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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2009-N-0441

Written Comments: Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools

The Center for Digital Democracy (CDD) urges the Food and Drug Administration to conduct a much more thorough investigation into the use and impact of digital health marketing techniques and technologies. The health and safety of U.S. consumers must be protected from inappropriate and potentially harmful use of digital marketing applications that have been embraced by pharmaceutical and health marketers. It is essential that the FDA craft regulations and guidance for Internet-related promotion that reflect a thorough assessment of contemporary marketing practices, especially since interactive communications will become the dominant form for the delivery of health information and advertising to both consumers and health professionals.

By using an array of new digital marketing tools—including behavioral targeting, social media, online video, and mobile—pharmaceutical companies now have unprecedented abilities to take advantage of consumers.¹ Many of the new interactive marketing techniques have been purposely designed to tap into the concerns and anxieties of individuals who are going online to seek health information. For the most part, however, they remain invisible to consumers. We believe that some of the techniques may be unfair, deceptive, and/or harmful.

The following are only a few of the practices that are quickly becoming state-of-the-art in pharmaceutical marketing, and that raise serious consumer protection and health issues:

- *Behavioral targeting* and other forms of online data collection designed to identify, track, profile, and target an individual consumer based on a information seeking behaviors related to illnesses or symptoms.
- Use of online video and advertising networks to create “*disease*” or “*condition-specific*” channels (without clear disclosure of sponsor relationships) that are targeted at consumers with specific health concerns.
- *Social media marketing* applications that stealthily eavesdrop and analyze conversations by and among health consumers, taking advantage of users’ networks of friends to orchestrate peer-to-peer brand promotion.
- The use of neuroscience research-based techniques (known as *neuromarketing*) to influence subconscious decision-making processes about pharmaceutical products.²

While the FDA is to be commended for its current review of Internet and social media promotion, including the letters on paid search engine marketing sent last spring, and the two days of hearings held in November 2009, we believe the agency must engage in a much more deliberate and thorough evaluation prior to the development of any standard, “best practice,” or safe harbor for social media and digital marketing. For example, in their presentations to the FDA, in November 2009, pharmaceutical marketers purposely painted a sanitized, storybook image of social media marketing. Missing were data and information related to the powerful capabilities of interactive marketing to promote relationships with specific brands, including its ability to foster what has been called consumer “micro-persuasion.” A number of commentators suggested that the emergence of social media and other tools promoting communication among consumers should usher in relaxed guidelines, including those for the release of adverse effect information. But “Direct to Consumer Digital Marketing” of pharmaceutical and health-related products requires the FDA to re-evaluate its standards for advertising practices, including how it determines what is truthful and non-misleading.

As CDD has explained and documented in filings with the Federal Trade Commission and Congress (often in partnership with U.S. PIRG and other leading consumer groups), the online advertising “ecosystem” poses significant challenges to consumers that require a range of meaningful policy safeguards.³ Digital marketing applications for selling cars, food, and financial products have already raised privacy and related concerns at the FTC. When applied to digital pharmaceutical and health marketing, such practices call for an even higher level of scrutiny and policy intervention. CDD acknowledges the important role digital and social media play in providing consumers with access to in-depth information and support on health products and issues. But by using such new services, U.S. health consumers should not be subjected to hidden digital marketing techniques designed to amass detailed profiles of their behavior and target them with specific drugs and treatments.

In the following pages, we describe the major practices that are shaping digital marketing, with specific examples of how pharmaceutical companies are employing them to reach and engage consumers. CDD can provide the FDA with additional information beyond these introductory Comments on the unique capabilities of digital advertising, including research from industry that examines its abilities to deeply engage consumers in products and services. But we urge the FDA to carefully review the research and related analysis conducted by major online marketers, including Google, Microsoft, Yahoo and others, so it can begin evaluating what new policy safeguards should be required for digital pharmaceutical and health-related interactive marketing.⁴

Data Collection, Behavioral Targeting, and Interactive Marketing on Health Conditions and Concerns

