MARKETING AND PROMOTION OF MEDICINES:



4 Things You Need to Know

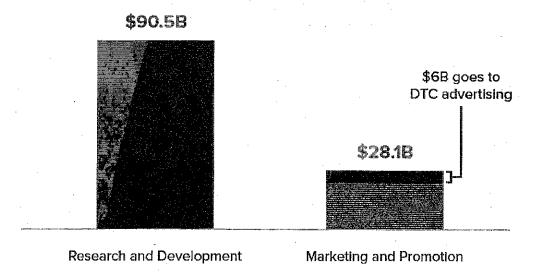
The marketing and promotion of innovative biopharmaceuticals is a highly regulated activity that benefits patients, supports the health care system and helps reinforce research and development (R&D) and innovation. Below are four facts that are important to recognize when considering biopharmaceutical marketing and promotion.

1. THE BIOPHARMACEUTICAL INDUSTRY SPENDS SIGNIFICANTLY *MORE* ON R&D THAN ON MARKETING AND PROMOTION.

The biopharmaceutical sector is among the most research-intensive of all sectors of the economy, spending tens of billions of dollars on R&D each year. Comparisons of spending on R&D versus marketing and promotion are often misleading and grossly overstate marketing and promotion spending, inflated estimates of marketing and promotion spending have propagated the false impression that the biopharmaceutical industry spends more on marketing and promotion than on R&D.

Accurate comparisons prove the opposite to be true. Recent data illustrates that U.S. biopharmaceutical companies spend roughly three times more on R&D (\$90.5 billion in 2016) than on marketing and promotion (\$28.1 billion in 2016), according to a recent study in the Journal of the American Medical Association (JAMA)).

Biopharmaceutical R&D is 3x Greater Than True Marketing and Promotion Expenses

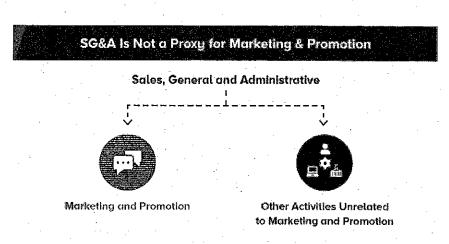


Sources: Research/America. U.S. Investments in medical and health research and development, 2013-2017, Fall 2018 (for R&D estimate). Schwartz LM, Woloshin S. Medical marketing in the United States, 1997-2016. JAMA. 2019;321(1):80-96 (for marketing and promotion estimate).

What is driving critics' often inflated and misleading estimates? According to the late Princeton professor Uwe Reinhardt, "...the [selling, general, and administrative] category represents many expenses other than selling expenses and should not be seen as an estimate purely of outlays on marketing, as the industry's critics occasionally do."² These types of expenses are encountered by nearly every industry that manufacturers, distributes and/or sells a product, regardless of — and unrelated to — marketing and promotion activities.

Reported sales, general and administrative (SG&A) expenses required in companies' U.S. Securities and Exchange Commission (SEC) filings but which are unrelated to marketing and promotion can include: shipping and distribution, rent, office furniture and supplies, utilities, salaries and compensation, repairs of equipment, postage, printing, overhead and other overly broad expenses.

More accurate estimates of biopharmaceutical company marketing and promotion expenses focus on activities such as consumer-directed advertising and promotion, product-specific advertising to health care professionals (HCPs), direct promotional communications with HCPs and speaker programs. It is also reasonable to include a fair share of salaries and overhead costs associated with these activities.



2. INVESTMENT IN R&D IS STRENGTHENED – NOT DIMINISHED – BY MARKETING AND PROMOTION.

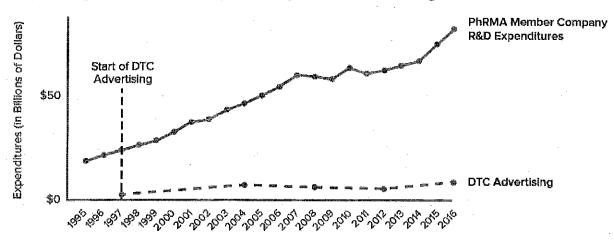
Biopharmaceutical companies' spending on marketing and promotion activities helps support sustainable investment in R&D. Some critics attempt to oversimplify the accounting by viewing R&D and marketing and promotion as a zero-sum game, where every dollar spent on marketing is a dollar less that can be invested in R&D. The economics driving the innovative biopharmaceutical sector do not work that way.

According to Harvard University economist Joe Newhouse,

"One sometimes hears it said that the industry would have more money for R&D if it would cut down its marketing costs. This comment reflects misunderstanding of the economics of the industry. If a firm did so, it would be less profitable and would attract less capital for R&D or would have fewer internally generated funds to invest [in R&D]."³

To illustrate, recently published data shows that R&D investment *grew significantly* during the same time that other data shows direct-to-consumer (DTC) advertising also grew (see below). In response to greater public interest in health care and a revised regulatory framework from the U.S. Food and Drug Administration (FDA), DTC advertising spending rose in the late 1990s. Meanwhile, in that same time period, R&D expenditures by PhRMA member companies intensified significantly, without any pause or dip associated with the initial spike or gradual growth in DTC.⁴

R&D Spending Has Increased Significantly as DTC Advertising Investment Grew Gradually



Source: PhRMA, 2019 PhRMA Annual Membership Survey, July 2019 (for R&D figures). Schwartz LM, Woloshin S. Medical marketing in the United States, 1997-2016, JAMA, 2019;321(1):80-96 (for DTC advertising estimates).

