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Coalition for Healthcare Communication

2014 Annual Report

A Quick Look Ahead

As 2014 comes to a close, we face an unprecedented number of acrimonious debates on Capitol Hill, concerns about the efficacy and future of the Affordable Care Act and a sometimes hostile HHS and FDA. In Congress, there seems to be consensus on only one relevant issue, i.e., that the corporate tax code needs substantial reform. As this tax reform is discussed and takes shape, we continue to fight proposals in the House Ways and Means Committee and the Senate Finance Committee to reduce the deductibility of advertising costs. We expect that issue will be front and center as long as corporate tax reform is considered.

Meanwhile, as we urge otherwise, HHS is insisting that textbooks and reprints are considered reportable transfers of value under the "Sunshine Act" rules. Additionally, FDA continues to provide guidance on social media that responds inadequately to the real needs of the industry as it develops marketing policy for the new media. On a positive note, FDA's drug center continues to approve new drugs at an aggressive rate. Indeed, as 2014 comes to an end, it promises to be a record year for drug approvals, both under the "breakthrough" designation and under the new approval program for mainstream drugs. Meanwhile, FDA seems on the precipice of approving new biologicals under its authority for approving follow-on biologics.

We are closely following the regulatory developments driven by First Amendment challenges to FDA bans on "off-label" marketing. Regulatory relief from significant prosecutions and sometimes multi-billion dollar off-label settlements, as well as Corporate Integrity Agreements and Deferred Prosecution Agreement, would be beneficial to our business. We expect further challenges to FDA marketing regulation from industry and others – especially in light of our significant Supreme Court victory in *IMS v. Sorrell,* and the follow-on *US. v. Caronia* decision – that reiterate the First Amendment protection of truthful industry communications. Indeed, the FDA has recently recognized the need to reform its rules in light of the First Amendment and has promised some new guidance as early as the end of this year. The Coalition is working closely with PhRMA and the industry-sponsored Medical Information Working Group (MIWG) and others to help guide FDA to a new, more rational approach to the regulation of marketing that is based on emerging research and peer-reviewed data.

In sum, the challenges to medical communication and marketing for 2015 look both familiar and difficult, but they are not insurmountable.

Our Goals and Our Members

As directed by the Coalition Executive Committee, our focus is on:

- Providing public policy intelligence to member companies; and
- Focusing advocacy efforts on government threats to the bottom line of our member businesses.

Members of the Coalition are as follows: HAVAS Health, IPG, Omnicom, Publicis, Ogilvy/WPP, Abelson Taylor, WebMD, Advanstar, the American Academy of Family Physicians, the American Association of Advertising Agencies, the Association of Medical Media, Beacon Healthcare, Connect Healthcare, Crossix, Frontline Medical Communications, Everyday Health Media, Reed Elsevier, Haymarket, HMP, KnowledgePoint360, the Massachusetts Medical Society, Pacific Communications, Radius Medical, Slack, Calcium/Vox Medica, Springer and Wolters Kluwer

2014 Outreach Activities

During the past year, the Coalition has engaged in outreach efforts both to raise the public profile of the organization and to better serve its members. These activities are described here.

PUBLIC/INDUSTRY OUTREACH

1. ***Refreshed Website*:** The Coalition has built on the momentum created by the renewed Website with continuously refreshed editorial content, blogging and public feedback.

2. ***SmartBrief*:** The Coalition-sponsored SmartBrief for Health Care Marketers pushes e-mail news summaries, which are sent free to Coalition member subscribers weekly (on Tuesdays), and include at least one Coalition news item with links back to the Coalition Website.

3. ***Industry Meeting Participation*:** The Coalition Executive Director participated in programming committees for meetings of the Drug Information Association, the Food and Drug Law Institute, and other commercial meeting organizations. In addition, the executive director appeared as a speaker, panelist or moderator at more than a dozen industry conferences for these and other groups to increase awareness of the Coalition and its issues.

MEMBER OUTREACH

1. ***Washington Meetings:*** On September 22 and 23, more than 50 Coalition Leaders met with industry and other medical policy experts in Washington, D.C. Dinner at the National Press Club featured the remarks of Nuala O'Connor, the head of the Center for Democracy and Technology, and former chief privacy office in major government and industry organizations. The next morning featured a speech by Washington commentator Mark Shields, an industry update on Washington policy issues by the Executive Directors, plus a deep dive on privacy by Washington and industry speakers.

2. ***New York Leadership Breakfast Briefings:*** On Jan. 16 and Nov. 10, the Coalition held member meetings at the offices of Ogilvy CommonHealth in New York City. The Jan. 16 meeting was highlighted by remarks from Cole Werble, Publisher of the *RPM Report* in Washington, covering immediate past and likely 2014 policy events in Washington. The Nov. 10 event was highlighted by Sally Susman, EVP of Pfizer, who focused on the public affairs and regulatory challenges to our industry and the opportunities for collaboration between Pfizer and the Coalition. Both events were attended by more than 60 members.