Online pharmaceutical and health marketing companies have developed an extensive data collection and interactive targeting apparatus. Few U.S. health consumers are aware that they are being identified, labeled, profiled, and tracked on the Internet while they search or access information on specific conditions or concerns. The dangers of online behavioral targeting as a threat to consumer privacy have been amply chronicled. But the role it plays in appropriating sensitive consumer health and medical information for targeted online marketing has been largely overlooked by regulators, and must now be addressed by the FDA.⁵

Behavioral targeting enables health marketers to stealthily follow consumers online—sometimes on many different websites—gather details on their interests and activities (including now through offline databases and through psychographic and demographic analysis), and then offer them marketing messages precisely honed to their behaviors related to an illness or condition. AOL and many other digital marketers employ a new generation of online “ad networks” to help track and then target individual consumers seeking health-related information.⁶ There are also a number of specialized health portals and networks that were created to target consumers based on specific conditions or concerns.

Dozens of examples of interactive health marketing data collection practices exist for different illnesses and various health products. For example, among the behavioral marketers working with pharmaceutical companies is Adify, which “target[s] previous visitors to the advertiser’s site” and “deploy[s] tracking beacons, then use[s] sophisticated logic to define targetable behavioral segments.”⁷ AdRx Media, an ad network comprising Britannica Health, HealthGrades, Healthy.net, Merriam-Webster Medical Dictionary, OrganizedWisdom.com, and Wrong Diagnosis, along with more than 50 other health and wellness information sites, “gives advertisers a way to reach consumers while they are engaged in seeking health information on more targeted sites beyond the largest health properties.”⁸ AdRx promises its clients “...access to more than 20 million health-conscious

consumers, with condition-specific targeting,” as well as a variation on behavioral targeting that follows patients over the course of their treatment, “by sequencing messaging to appear within the patient lifecycle, from pre-diagnosis to diagnosis to condition management.”⁹

A number of advertising-driven health portals have emerged in recent years, each promising a variety of services for precision targeting:

- *Good Health Media*, with over 27 million unique visitors monthly, offers a “geo-medical targeting service” that “identifies groups with common sets of conditions/health-related characteristics by geographic region via insurance claims and individual ‘opt-in’ data.” Using keyword search analysis, GHM targets three broad audience categories: Consumer Health Conditions (Diabetes, COPD, Depression, Heart Health and many more); Consumer Wellness (Nutrition, fitness enthusiasts); and Healthcare Professionals (Sites and platforms to reach Doctor, Nurses).¹⁰ (It is unclear from the company’s website how insurance claim information is obtained or utilized, but such practices raise serious privacy issues.) “Pharmaceutical brands seek large, condition-specific audiences online, and we have the most precise solution available,” explains Bill Jennings, CEO of Good Health Media. The company “utilizes cutting edge behavioral targeting technology to identify and reach very large condition specific audiences like diabetes, asthma, high cholesterol, and arthritis. There is simply no better way to achieve high reach and optimization aimed at top health categories.”¹¹
- *Healthline* offers HealthSTAT (Semantic Taxonomy Ad Targeting), “a new ad-focused application that recognizes rich health-related concepts (as opposed to simple keywords) within the content on Healthline.com, and matches them with contextually relevant health advertising,” often in the form of what it calls “Behavioral Takeover” ads—rich media ads that pop up and take over an entire screen, “based on user behavior (e.g., 2 visits to condition article plus 1 to treatment).”¹²
- *HealthCentral*, an array of “highly targeted condition and wellness specific interactive health sites... offers advertising solutions across 35 condition-specific categories.”¹³ “We provide an interactive platform for users to engage personally with ‘someone like me;’ other people encountering similar health challenges.”¹⁴
- *Everyday Health* provides “consumers, advertisers and partners with content and advertising-based services across a broad portfolio of websites that span the health spectrum,” attracting an average of 26+ million unique visitors per month, with “over 38 million consumers [who] have registered on our websites to obtain personalized content and features, ...and over 1.7 million consumers [who] have paid for a

premium subscription service.” According to the company’s S-1 Form, filed recently with the Securities and Exchange Commission,

