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Are Pharmaceutical Direct-to-Consumer TV Ads Appropriate in an Industry Environment Focused on Specialty Medicines? A Commentary

Are Pharmaceutical Direct-to-Consumer TV Ads Appropriate in an Industry. Environment Focused on Specialty Medicines? A Commentary

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1. The Appropriateness of DTCA Debate

No pharmaceutical topic causes as much passionate difference of opinions between industry and medical community representatives as the practice of direct-to-consumer advertising (DTCA), with the likely exception being drug pricing. While the above quotes may appear to be dated, the debate still rages on today about the appropriateness of DTCA and its alleged adverse effects on the healthcare system. For example, long-time industry critics, like Dr. Jerry Avorn (quoted above), often associate high drug prices with what they claim are inappropriate and unnecessary costly sales and marketing practices. In addition, critics claim DTCA encourages inappropriate prescribing through pushing patients into more expensive patented branded drug therapies where therapeutically equivalent and lower cost generics exist. However, demonstrating real empirical evidence to make the former connection is lacking, and where plausible explanations exist why prescribing newer branded drug technology is preferred over older generic drug technology. These are examples, as often is the case in pharma policy debates, where ideology trumps (pun intended) substance. The two quotes at the beginning of this white paper are a microcosm of the vast chasm of opinions regarding the appropriateness of DTCA on a wide range of issues.[1] More recently, the American Medical Association (AMA) in November 2015 called for a ban on DTC ads of prescription drugs and medical devices.[2] Questions persist about the risks of DTCA to patients, potential for prescribing bias, effects of DTCA unnecessarily increasing drug spending, are current PhRMA guidelines stringent enough to restrain inappropriate DTCA, and should the FDA do more to regulate DTCA?[3-6]

> Just as every other industrialized nation has figured out how to promote healthcare to all their citizens and how to get drug makers to negotiate the prices of their products, each of those countries (with the exception of New Zealand) also bans direct-to-consumer advertising for prescription drugs...
>
> ***Jerry Avorn, MD***
> *Professor of Medicine, Harvard Medical School*
> *excerpt from a* New York Times *article published August 4, 2009*

Yet, despite criticisms and the heated debate on the appropriateness of this channel, DTCA spending continues to grow. The drug industry spent approximately $5.6 billion on DTCA in 2016 (excluding digital spending), with the top company spending over $1 billion, the 2nd through 5th ranked companies spending between $352 - $458 million, and the 6th through 10th ranked companies coming in at $206 - $291 million, according to data reported by Nielsen.[7] What is interesting however is not only the number of brands now utilizing DTCA but also, and maybe what's causing concern, for what medical conditions these brands treat. A look at the drug indications of leading brands utilizing DTCA find both large-patient population chronic conditions but also smaller niche-therapy conditions in sync with the growth in spending on specialized medicines.[8] For example, we see DTC ads for

drugs indicated for the treatment of type 2 diabetes, erectile dysfunction, smoking cessation, heart failure, atrial fibrillation, COPD/asthma, pneumococcal pneumonia, and hepatitis C but also plaque psoriasis, Crohn's disease, ulcerative colitis, rheumatoid arthritis, diabetic nerve pain, and non-small cell lung cancer. Moreover, these DTC-advertised medicines treat more specialized conditions with greater adverse health effects and often carry more patient drug side-effects. Thus, when viewing TV DTC ads, due to fair balance rules of disseminating both benefits and risks, the treatment often sounds worse than the disease. Further, newer specialized medicines are often of a more complex construction, such as biologics, thus there exist challenges of accurately and fully presenting how a drug works on TV within a minute time frame. These medicines are also more expensive to payers. Lastly, TV DTC ads rarely (if ever) mention anything about measures of value, such as, producing a health outcome effect at a drug treatment cost. TV DTC ads often carry messages how coupons or patient assistance programs are available to help those who are less able to afford their medicines, and the extent of drug plan coverage, but not cost-effectiveness. This is likely why both providers and payers dislike TV DTC ads in encouraging patients to seek out drug therapies that may not be justified on cost-effectiveness, or more technically speaking, quality-adjusted life years (QALY) threshold grounds as measured in other countries when deciding on governmental reimbursement (e.g., the National Institute for Care and Excellence in the UK provides evidence-based guidance for the National Health Service).