3. ***Industry Leader Messages:*** The Executive Director sent eight "Industry Leader" memos during the past year, which included relevant background and back-channel information on major issues before the courts, Congress, HHS and the FDA. These messages are sent via e-mail to the Executive Committee and to senior leaders in contributing companies.

4. ***Executive Briefings:*** The Executive Director visited more than a dozen agencies and publishers for executive briefings and regulatory strategy sessions.

5. ***Policy Education Sessions*****:** The Executive Director and the Foundation Executive Director visited several member companies, providing customized senior staff education.

Current Challenges and Action

THE "BIG FOUR" CHALLENGES/OPPORTUNITIES

Healthcare marketers face many obstacles in today's highly charged political environment. Specific challenges requiring the Coalition's attention and support include:

(1) Congressionally imposed taxes on medical marketing;
(2) Government and organized medicine efforts to restrict industry collaboration with prescribers, opinion leaders and academia;
(3) FDA's high-profile enforcement actions and guidance documents related to marketing, including Internet and social media; and

(4) Federal and state efforts to restrict marketing data gathering and use, including state restrictions on prescriber data and federal privacy proposals to limit Internet data gathering.

Each of these challenges and the corresponding Coalition efforts to mitigate their impact is highlighted below.

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Challenge 1*: Potential Federal legislation to increase taxes on medical communications and marketing*

Background: Congressional leaders proposed reducing the tax deduction on medical marketing expenditures in both the House and the Senate in 2014. In the House, Ways and Means Committee Chairman Dave Camp (R-MI) proposed to deduct only 50% of the costs of marketing in the year expended and amortize the other 50% over the subsequent 10 years. In the Senate, Finance Committee Chairman Baucus (D-MT) proposed deducting 50% in the year expended and amortize the rest over five years. The Congressional Budget Office estimated that the provision would raise more than $169 billion over 10 years. The Advertising Coalition (TAC) estimates that the Camp proposal would increase the after-tax cost of marketing by 12% in the first three years. These estimates and the desire by the White House and both Houses in the Congress to reform the corporate tax code virtually ensures that the advertising tax issue will be debated during the next Congressional session, and maybe beyond.

Coalition Actions:

1. Collaborating with The Advertising Coalition (TAC) through the D.C.-office of the American Association of Advertising Agencies to ensure that medical marketing issues are addressed in the policy debates on Capitol Hill. The TAC, which comprises the major advertising and media associations, monitors all marketing-related legislative proposals. In 2014 the TAC met often with members of Congress and their staff on major proposals. In addition, on several occasions this year, TAC member executives met in "grassroots" meetings with Members of Congress. Late this year, the TAC members were meeting with Members and staff on both sides of the Hill, including meetings with the new Senate Finance Committee Chair, Sen. Orrin Hatch (R-UT) and the presumed Ways and Means Committee Chair, Congressman Paul Ryan (R-WI). In these meetings, the Coalition and TAC members used the research published by the HIS Global Insights of the Economic Effects of Advertising on jobs and U.S. economic activity. According to the HIS studies, advertising helps produce 21.7 million jobs (or 16% of all jobs in the United States) and advertising helps generate $5.8 trillion or 17.2% of the United States' economic activity. A new tax on advertising would greatly inhibit those effects.

2. Developing and circulating – through its Website postings and other written and meeting venues – information and research updates on the value of industry communication in the delivery of effective, efficient healthcare in America.

3. Preparing for a grassroots appeal from our members by setting up a system to alert members of specific threats to marketing and enabling efficient, targeted messages that can be sent to Members of Congress and their staffs.

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Challenge 2: *Growing efforts to suppress manufacturer and marketing industry collaboration with prescribers, opinion leaders and academia*

Background: The pressure to reduce our access to medical professionals has increased in several ways:

1. The "Sunshine Act" section of the Affordable Care Act created a national registry of payments to physicians that is being developed through an HHS rulemaking. Data collection by biopharma and device companies began on Aug. 1, 2013, and the first national registry of such payments was released by HHS in November of this year. The most troubling aspect for Coalition members was the HHS decision to include medical textbooks and journal reprints among the items that must be reported.

2. In addition to state and federal payment registries, several states and medical organizations have created guidelines and other restrictions on collaboration with physicians. The Sunshine Act does not preempt existing state laws or additional provisions by the individual states. Therefore, state programs like those in Maine, Massachusetts, Minnesota, New Hampshire and Vermont have continued; several states have enacted measures requiring that additional transfers of value be reported.

3. Efforts by organized medicine to limit industry access to medical schools, hospitals, specialty societies, physician group practices, etc., continue to grow and are fueled by campaigns led by organized medicine, journal editors, the Institute of Medicine and others.

4. ProPublica, a self-styled advocacy group supporting investigative journalists, has continued a well-coordinated and extensive publicity program to discredit doctors who collaborate with industry, especially in marketing.

Coalition Actions:

1. Supporting allies, including PhRMA, industry companies and professional groups advocating and participating in industry collaborations to emphasize the importance of

education and communication in the delivery of effective and efficient healthcare in America.