The unique composition of the Everyday Health portfolio, together with our large consumer audience, database of registered users and customized content offerings, has created an attractive platform for national, regional and local advertisers. This aggregation of trusted websites provides a diverse set of highly-targeted solutions for advertisers, including display advertising, integrated sponsorships, custom e-mail campaigns and lead generation products.... Our advertisers consist primarily of pharmaceutical and medical device companies, manufacturers and retailers of over-the-counter products and consumer-packaged-goods and healthcare providers.... Our focus on customized offerings, in addition to our engaged consumer base, allows advertisers to effectively target their desired audience through highly immersive and interactive campaigns. Our suite of advertising solutions, when combined with our extensive database of information voluntarily provided by millions of registered users, can facilitate advertising campaigns that are directed at specific geographic areas, demographic groups, interests, issues or user communities. Moreover, our data-driven focus enables us to provide detailed post-campaign reporting and metrics that allow advertisers to measure their results and evaluate the effectiveness of their campaigns.¹⁵

Pharmaceutical companies have created both branded and “unbranded” sites that are used as tools for data collection and behavioral targeting:

- *ShareYourPain.org* was developed by Blue Diesel on behalf of Cephalon, a global biopharmaceutical company with medications that treat central nervous system disorders, cancer, pain, and addiction. To create the site, Blue Diesel analyzed how the target group of consumers browsed the Web to find their own treatments, identifying “what search engines were most frequently used, what words and phrases they searched, and what other tools were utilized in their quest for pain treatment information.” According to the company, *ShareYourPain.org* “allowed the client to engage the target audience and collect data to further marketing efforts for their brand.... Data from the site was used to direct other marketing efforts for the brand.”¹⁶
- *The Caring Alliance* describes itself as “a network that connects advertisers and publishers with family caregivers and decision makers who are responsible for the care of their aging parents.” Among the network’s offerings to advertisers are Geo-Targeting (by state, MSA, city, or zip code), Contextual Targeting, Demographic Targeting, and Role-Based Targeting.¹⁷

The pharmaceutical and health marketing field is incorporating the latest developments in data collection, analysis, and targeting.

- Offline databases are increasingly incorporated into digital marketing strategies, enabling companies to amass greater amounts of detailed information about individual consumers than they would be able to generate from online sources alone. AOL Advertising, for example, uses outside data sources for its targeting efforts on behalf of an over-the-counter pharmaceutical company: “Existing brand consumers and key competitor brand users were identified and targeted using household-level purchase data from IRI, plus AOL Advertising’s demographic and psychographic targeting solutions. By partnering with Nielsen’s HomeScan panel and using our Target 2 Measure product, AOL’s research team was able to link online ad exposure to offline sales impact, thus demonstrating ROI.”¹⁸
- Ad exchanges allow individual users to be auctioned off to a specific advertiser in real time for ad targeting. Increasingly, the targeting is accompanied by what is known as “data optimization,” i.e., the use of various information resources to build up a more complete profile of a user. For example, Google/DoubleClick’s Ad Exchange Health focus has 36 categories, from Arthritis and Diabetes to Respiratory Conditions and Sleep Disorders.”¹⁹ Another advertising network, ADSDAQ, offers 50 health-related categories, from A.D.D. and Alzheimer’s Disease to Weight Loss and Women’s Health.²⁰
- Email marketing can also incorporate behavioral targeting techniques. For example, ExactTarget’s “one-to-one digital communications solution” offers its clients “precision targeting tools to dynamically turn your transactional emails into powerful marketing messages that your subscribers want to receive.”²¹
- Search marketing for health conditions has evolved into a highly sophisticated practice that can target information seekers through a variety of techniques, including the sale of related keywords, so-called organic search marketing, and reaching consumers through what is called “top of the search funnel.”²²

