

Insights. Collaboration. Advocacy.

Bitter Pills: The Political Environment for DTC Advertising

Dan Jaffe

Executive Vice President, Government Relations
Association of National Advertisers

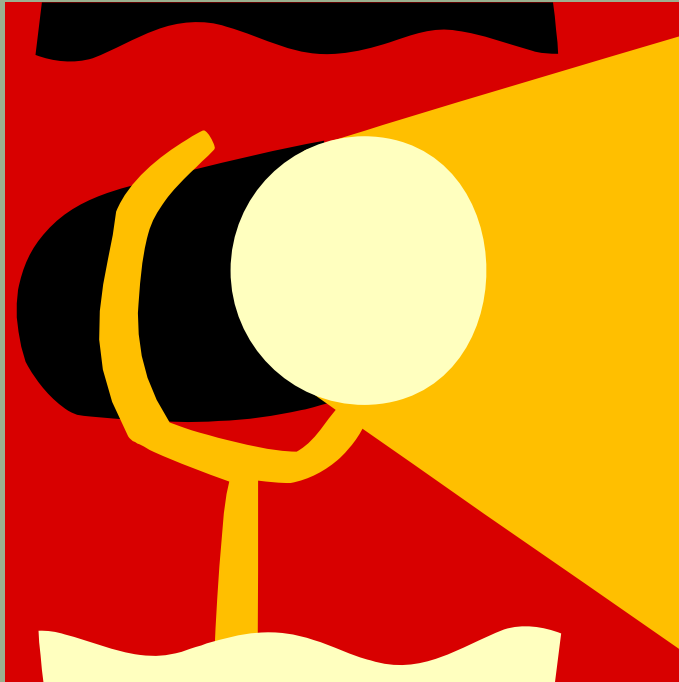
The logo for the Association of National Advertisers (ANA), consisting of the letters 'ANA' in a large, bold, white, sans-serif font.

Leading the Marketing Community

Four Goals

- How we got here: political, regulatory, legal status of DTC advertising
- Why it matters: importance of DTC ads
- What could happen: precedential significance of the debate over DTC
- Going on the offense: Repositioning the debate

The Hot Spotlight Shines on DTC



- 2007 was a watershed year for DTC advertising
- But 2008 has been déjà vu all over again
- What will a new administration do to DTC?
- What can you do to protect DTC advertising?

Ingredients for a Soap Opera

- Sex (ED medicines)
- Controversy (Vioxx, Vytorin and Dr. Jarvik)
- Money (cost of prescriptions to patients and the federal government)
- Politics (impact of the 2006 and 2008 elections)



Taking the Political Pulse



- Democrats took control of Congress in 2006
- Drug cost/safety were important political issues
- FDA reform was a major priority for Democrats

The Political Reality

- DTC by far the most heavily regulated advertising category in the US
 - Can't get on the market without approval
 - Can't sell product without doctor approval
 - Self-regulation
- Millions have extremely serious health conditions
 - Diabetes
 - High blood pressure
 - High cholesterol
- DTC serves an important education function

Kennedy-Enzi Bill

- Two year moratorium on advertising
- Preclearance of ad content by FDA
- FDA mandated warning language
- Passed by 11-10 vote in HELP committee with Senator Obama voting “aye”



Ad Restrictions Dropped During Floor Debate

- We worked closely with Senators Enzi, Pat Roberts and Richard Burr
- Brought in First Amendment analysis from ACLU, Washington Legal Foundation and others
- Moderate Democrats weighed in with Sen. Kennedy
- Senate bill included new FDA enforcement powers and civil monetary penalties

But Wait, There's More...

- House Dems Propose Even Stronger Limits
- Pallone-Waxman Bill:
 - Three year moratorium on new ads
 - Preclearance of content by FDA
 - Mandated ambiguous warning language
 - Black triangle in new drugs ads
 - FDA approval of marketing plans



To the Rescue: Towns/Buyer Alternative

- Took on Reps. Pallone and Waxman in Energy and Commerce Committee
- Stripped out the DTC ad restrictions and adopted new enforcement powers and civil monetary penalties
- Passed Health Subcommittee 23-9



DTC Ultimately Prevailed in 2007 Debate



Roberts/Towns Substitute

- Defeated multi-year moratoriums
- Defeated FDA preclearance of content
- Defeated new warning symbols and language
- Created new FDA enforcement powers with civil monetary penalties



The Battle is Far From Over

- Unresolved issues
 - Studies mandated by drug safety bill
 - Hearings in Oversight Subcommittee of House Energy and Commerce Committee
 - New restrictive legislation introduced to re-open the debates we won last year
 - States get into the act: Merck settlement with 30 state attorneys general over Vioxx

Emanuel's Choice

- Rep. Rahm Emanuel (D-IL), the fourth-ranking Democrat in the House leadership: Either give up the prescription drug advertising deduction or lose the investment credit for R & D



FDA Studies Several DTC Issues

- The need for 1-800 number in TV ads
- Impact of DTC ads on children, elderly, and racial/ethnic minorities
- Impact of visual images on how consumers understand risk and benefit information



Energy and Commerce Investigation

- Oversight and Investigation Subcommittee holds hard-hitting hearing on May 8th
- Looking into marketing for Lipitor, Vioxx and Procrit
- Chairmen Dingell and Stupak write drug companies for more information

Dingell-Stupak Letters

- Asks companies to “voluntarily:”
 - Not market products in DTC ads until a valid outcomes study of the product is completed and the results are released
 - Place a two year moratorium on ads for new products as recommended by the IOM
 - Add the FDA’s toll-free MedWatch phone number to all DTC ads
 - Add a “black-box” warning to ads if such a warning is required for labels