2. Supporting the Association of Clinical Researchers and Educators (ACRE), the physician group that favors industry collaboration, including ACRE's official statement respecting the value of industry support and research for educator and industry collaboration.

3. Organizing industry meetings with officials of the HHS Centers for Medicare & Medicaid Services on proposed rules implementing the Sunshine Act, particularly the decision to include medical texts and reprints among reportable items. The Coalition coordinated these meetings on behalf of Coalition members, including the American Medical Association, Elsevier, the Massachusetts Medical Society, Slack Publishers, Wolters Kluwer, Springer and other publishers.

4. Cooperating with a major industry and Capitol Hill effort to enlist state medical societies, medical organizations and Members of Congress to urge HHS to reverse its decision on medical texts and reprints.

5. Coordinating the efforts of industry partners to urge House Members Michael Burgess (R-TX) and Allyson Schwartz (D-PA) to introduce HR 5539, to exempt peer-reviewed journals, journal reprints, journal supplements, and medical textbooks. As part of that effort, the Coalition supported a special briefing for Members and staff on the measure on Nov. 13.

5. Remaining visible at industry and government events and to the press to advocate for the value of marketing and industry collaboration with physicians.

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Challenge 3: *High-profile marketing enforcement by FDA DDMAC/OPDP*

Background: Marketing enforcement through Warning Letters and Untitled Letters from the FDA's Office of Prescription Drug Promotion has increased significantly during the past few years. Although these letters cite traditional infractions, the FDA actions are more frequent and less predictable. In addition, approval times for launch campaigns have become longer, effectively shortening the patent protection period for new drugs and new indications.

Additional FDA issues include:

1. *Internet and Social Media*: FDA guidances on Internet and social media policies have led to little useful new guidance on marketing in the new media.

2. *Research studies on DTC Advertising:* As of late November 2014, the FDA has announced its intent to launch six new studies of DTC advertising. Although one of these studies suggested that existing mandated warnings may be too long, others involved questionable hypotheses that could form the basis for further regulation of consumer advertising.

Coalition Actions:

1. Advocating the development of clear FDA standards for medical marketing enforcement, especially those that would clarify the off-label restrictions, as well as those that add more speed, predictability and consistency to enforcement activities and drug marketing approvals.

2. Participating in the proceedings and policy discussions at FDA by providing formal comments to FDA proposals on social media and DTC advertising.

3. Increasing the profile of the Coalition with FDA and industry through participation in the Alliance for a Stronger FDA, the Drug Information Association and the Food and Drug Law Institute, as well as engaging with the Washington and medical marketing trade press.

4. Advocating for swift, clear guidance by the FDA for Internet and social media communications, which includes acting as liaison to FDA for the Digital Health Coalition.

5. Filing official comments to FDA in major proceedings, following meetings with members highlighting specific data and information. The Coalition filed comments on a proposed research study hypothesizing that much of the current information required in DTC advertisements is counterproductive, and on a proposed guidance on social media marketing.

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Challenge 4: *Federal and state efforts to restrict marketing data gathering and use, including state restrictions on prescriber data and federal privacy proposals on online data gathering*

Background: State efforts to restrict use of prescription data were largely invalidated by the Supreme Court decision in *IMS v. Sorrell.* Meanwhile, the Coalition does not underestimate the will and creativity of state legislatures, and several states have amended their "Sunshine" statutes to conform to the federal law, including creating new, state-only

provisions. Similarly, several Members of Congress, the Federal Trade Commission and the Department of Commerce have proposed privacy restrictions that would severely limit the ability of industry to gather and use online data. However, in the second half of 2014, the focus of privacy provisions has moved from "do-not-track" proposals to proposals that would increase the security of privacy information held in private and government hands.

Coalition Actions:

1. Coordinating the filing of "friend of the court" briefs challenging limits to medical marketing (as the Coalition did in the Supreme Court *IMS v. Sorrell* case).

2. Continuing collaboration with industry on prosecutions by FDA, the HHS Inspector General, and state and private plaintiff actions against companies under the "off-label" and "false claims" provisions.

3. Becoming involved with a "citizen petition" to FDA filed by the Medical Information Working Group (MIWG) of several major biopharmaceutical companies requesting more specific guidance on off-label policies. This includes collaborating with PhRMA in the development of a White Paper and a letter to FDA requesting immediate guidance on company use of economic and comparative effectiveness data.

4. Participating with the Washington office of the 4A's in formal coalitions focused on evaluating online privacy proposals by Congress, FTC and the Department of Commerce.

5. Participating with the Washington office of the 4A's in the Digital Advertising Alliance, including the development of self-regulatory principles for online collection of Web data and the creation and implementation of the program with the National Advertising Division of the Better Business Bureau. Most major advertisers and agencies are now adopting the new AdChoices icon for Web banners.

In Closing

Careful monitoring and proactive advocacy are essential to serving our membership and preserving our mission. Your interest and participation are critical as we shape our strategies for another challenging year.