All of these practices call for further investigation by the FDA. In addition to data collection, the agency needs to examine the privacy policies and practices of pharmaceutical companies online. Little information is currently provided on what is being collected from users of health-related sites and how such data are used. In some circumstances, health consumers must first provide information prior to accessing the online services. For example, in our research, we found a Facebook-connected application for a health-related product that required individuals to provide access to their profile information before they would be able to obtain

additional information.²³

Audience Segmentation: Using Sensitive Data to Classify Health Consumers

Audience segmentation—dividing masses of consumers into much smaller affinity groups (e.g., Business Travelers, Sports Fans, Technophiles) for the purpose of targeted marketing—is a longstanding advertising practice. Its use by pharmaceutical marketers, especially in the digital context, raises a number of critical issues. The segments into which pharmaceutical companies divide their audiences go far beyond demographic and lifestyle categories to include highly personal and sensitive information relating to one’s health. For example, as Mark Miller, senior vice president for healthcare marketer Epsilon, explains, “Segment profiling dimensions include (but are not limited to): market size, geo-demographic characteristics, medication usage, self-care behaviors, bio-metrics, insurance coverage/ usage, needs/attitudes/behaviors and media consumption.”²⁴ The goal of those data collection and analysis efforts is to influence consumer behavior in some of the most personal and profound decisions they will ever have to make, concerning their own and their family’s health.

In some instances, segmentation techniques are employed to drill down into a specific market for a particular drug, in an effort to “drive increased adherence to therapy (especially when a patent is about to expire, and a company is facing competition from generic and alternative products). Such was the case with AstraZeneca’s beta-blocker Toprol-XL. The company “was looking for a feasible way to increase patient adherence to the drug and to develop an extended database to support new product launches within the cardiovascular category.” AstraZeneca called on the Rosetta agency to segment its patient database into actionable categories, permitting different customer-relationship techniques for each group. “Leveraging its patented patient Personality-based segmentation insights, Rosetta developed Heart Horizons, a fully integrated, online customer relationship program about heart health designed to convert, support, and drive persistence to drug therapy for Toprol-XL.”²⁵

Web analytics and audience segmentation often go hand-in-hand in modern interactive advertising. For example, HealthCentral “uses a semantic ontology to analyze search keywords” to assign one of the following labels: Condition, Symptom, Treatment, Other. These labels, in turn, are used by HealthCentral to tell marketers “a great deal about who is coming to your site: Worried about a symptom? Received a diagnosis? Managing a treatment regimen?”²⁶

Social Media: Promoting pharmaceuticals via the “social graph”

Social media marketing is a new form of interactive advertising that takes advantage of a person’s social relationships online—their so-called social graph—for brands

and other advertising. New surveillance tools have been developed to monitor conversations among social network users to identify what is being said about a particular issue or product. Marketers then work to insert brand-related messages into the social dialogue, often by identifying and targeting individuals considered brand “loyalists” or “influencers,” and encouraging them to generate buzz through their networks of friends. Increasingly, advertisers are using Facebook’s marketing apparatus—which is largely invisible to its users—to develop a brand presence on its pages so it can strongly connect to the social communications of a very large pool of consumers. Ultimately, much of social marketing is a non-transparent form of viral marketing that is designed to trigger peer-to-peer support for a brand or product. When used to promote pharmaceutical and health-related products, the practice raises particularly serious issues. While drug companies may argue that they use social networks in order “listen” to their consumers, social media marketing is a key advertising technique designed to influence perception and information of a brand without a clear understanding by the public of the techniques and targeting used.²⁷

Pharmaceutical and health marketers have managed to insinuate themselves into social media conversations in a variety of ways:

- *Heartbeat Digital’s BuzzScape* “allows clients to monitor discussions that flow in and out of the tens of thousands of message boards, forums, blogs and social networks that increasingly dominate the online environment. ‘We translate ‘buzz’ into ROI,’ said Bill Drummy, chairman and CEO of Heartbeat. ‘In a sense, we eavesdrop on public conversations among people with a shared interest, then use what we learn to create interactive marketing campaigns that address the identified needs, wants and gaps in knowledge of target audiences.’” Heartbeat Digital’s healthcare clients include Abbott Laboratories, Amgen, Baxter Bioscience, Biogen, BD, Eli Lilly and Company, Genentech, GlaxoSmithKline, Johnson & Johnson, Lifeline Schering, Memorial Sloan-Kettering Hospital, Merck, Millennium, Organon, Roche Diagnostics, Sanofi-Aventis, and UCB Pharma.²⁸
- *Semantelli’s BrandAlert Pharma* serves as a social media early-warning system—“the pharmaceutical industry’s first actionable, Semantic Web 3.0 platform that provides trends, insights and alerts from intelligence gathered through social and other web media channels never considered before,” such as “Realtime alerts when brand is discussed in 30+ FDA sites (including MedWatch and CDER).”²⁹
- *PatientsLikeMe* offers a new service, *PatientsLikeMeListen*, to its industry partners. In addition to giving pharmaceutical companies “unprecedented insight on how your brand is perceived,” the monitoring service also provides startling amounts of personal data about the online conversants, including gender, age, time on treatment, time since diagnosis, disease