3. MARKETING AND PROMOTION BENEFIT PATIENTS, PROVIDERS AND THE HEALTH CARE SYSTEM.

DTC advertising has proven to benefit patients by raising disease awareness, removing stigma from certain conditions, promoting adherence to medicine and encouraging productive patient-provider discussions. A recent survey of consumers demonstrates the positive contributions of DTC advertising to patients' awareness of conditions and treatments, including that DTC ads: allow people to be more involved in their health care, alert people to symptoms related to medical conditions and tell people about new treatments. The survey also found that nearly two-thirds of respondents reported that DTC advertising reminded them to take a specific action to manage their health care, including to schedule an appointment with a physician, receive a preventative vaccine or refill a prescription.⁵

DTC Advertising Increases Awareness of Conditions and Treatments

How Strongly Do You Agree or Disagree with Each Statement? Percentage Who Agree with Each Statement (Survey of consumers, N=1564, April 2017)

DTC ads allow people to be more involved in their health care

DTC ads alert people to symptoms that are related to a medical condition they may have

DTC ads tell people about new treatments



Source: Princeton Survey Research Associates International, "2017 Direct to Consumer Advertising Survey," April 2017.

These findings echo a prior landmark survey by the FDA, which concluded that "[b]y and large, DTC advertising seems to increase [patients'] awareness of conditions and treatments, motivate questions for the health care provider, and help patients ask better questions." DTC advertising also promotes overall care initiation. A 2019 study found that, due to DTC advertising, people between the ages of 40 to 60 were more likely to have visited a health care provider.

In addition to reminding people to visit their health care provider, DTC advertising can serve as a helpful reminder for patients to take their medicines. One recent study found that "disease-specific DTC advertising can help people remember to take their prescription medication when viewed, which may lead to more positive medication-taking behavior and increased medication adherence." Improving medication adherence can lead not only to better health outcomes for patients, but also to significant savings for the broader health care system. Experts estimate that better use of medicines could eliminate up to \$213 billion in U.S. health care costs annually, representing 8% of the nation's health care spending.9

Biopharmaceutical companies also share information directly with health care professionals. These communications are important for sharing the latest information on new medicines with prescribers, including the benefits and risks of medicines, new clinical studies and data, new dosing information and emerging safety and risk information.

Timely access to this information helps all stakeholders in the health care system, especially physicians, to deliver the most effective patient care possible. A KRC Research survey found that most physicians recognize and value contributions made by these companies and their representatives, finding this information up-to-date, timely and useful.¹⁰

Physicians Report a Range of Benefits from Marketing and Promotion

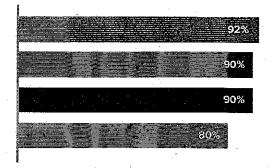
Physicians Say Interactions with Biopharmaceutical Company Representatives Help Them To: (Q59-62, Base size: N=502)

Learn about known potential side effects of medicines

Learn about new indications for medications and treatments

Learn about benefits and risks of medications and treatments

Have the opportunity to provide feedback to a pharmaceutical company about a specific medicine or treatment



Source: KRC Research. "Survey of Physicians About Pharmaceutical and Biotech Research Company Activities and information." Washington, DC: KRC, February 2014.

Marketing and Promotion Do Not Lead to Inappropriate Prescribing

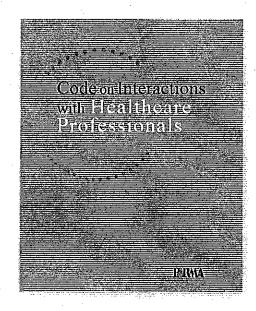
It is important to note that, although most physicians appreciate information from biopharmaceutical companies, they do not use it in isolation. A recent KRC Research survey found that physicians prescribed for each of their patients based on their professional judgement as well as each patient's clinical situation and individual needs. Namely, the survey found that the number one factor in prescribing decisions was a physician's own clinical knowledge and experience.

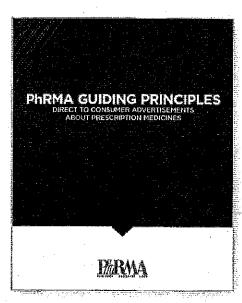
Furthermore, DTC ads do not increase inappropriate prescribing and, in fact, have been found to promote competition. A 2017 study found that DTC ads within a specific drug class increased sales of non-advertised, competitor products within the same class. Another recent study of women with breast cancer found that DTC advertising resulted in increased appropriate prescribing and no significant change in prescribing to younger women who would not benefit. 12

4. MARKETING AND PROMOTION ACTIVITIES ARE HIGHLY REGULATED BY THE FDA, AND COMPANIES DEVOTE SIGNIFICANT RESOURCES TO ENSURE RESPONSIBLE AND TRUTHFUL PROMOTION.

The FDA closely regulates marketing and promotion to help ensure materials are accurate and non-misleading, and include a "fair balance" of the product's benefits and risks. The FDA's Office of Prescription Drug Promotion (OPDP) oversees biopharmaceutical marketing and promotion activities. Through its enforcement of the Federal Food, Drug, and Cosmetic Act and regulations, as well as its guidance to industry and routine monitoring activities, OPDP helps ensure, among other things, that prescription drug ads do not omit material facts, including risk information.

In addition to the drug advertising oversight by the FDA, PhRMA has issued a Code and Guiding Principles that provide guidelines for companies' promotional communications. Signatories to the PhRMA Code on Interactions with Health Care Professionals¹³ indicate their commitment to following the highest ethical standards as well as all legal requirements, and certify annually to having policies and procedures in





place to foster compliance with the requirements of the PhRMA Code. Additionally, PhRMA members have all voluntarily signed onto the <u>Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines</u>, which offer guidelines for enhancing the educational value of DTC advertisements. These are designed to ensure that DTC advertisements and company interactions with health care providers communicate scientifically-accurate information that helps educate and support patients and providers.

Read more on the industry's contributions at https://www.phrma.org/.

Endnotes

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