2. How Should Companies Approach and Measure DTCA?

What should companies do? To be clear, we are not in favor of banning DTC ads, or put another way, suppressing commercial speech which the US Supreme Court has ruled as being protected under the First Amendment, especially given the rigorous regulatory and oversight review process in the US on sales and marketing practices.[9] The following words previously published in a medical journal make our point (noted in the context of trying to suppress detailing through restricting the dissemination of prescriber-level data):[10]

> Promoting public health is best achieved by encouraging greater competition of medical information through supporting free speech from all FDA-regulated sources, and not arbitrarily suppressing certain forms of speech simply because it does not conform to one's ideological views. Our empirical study, while not analyzing patient health outcomes, provides initial affirming evidence to the words of the Court's majority opinion that suppressing commercial speech is not in the best interest of physicians and patients.

However, what companies cannot do is to continue engaging in current practices of measuring DTCA effectiveness *solely* in terms in Rx-volume generation (or measuring the added value through an incremental patient-stream generated by DTCA). Structural modeling through non-linear regression techniques allows for estimating the direct and indirect effects of DTCA through various mediums (e.g., TV, magazines and print, digital) on Rx-volume. Ad-stock models on DTCA allow for measuring depreciating effects over time, while assuming differentiating lag structures per DTCA channel on Rx-impacting volume. In addition, the current state of DTCA modeling also estimates interaction effects with other key sales and marketing channels expected to be coordinated with DTCA, particularly detailing. Lastly, subnational models on DTCA effects are done allowing for determining which DTCA medium is best allocated by region.

> "An important benefit of direct to consumer (DTC) advertising is that it fosters an informed conversation about health, disease and treatments between patients and their health care practitioners…A strong empirical record demonstrates that DTC communications about prescription medicines serve the public interest…"
>
> ***The Pharmaceutical Research and Manufacturers of America (PhRMA)***
> *"PhRMA Guiding Principles: Direct to Consumer Advertisements about Prescription Medicines" published December 2008 and revised in March 2009*

However, the pharma environment has radically changed, where demonstrating measures of drug value are critical to brand success. Demonstrating measures of value affect drug adoption decisions on treatment guidelines determined by providers and payers, meet payer concerns showing how drug utilization reduces overall treatment costs, can support a growing prevalence of performance-based managed care contracts, and address patient concerns over access and affordability. Below is a non-exhaustive list of suggested strategic, tactical, and analytical steps brand teams should take to make TV DTCA more effective and efficient while mitigating concerns raised by industry critics and members of the healthcare community against running TV DTCA for specialty medicines:

(a) While the focus of TV DTC ads is for patients, remember they are also seen by providers and payers. Physicians may adversely react to DTCA as companies may be perceived as biasedly pushing patients into drug therapies that are inappropriate for their conditions, and causing friction between them and their patients. Physicians may also view such ads as infringing upon what they think are drug treatments in the best interests of patients given their intimate knowledge of their medical history and other relevant information. For drug treatment options involving complex diseases, physicians may believe such information exchange is best left in discussions between the physician and patient weighing individual benefits and risks/costs. Payers may also view such ads as unnecessarily driving up managed care plan drug costs through increases in branded drug utilization over therapeutically equivalent generics. So, while DTCA campaigns are designed to be seen and acted upon by patients, it is important to consider the effect such ads have on other key decision-makers in the healthcare system that can contribute to or work against brand success.

(b) For drugs with significant side-effects and are very complex to explain, contemplate running unbranded TV DTC ads, with more detailed follow-up messaging to providers and payers. A physician can explain the relative benefits and risks of a drug for their patient in the office. Prior research has shown that prescriptions from existing patients can *decrease* after seeing a TV DTC ad noting a significant number and severity of side-effects. Unbranded TV DTC ads are not popular with

brand leaders since they do not tout the brand but rather encourage patients to seek action and advice from their physician. If, however, a brand has a dominate market position, funneling more patients into a physician's office will generate more drug utilization, without the potential chilling effects of disseminating risk and side-effect fair balance information in a branded TV DTC ad. The added benefit is then the decision as to whether the drug is the right choice is between the physician and patient without potentially HCP-perceived biased information from drug companies. Statistical analyses combined with market research data can determine whether branded or unbranded TV DTCA is the best choice. For new brands entering the therapy class and thus not having a current dominant market position, think about the timing of when to conduct branded DTCA so as not to benefit the leading brand(s). Thus, for new drug entrants in a therapy class, the coordination of conducting DTCA with other sales and marketing channels is critical for success.