progression, disease type, symptomology, longitudinal variation, and supporting therapies.³⁰

- In 2007 Pfizer forged a partnership with Sermo, the nation's largest online physician community, "designed to redefine the way physicians in the U.S. and the healthcare industry work together to improve patient care.... Through this collaboration, Sermo's community of physicians will have access to Pfizer's clinical content in tangible ways that allow for the transparent and efficient exchange of knowledge. With access to comprehensive and up-to-date information on Pfizer products, physicians will be able to find the data they need, when they need it, to make informed decisions."³¹
- Among its "Solutions for Pharma-Health Marketers," Nielsen Online offers "BuzzMetrics services, supported by our expertise in measuring and analyzing online buzz and word-of-mouth, deliver insights to proactively manage online exposure:
 - How patients and caregivers feel about your brand, product or service—in their words
 - Specific issues that are being discussed around your brand, products or organization
 - Events, trends and issues influencing the buzz around your brand
 - Insights into the doctor-patient relationship and analysis of doctor/healthcare professional discussions relevant to your brand
 - Guidance to proactively manage, minimize or avoid potential issues surrounding your reputation
 - Tools to leverage CGM to drive brand credibility and ultimately sales.³²
- As part of its effort to market Gardasil, a cervical cancer vaccine, Merck engaged the Rapp agency to set up a branded Facebook page, Take a Step Against Cervical Cancer, "triggering news feeds and advocating our message. A destination where anyone can find out the facts about cervical cancer and how to prevent it, the page also allows visitors to feel inspired, educated, and empowered to act for themselves and to help others. A key feature is a virtual wall that visitors can 'tag' with a logo and message. It allows each visitor to express their own uniqueness and intent."³³

Unbranded" sites (i.e., those focused on a specific disease or health condition, but sponsored—behind the scenes—by a pharmaceutical company that markets a treatment for the disease or condition) also warrant FDA scrutiny, especially those that purport to be user-driven communities. Dose of Digital blogger Jonathan Richman describes the benefits—to pharmaceutical companies, anyway—of unbranded sites, but also reveals the underlying threat to consumer welfare that they pose: "Unbranded experiences ... reduce regulatory risk since your brand isn't

mentioned, people can have ‘off label’ discussions where they talk about indications where your drug isn’t approved. It allows them to have the type of interaction they expect (i.e., one that isn’t constantly censored by a company worried about regulatory risks).”³⁴

Neuromarketing: Tapping into the Subconscious to Trigger Health-related Marketing Messages

One of online marketing’s foundational concepts is to engage consumers through subconscious means, including through the use of neuroscience-based techniques. Neuromarketing is increasingly employed to research, design, and implement online advertising campaigns—including those for health and medical products.³⁵

NeuroFocus, a firm that specializes in the application of brainwave research to advertising, programming, and messaging, uses “neurological testing [that] delves down to the subconscious mind,” far below such “corrupting factors” as education, language, and cultural variances.³⁶ Measuring as many as 64-128 sectors of the brain at 2,000 times per second, NeuroFocus promises results that are “unambiguous, accurate, and actionable.” In the words of NeuroFocus CEO A.K. Pradeep, because each response is “subconscious” and delivered in one-third of a second, the result is “a scientific measurement without biases and pitfalls. A sample size of 20 will produce 20 perfect responses.”³⁷ In 2008, the Nielsen Company made a “strategic investment” in NeuroFocus.³⁸

