	4.17 (1.00)	Yes	4.08 (1.14)	Yes	No ($t = -.72, p = .471$)
Seeking publicity for a drug	3.91 (1.06)	Yes	3.51 (1.27)	Yes	Yes ($t = -2.90, p = .004$)
Posting about a drug on social media	3.70 (1.17)	Yes	3.33 (1.35)	Yes	Yes ($t = -2.50, p = .013$)
Paying celebrities to post on social media	3.95 (1.22)	Yes	3.63 (1.41)	Yes	Yes ($t = -2.01, p = .047$)
Sales communications to doctors (overall)	3.48 (1.06)	Yes	2.65 (1.19)	No	Yes ($t = -6.38, p < .001$)
Showing a drug brochure or handout to doctors	3.28 (1.28)	Yes	2.60 (1.33)	No	Yes ($t = -4.55, p = .001$)
Giving out a drug study after FDA approval to doctors	3.67 (1.20)	Yes	2.57 (1.27)	No	Yes ($t = -7.74, p < .001$)
Presenting preplanned drug information to doctors	3.51 (1.17)	Yes	2.69 (1.31)	No	Yes ($t = -5.69, p < .001$)
Sending preplanned drug information to doctors	3.48 (1.21)	Yes	2.74 (1.34)	No	Yes ($t = -5.00, p < .001$)
Continuing education for doctors (overall)	3.98 (.82)	Yes	3.63 (1.09)	Yes	Yes ($t = -2.99, p = .003$)
Funding continuing education for doctors	3.81 (1.12)	Yes	3.37 (1.32)	Yes	Yes ($t = -3.12, p = .002$)
Paying a doctor to present about a drug	4.19 (1.05)	Yes	4.00 (1.25)	Yes	No ($t = -1.39, p = .167$)
Paying a doctor to present about a disease	4.14 (1.04)	Yes	3.66 (1.36)	Yes	Yes ($t = -3.24, p = .001$)
Providing meals to doctors during meetings	3.37 (1.38)	Yes	3.13 (1.38)	No	No ($t = -1.49, p = .139$)
Paying a doctor to write about a drug study	4.19 (1.03)	Yes	4.05 (1.19)	Yes	No ($t = -1.11, p = .270$)
Paying someone to help a doctor write about a drug study	4.16 (1.04)	Yes	3.95 (1.30)	Yes	No ($t = -1.47, p = .144$)
Giving out a drug study before FDA approval	4.02 (1.09)	Yes	3.27 (1.44)	No	Yes ($t = -4.85, p < .001$)
Public relations about a disease (overall)	3.56 (1.02)	Yes	3.04 (1.15)	No	Yes ($t = -4.10, p < .001$)
Advertising about a disease	3.50 (1.20)	Yes	3.07 (1.32)	No	Yes ($t = -3.00, p = .003$)
Seeking publicity for a disease	3.50 (1.19)	Yes	2.89 (1.33)	No	Yes ($t = -4.10, p < .001$)
Providing grants to disease-related organizations	3.67 (1.25)	Yes	3.14 (1.40)	No	Yes ($t = -3.40, p = .001$)
Marketing research and strategy (overall)	3.65 (.93)	Yes	2.86 (1.14)	No	Yes ($t = -6.38, p < .001$)
Reviewing consumer surveys	3.46 (1.17)	Yes	2.64 (1.27)	No	Yes ($t = -5.81, p < .001$)
Reviewing doctor surveys	3.52 (1.24)	Yes	2.65 (1.24)	No	Yes ($t = -6.19, p < .001$)
Purchasing doctor prescription databases	4.03 (1.10)	Yes	3.50 (1.39)	Yes	Yes ($t = -3.56, p = .001$)
Creating strategic goals about consumers	3.59 (1.13)	Yes	2.79 (1.36)	No	Yes ($t = -5.40, p < .001$)
Creating strategic goals about doctors	3.65 (1.16)	Yes	2.72 (1.31)	No	Yes ($t = -6.46, p < .001$)

Note.—Comparisons to scale midpoint of 3, $p < .05$.

This research also extends the literature by examining the reactions of both consumers and doctors to 24 different pharmaceutical drug company activities, assessing their persuasion knowledge, regulatory beliefs, regulatory knowledge, and regulatory desire. Prior studies have typically focused on a single respondent group, such as consumers or medical students, and have measured opinions or attitudes about a single or a limited set of activities, such as DTC drug advertising (Bell, Kravitz, and Wilkes 1999; Huh, Delorme, and Reid 2004) or drug detailing (Sierles et al. 2005, 2015; Hyman et al. 2007; Soyk et al. 2010; Austad et al. 2011).

Implications for Public Policy

This research has potential implications for FDA actions. The literature has already demonstrated that pharmaceutical companies often use a wide variety of activities to serve their promotional goals (Topol 2004; Spence et al. 2005; Hill et al. 2008; Psaty and Kronmal 2008; Ross et al. 2008). Our work highlights that several of these activities are subject to little if any FDA monitoring. Activities that are not monitored by the FDA include continuing education, ghost writing and guest writing, detailing scripts used by sales representatives, response letters sent by medical affairs offices, advertising about a disease, seeking publicity for a disease, providing grants to disease-related organizations, marketing research about consumers, and strategic goals for doctors and consumers.

A concern about these unmonitored materials is that they could represent potential loopholes in FDA enforcement. For instance, if the FDA sends a warning letter to a pharmaceutical company mandating that it cease using a particular promotional claim that is violative, the claim could possibly be removed from materials that are monitored by the FDA but remain in nonmonitored materials such as the detailing scripts used by the company's sales representatives and the response letters sent by the company's medical affairs staff. Furthermore, the company's marketing research and strategy materials could possibly show that the company is intentionally continuing to make the violative promotional claim, and that doctors are continuing to hear the claim in continuing education which is not FDA monitored and/or from sales representatives whose detailing scripts are not FDA monitored.

As a result, a company might possibly continue to make a violative promotional claim for months or even years after an FDA warning letter has been issued. Therefore, the FDA and Congress might possibly want to consider some strategic changes in FDA regulatory oversight to allow the

agency to monitor at least some of the materials that it currently does not monitor (e.g., the detailing scripts that are used by pharmaceutical sales representatives). Additionally, the FDA might possibly want to try to educate consumers and/or doctors about the scope of its monitoring. For instance, doctors overestimated FDA monitoring of continuing education, and consumers overestimated FDA monitoring in many areas, so the FDA might want to inform both groups of the scope of its regulatory oversight.

Research Limitations

One limitation of our research is that we were unable to fully test our conceptual model, which extends the persuasion knowledge model to include regulatory beliefs and regulatory knowledge. Future research should test the full conceptual model and also study behavioral outcomes. Another limitation of our research is that, while we tried to use clear and concise descriptors of each activity in our surveys, it is possible that some consumers and/or doctors may have interpreted these descriptors differently from what we intended. Furthermore, while we characterized FDA regulatory oversight as present or absent to the best of our ability based on existing documents and wording, some of the wording is arguably ambiguous and subject to interpretation. Finally, while we tried to obtain representative samples of consumers and doctors, larger sample sizes may be needed to reach more definitive conclusions.

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