(c) Coordinate and complement TV DTC ads with messages delivered through other channels. Academic research and industry professional statistical modeling shows positive synergistic effects of running DTCA campaigns when linked to other channels, especially detailing. Look to using digital channels as well to complement messaging, especially for those physicians in "No-See" detailing offices due to imposed sales rep physician-access restrictions.

(d) For more complex disease states and drug delivery mechanisms, consider using MSLs (medical science liaisons) to disseminate scientific/clinical information to complement TV DTCA messages.

(e) Rather than using DTCA, consider using direct-to-patient advertising (DTPA) to targeted audiences in disease-targeted physician offices, specific hospital settings, and clinics. The benefit here is that the messaging can be seen by patients who have already been selected and targeted to those likely seeking and/or receiving a drug treatment. For example, show DTP ads for an anti-cancer drug in the waiting room in an oncology group practice setting. This will likely make the economic ROI returns

more beneficial and allow for critical medical/clinical/scientific information to be seen by those who would benefit most (including physicians and office staff).

(f) Consider using KOLs (key opinion leaders) per region and/or key local areas to augment TV DTCA messages. Similarly, target key prescribers and influencers within large group practices for additional scientific/clinical messages.

(g) Go beyond current professional modeling practice of associating DTCA with prescription volume change to improvements in patient drug adherence, and eventually health and economic outcomes. DTCA is a mechanism by which useful medical information is conveyed to potential and actual patients. If patients seek therapy for their condition due to DTCA, then this produces benefits. If DTCA is seen by current patients and reminds them to stay drug adherent, then this too will produce positive health and economic outcome effects. Develop statistical modeling analyses from HEOR (health economic and outcomes research) and RWE (real world evidence) for key providers showing differentiating health outcome effects from drug utilization, and to payers on measures of economic value (reductions in total treatment costs, reductions in side effects from alternative drug therapy use, improvements in cost-effectiveness) resulting from increases in patient drug utilization and adherence created through effective DTCA.

(h) Analyses should also be conducted to see whether there are positive category expansion effects, i.e., people exposed to TV DTC ads who should be on drug treatment but would not be if not exposed to the ads. This is especially true for asymptomatic conditions (e.g., dyslipidemia, diabetes, hypertension, Hepatitis C) and where significant numbers of patients who should be on drug therapy are not. Innovation advances in curing costly diseases, like in Hepatitis C, that are very expensive to treat in patients if not placed on drug therapy, represent a significant benefit to running DTCA. This represents a social value to TV DTCA. People who remain off drug therapy will ultimately cost the healthcare system more to treat. Higher costs will ensue due to an increase in the severity of their disease, the occurrence of related co-morbidities, and the need for more invasive and costly treatments than seen through earlier drug intervention.

(i). Ensure service reps engage physician-office individuals with information on enrolling patients in disease management programs, coupon availability, enrollment in a PAP (Patient Assistance Program), and managed care access and co-pay data.

(j). Generate analysis showing how patients who see and take action as a result of viewing a TV DTC ad are more drug adherent (using APLD, Anonymized Patient-Level Data), experience lower side effects, and are involved in other health-related activities that can improve health outcomes. Differentiate analyses for new versus existing patients who are exposed to TV DTCA.

3. Conclusions

Sales and marketing practices by the pharma industry have been and continue to be vigorously attacked by critics who wish to see a ban or severe restriction on such activities conducted by companies. Calls to ban DTCA epitomize what critics say is wrong about pharma sales and marketing practices. These calls will continue with greater intensity from patient advocacy groups, physicians, payers, and policymakers, especially as the hot-button issue of drug pricing increases given the industry's shift to more expensive personalized-targeted specialty medicines. We take a more balanced viewpoint on this issue. The extreme position of banning the dissemination of FDA-regulated medical information is not the answer. However, neither is the continuation of old ways by pharma companies. The industry is losing the optics battle, with TV DTCA being the posterchild for what critics allege as to what's wrong with pharmaceutical marketing. Companies need to think more strategically, develop the right tactics, and expand the outcome measures from DTCA through employing advanced analytics given the wider range of data now available if they wish to continue using TV DTCA for the benefit of patients and the healthcare system.

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