Pradeep has described the research in support of his company’s approach to neuromarketing:

...[W]e have identified 67 specific ‘best practices’ that should be implemented when words and images are presented on a screen (any screen, from a TV or PC to a mobile phone or movie theater). They are the result of advanced neurological research into various brain functions, and especially research that has delved into the mysteries of diseases like Alzheimer’s, and brain conditions like ADD/ADHD, obsessive/compulsive behavior, and bipolar disorder.³⁹

Among the pharmaceutical companies that have turned to NeuroFocus for assistance is Alcon, which sought help with a 30-second DTC TV spot for Pataday, a new prescription eye drop.

They wanted precise neuroscientific measurements of exactly how allergy sufferers responded to this new DTC ad. Specifically, Alcon asked NeuroFocus to use its proprietary methodology to answer:

- What are the most influential and most distracting components of this DTC ad?

- Which demographic is impacted most strongly? Least? Why?
- Did the audience act –did they make doctors appointments to obtain a prescription? Why or why not?
- What is the longevity of its influence/motivation?

Subconscious Resonance testing revealed how strongly or weakly the spot communicated client-determined attributes (such as “relief” and “fast-acting”). These unconscious attributes are revealed neurologically at a pre-verbal level and would have been impossible to obtain using traditional verbal self-reporting measures. Gender differences revealed in the brainwave response also gave Alcon critical information about its consumers’ deepest responses to their product. Recommendations were made to emphasize some attributes in subsequent print and online spots, and to de-emphasize others, in accordance with Alcon’s campaign goals.⁴⁰

Other companies have turned to similar techniques, including functional magnetic resonance imaging (fMRI) and eye-tracking studies, in an effort to assess the effectiveness of various advertising campaigns. Google, Microsoft and Yahoo and others have all conducted research involving neuromarketing.⁴¹ Researchers in the User Experience department at Digitas Health, for example, created psychological profiles to “recognize and capitalize on the needs and values of health information seekers:

In recent research conducted with 21 participants explicitly interested in specific health-related topics, we mapped their behaviors to three distinct personas and formulated a strategy for each.... In persona-driven design, research-based profiles are used to find and illuminate the path to success, rather than to define it. While defining a campaign objective based upon a demographic profile establishes measurable goals, referring to personas throughout the design process allows the creative and media teams the opportunity to evaluate or test content, interaction, creative, and placement before the campaign goes live.... Subjects were first asked to just “surf the Web” to establish their eye-tracking patterns (and rapport with the facilitator). Once the device (an SMI iView X RED) was calibrated, the unit remained unnoticed by the participants and enabled the recognition of scanning and reading behavior for each participant.... Analyzing the entire population, we distilled three distinct personas [“Allen,” “Christina,” and “Vivian”] with similar needs but significantly different values that inform the content, design, and placement of ads.... The best strategy to reach Allen is through a sponsored partnership.... The best strategy for engaging with Christina is the use of quizzes, polls, and the promise of interactive content that will allow her to express.... The best strategy for Vivian is to appeal to her empathy with the promise of personally relevant content on a topic of personal interest....⁴²

Marketers are particularly interested in research that addresses how “specific patterns of brain activation predict purchasing,” the potential “shopping centers in the brain,” and the neurological basis of purchasing.⁴³

Interactivity and Engagement: Harnessing Online for a “Brain Engaged Level of Intimacy”

As in other areas of modern digital advertising, pharmaceutical marketing is often tied to interactivity and engagement. Engagement is a key concept of digital marketing in particular, designed to draw website visitors into longer lasting, more intimate, and often emotional, relationships with brands and products. In evaluating how online pharma and health sites engage in digital marketing, the FDA needs to carefully assess how core concepts of engagement—which also involve data collection, personalization, community relationships and interactivity—have been used when developing a campaign or marketing a product.