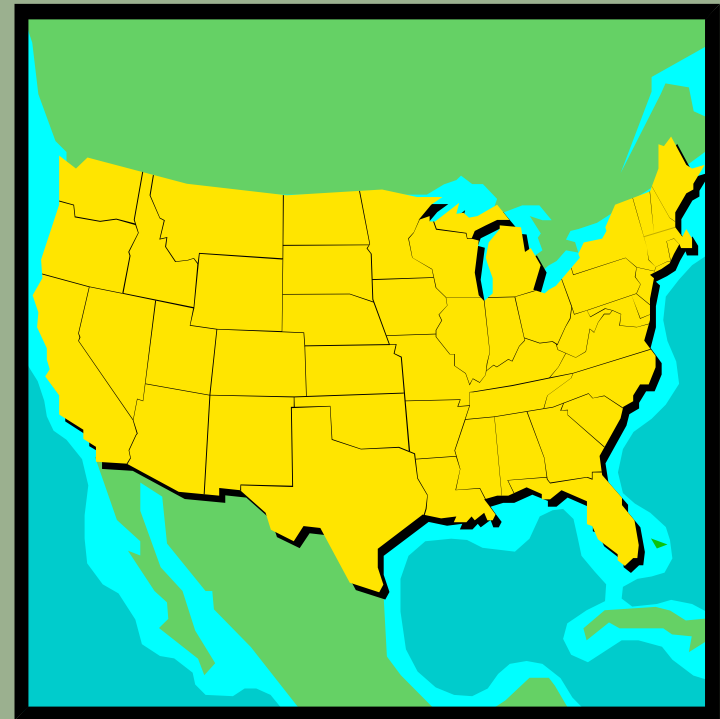
Piling on in the Congress

- Bill from Reps. DeLauro and Emerson would impose three-year moratorium on DTC ads
- Senate Aging Committee held hearing on DTC marketing of medical devices
- Legislation to give FDA authority over OTC ads



States Get in on the Act

- Merck reaches \$58 million settlement over marketing of Vioxx with 30 state attorneys general
- Merck agrees to submit ads for preclearance and delay running ads for as long as FDA demands
- Creates dangerous precedent and potentially undermines victories we had in Congress



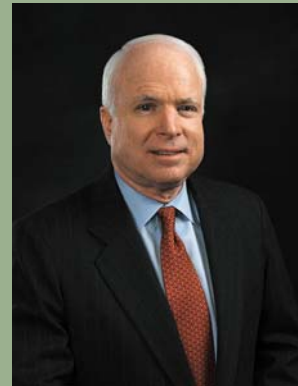
Washington Has EAD

- We face a new disease known as EAD: Election Anxiety Disorder
 - Democrats will probably pick up more seats in both Senate and House
 - Anti-business rhetoric coming from both presidential campaigns
 - Change is on the way, whichever party wins the White House
 - New President will pick a new FDA commissioner



Where They Stand

- Senator Obama voted for drug safety bill in HELP Committee that contained serious ad restrictions
- Senator McCain:
 - Supported restrictions on tobacco advertising and political ads (McCain-Feingold)
 - Supported ad tax restrictions in 2000 campaign
- Senator Biden supported ad tax restrictions in the late 1980's



Two Bottom-Line Threats: Ad Taxes or Moratorium

- Federal government will face serious revenue issues
- DTC is an attractive target – some argue that DTC ads drive up the cost of health care
- Moratorium and other ad restrictions will be back on table again
- Ad tax battle could be across the board or over DTC ad spending
- Rep. Pete Stark, the no. 2 Democrat on House Ways and Means Committee supports restrictions on deduction for DTC ads

We're Talking About Serious Money



- Loss of deduction for DTC advertising would cost businesses multi-billions of dollars in new taxes annually
- Drug ad moratorium could result in billions of lost sales

Advertising Industry Fights Back

- Advertising Coalition represents all segments of industry, including PhRMA, and holds grass roots meetings with key members of Congress
- Global Insight Report quantifies economic value of advertising in every state and Congressional district
- PhRMA marketing code demonstrates commitment of industry to responsible marketing practices



Our Ultimate Safety Net

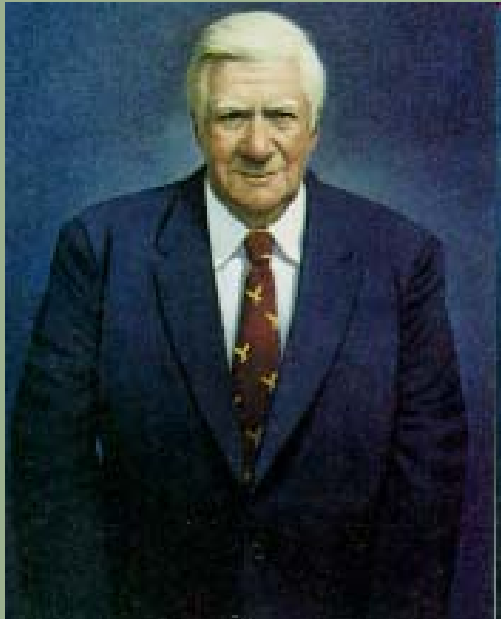
- Studies from FDA, *Prevention* magazine and National Medical Association show that consumers receive valuable information from DTC ads
- Consumers have a First Amendment right to get this information and pharma companies have a First Amendment right to speak
- Any content-based taxes or restrictions raise serious constitutional issues



Repositioning the Debate

- Industry is on the defensive
- We should proactively support DTC as a major societal benefit

Tip O'Neill: “All Politics is Local”



- We need your help!
- Start a dialogue with your elected representatives
- Get involved in your trade association