



John F. Kamp, JD, PhD

Executive Director of the Coalition for Healthcare Communication

Dr. John F. Kamp is Executive Director of the Coalition for Healthcare Communication, a drug-marketing group with offices in New York City and Washington, DC. He is also of counsel with the law firm Wiley Rein LLP, and is a well-known advocate for First Amendment rights of individuals and corporations. His professional experience includes 10 years with the Washington, DC, office of the American Association of Advertising Agencies and nearly a decade in public policy positions at the Federal Communications Commission (FCC). Before moving to Washington, Dr. Kamp taught journalism at the University of Iowa and at Tulsa University.

Dr. Kamp earned his bachelor's degree at the University of Notre Dame, his doctorate from the University of Iowa School of Journalism in Iowa City, and his juris doctorate at the University of Tulsa School of Law.

Dr. Kamp is a frequent speaker at industry meetings on ethical, legal, and political issues surrounding drug marketing, and is recognized as an authority in these issues by the print and broadcast press. He serves on the public advisory committees of the American Academy of Family Physicians and Medscape. He is on the editorial boards of the *Rx Compliance Report*, *Medical Marketing and Media*, and the *FDA Advertising and Promotion Manual*. Dr. Kamp is co-author (with Wayne Pines) of 3 books on compliance with FDA policy published by FDA News, including *DTC Advertising and Promotion: The Changing Environment*, published in January 2006. He is also a public member of the National Advertising Review Board, the self-regulation body of the advertising industry run by the National Better Business Bureau.

Disclosure: John Kamp is Executive Director of the Coalition for Healthcare Communication, a policy group with membership from trade associations including the American Association of Advertising Agencies and the Association of Medical Media, and America's leading medical marketing and education companies, Kamp has provided regulatory and strategic consulting and/or regulatory training for several marketing companies, including Sudler & Hennessey, and drug and device companies, including Cephalon and Wyeth. Kamp owns stock in companies in the drug and device industries, including Johnson & Johnson, Pfizer, Amylin, Abbott, and Sucampo and in related communication and media companies, including McGraw-Hill, Omnicom and WPP Group. Kamp also serves as "of counsel" at Wiley, Rein in Washington, DC.

Mr. Kamp is not an expert in the practice of medicine and does not make therapeutic recommendations for any specific drug, device or procedure. Moreover, any discussion of "on label" and "off label" use will be in the context of public policy; good industry practice; and/or government rules, procedures and enforcement actions.



COALITION FOR HEALTHCARE COMMUNICATION

Healthcare Marketing in the Wake MMA, FDAAA and Health Care Reform

**Alliance REMS Conference
April 9, 2010**

Agenda

Who We Are

Our Mission

Our Passions

What Legislation Matters to You

What Needs to Happen

Coalition for Healthcare Communication

Who Are We

AAAA

AAFP

Alliance Healthcare Information

Ashfield Medical

Association of Medical Media

Elsevier

Euro RSCG Life

Haymarket

Healthline Networks

Inventiv

IPG McCann-Draft FCB

KnowledgePoint360

Massachusetts Medical Society

Omnicom

Physician Education Resources

Publicis Healthcare

Slack

US HealthConnect

WPP



The Coalition Mission

**To promote and protect the benefit
of the free flow of healthcare information
for society and individual patients**

Coalition Passions

- Biopharma and device companies have a First Amendment right and a social responsibility to educate healthcare providers and patients about their products
- Self-regulation is a hallmark of great marketing and good business
- Marketing is just as important as R & D

What's Changed that Matters To You

The Big Three Statutory Changes (for now)

- 1. MMA – Medicare Part D adds drugs to Medicare**
 - In effect, the first stage of health care reform for our industry
 - The government become the biggest payer of prescriptions
- 2. FDAAA empowers FDA to more aggressively manage drug risks**
 - Including codification of Risk Evaluation and Mitigation Strategies (REMS)
- 3. Health Care Reform**
 - Including elevation of “comparative effectiveness” research, accelerating the trend toward a national standards of medical care, including prescribing decisions

Who “Wins” in Healthcare Reform

- 30 Million uninsured patients
- Pharmaceutical Marketers/Educators
- Industry – pharma, bio and devices

Pharma Marketers

- No sweeping change in the tax treatment of marketing expenses
- No direct limits on marketing messages or media
 - No DTC Ban
 - No new content mandates or bans (although FDA keeps tightening)
 - No new disclosure mandates, particularly inclusion of comparative effectiveness data
 - No ban on the marketing use of prescription data (although the state versions continue)
- But “Transparency” provision creates national registry of payments to prescribers

Industry, especially pharma

- PhRMA “deal” costs 80-90 Billion dollars starting in 2012, but
 - Retains US pricing, profit system for drugs and biologics
 - Adds 30+ million insured purchasers of medicines
 - Phases out “donut hole” in Medicare Part D
 - Reducing senior anxiety, anger at industry
 - Reducing incentive for patients to use generics
 - Establishes 12 year exclusivity for biologics
 - Creates new drug type approval regime for follow-on biologics
 - Avoids more aggressive price discounts (for now)
 - Avoids “re-importation” price pressures
- Device industry pays more tax, but retains business model

FDAAA – New Broad Safety Powers for FDA

- Active surveillance system
- REMS
 - Communication programs
 - Marketing channel controls
 - Restricted use
 - Follow up review, revisions, etc.
- Labeling powers
- New power to require studies, reports, and clinical trials

Your REMS Questions

- Do you think the FDA will put resources into public education about REMS?
- Do you believe REMS is designed more to win back public confidence in the FDA rather than actual outcomes?
- Do you think REMS will result in measurable improved public safety?
- Are there formal plans by the government to measure the impact of REMS and report back?

What Must Happen

- **Value of Medical Communication Must Be Made Clear to Policy Makers**
 - Patient care, patient care, patient care
 - Must measure outcomes, circulate proof
 - Doctors and patients must join effort
- **Communication professionals must respect economic & political realities & be prepared to adapt to rapid change**
- **Must BE and be SEEN as part of the solution to the delivery of effective, effective patient care**

For Further Information

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