As Microsoft’s Caroline Vogt observed in “The Intimacy of Online” (quoting Salzman and Matathia’s *Next Now: Trends for the Future*), “Brands that live on the internet or through the internet achieve a hands-on, eyes on, brain engaged level of intimacy with consumers that is unparalleled in most of the offline world.”⁴⁴ In addition to winning loyal customers, user engagement yields something equally important—more information from consumers about individual needs and preferences, personal data that is then used to personalize marketing messages to specific individuals. As GlaxoSmithKline’s Julie Wittes Schiack explained at the first annual meeting of the PMRG Institute in 2007, “The deeper the engagement the richer the insights.” In marketing its diet drug alli, GlaxoSmithKline built private online communities designed to collect consumer data. “A first-of-its-kind OTC drug launch required a new approach to listening to, and understanding, weight-challenged consumers—new ways that would get at consumers hearts and minds and provide an intimate experience, which allowed the company to go deeper than ever before. GSK Consumer Healthcare partnered with Communispace spanning 2+ years to create five private online communities that became the center of gravity for the entire multifaceted market launch of alli.”⁴⁵

Other marketers have turned to online games to attract viewers, who may not even be aware that they are the targets of a particular campaign. In marketing the prescription drug Ambien, for example, Sanofi-Aventis used a dedicated website, SilenceYourRooster.com, built around a Flash-based game to tout the drug’s sleep-inducing powers.

As an example of online engagement being put to use on behalf of a pharmaceutical product (Testim), Auxilium engaged the services of company called e-tractions to target the estimated 5 million men living with symptoms of low testosterone. The objectives for the campaign were “... to drive traffic to www.testim.com..., to encourage registrants to download a rebate coupon to stimulate demand..., to

collect names and email addresses of registrants so that TESTIM could communicate with registrants through permission-based emails on a regular basis..., [and to] use the registration as a means to better understand the demographic and behavioral profile of potential TESTIM patients.”⁴⁶

Mobile Marketing

Many of the same consumer data collection, profiling, and behavioral targeting techniques that have raised concerns in the more “traditional” online world have now been brought into the mobile phone marketplace. U.S. consumers will increasingly rely on their mobile devices for a wide range of services, including sensitive transactions related to health. Thus we should not permit the expansion of behavioral targeting into the mobile world (where it will be combined with precise location information and history) without strong privacy and consumer health-related safeguards in place.⁴⁷ “Mobile’s ability to provide superior targeting beyond age and gender,” notes Peter Nalen on the Compass Healthcare Communications blog, “to include location, time of day and day of week, and to facilitate two way communication between advertisers and consumers, makes it one of the main reasons that mobile is now. Not only does Mobile have a ubiquitous presence — with us 24/7—it can also reach more people, more efficiently, and with greater targetability. By building relationships via timely, relevant and valuable interactive conversations, Mobile can form the basis for strong long term relationships.”⁴⁸

The relationship of pharmaceutical and health products to the growth of mobile advertising requires an examination by the FDA. How various mobile “apps” are promoted—such as through “calls to action” on very small screens—needs careful evaluation. For example, as part of its “Get Ready for Bed” campaign, Johnson & Johnson subsidiary McNeil Consumer Healthcare launched an iPhone app on behalf of its Tylenol product. “The Tylenol PM Sleep Tracker iPhone application lets users track their sleep hours and moods, see their sleep history over time, add notes and customize their icons and get tips to help them sleep better.... Tylenol PM Sleep Tracker ads across [mobile ad network] AdMob’s network issued a call-to-action urging consumers to click through to the App Store to immediately download the application.” The “ad campaign that ran across iPhone sites and applications drove close to 3,000 downloads and increased Tylenol’s ranking in the App Store from No. 120 to 14, which in turn drove additional organic viral spread of the application.”⁴⁹

As the Consumers Union’s Steve Findlay declared at the FDA’s hearing last November, “...the advent of smart phones, ever-ready internet, digital media, new means of person-to-person communication (Text, Twitter, etc), and the Internet’s evolution to become a vast social networking medium have all posed new questions about how drug information and promotion is shared.” We concur with Consumers Union’s cautionary note on this front:

Email, text messaging and social networking sites pose different challenges.

We don't believe drug or device companies should be engaged in any promotion of their products via direct email or text messaging to consumers, blast email or email list- serves, chat rooms, or social networking bulletin boards that are operated by third parties. Period. The only legitimate use of such tools to communicate directly with consumers is via a company's own Web sites. And in that case, we believe full "fair and balanced" information rules should apply.⁵⁰

Recommendations

The FDA should conduct a thorough investigation and analysis of contemporary Digital Direct Marketing to Consumers of drug and health-related products and information. Online marketing seamlessly blends many different techniques that are designed to influence behavior through a range of related interactive applications, including the story-telling ability of interactive video to foster emotional responses. We urge the FDA to issue a report and recommendations designed to inform both consumers and health professionals of the issues raised by interactive ads for these products and services, including potential adverse effects. Specifically, the FDA should promptly undertake the following:

1. Examine and analyze the data collection and usage practices of pharmaceutical advertisers to assess the extent of consumer information collected through websites, social networks, online video sites, and other interactive means. This should include personal information, IP addresses, cookies, flash cookies, Web bugs, tracking pixels, Web analytic tools, conversational and sentiment analysis, and any other "data-mining" applications. We urge the FDA to resist suggestions that such data collection methods are appropriate because they can help identify risk-averse-related information. The FDA should provide the public with information on what data are collected and how they are used. (For example, what is considered by pharmaceutical marketers to be so-called non-personal information?) As the FDA knows, the FTC is currently in the process of re-evaluating what is considered personal and non-personal information—and it should work closely with that agency.⁵¹
2. Require companies engaged in digital marketing of health products under its purview to provide information on the kinds of online targeting techniques and methods they utilize, especially behavioral advertising and retargeting. Consumers need to know whether and how they are being tracked and targeted—including via "condition-specific" channels. This should include information on specific targeting and data collection and analysis techniques undertaken by their own or "unbranded" sites, as well as on health-oriented and ad-supported sites, other online advertising networks, and ad exchanges. The FDA should specifically ask

whether companies are profiling and targeting consumers based on racial and ethnic data.⁵²

3. Conduct its own review of the privacy policy pages on websites and services, including the leading social networks promoting health products under its purview. It should immediately require health marketers to provide adequate information on privacy policies, instead of incomplete or relatively inaccessible content (and work with the FTC to develop new rules for consumer privacy related to health information marketing online).⁵³
4. Analyze how health-related social media marketing influences consumer behavior and attitudes on drug use and about medical conditions. The agency should examine social media marketing applications for the health market designed to foster “viral” marketing approaches, including the targeting of specific consumers in order to influence their own network of relationships.⁵⁴
5. Obtain from pharmaceutical companies a list of the keywords used for paid search campaigns. The companies should also be required to inform the FDA of the techniques and applications they may use in so-called organic search to show up prominently in the results. U.S. consumers should be informed by the FDA of the implications of search marketing practices when they are looking for information and advice.⁵⁵
6. Evaluate the role of Web design, including the use of eye-tracking and so-called “A/B” testing for landing pages to influence how consumers react to content on pharmaceutical and health-ad-supported sites and services. The issue of how best to present risk information and other important disclosure information needs to be understood in the context of work by digital marketers on engagement, including design.⁵⁶
7. Investigate the use of so-called “unbranded” sites funded by pharmaceutical companies, in order to assess whether such sites are structured and designed to support the promotion of specific drugs. The agency should also analyze whether the interactive environment created for such sites provides a balanced and honest reflection of the health risks and condition-specific issues.
8. Conduct an inquiry on the use of neuromarketing-related techniques designed to influence or measure subconscious responses.⁵⁷
9. Work with the Federal Trade Commission and other appropriate agencies to develop a set of policies for regulating the use of behavioral targeting, data collection, and other digital techniques in the marketing of drugs and health-related products.

As we stated earlier, CDD concurs with Consumers Union's recommendations made to the FDA last November, which also called for an investigation of online marketing practices. These Comments are designed to raise some of the fundamental questions, and we are happy to provide more data and information. We will soon be requesting a meeting with Dr. Hamburg and other FDA officials from the Division of Drug Marketing, Advertising, and Communications to discuss our concerns and proposals for governing Digital Direct to Consumers health marketing.

Respectfully submitted,



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