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“DTC Advertising: Is It Helping or Hurting?”

Statement before the
Federal Trade Commission
Health Care Workshop

September 10, 2002

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Influence of DTC Ads on Cost and Utilization

Research we have conducted over the past three years has led us to conclude that DTC ads are one element – and probably an increasingly important one – in the recent sharp rise in the demand for, expanded use of and increased spending on prescription drugs.

But we believe that the magnitude of the effect of DTC ads on numerous factors – the demand for drugs, public perception of drug safety, prescribing trends, the public's health, drug costs and overall health care costs – has *not* yet been accurately quantified.

That is significant. It is still feasible that DTC ads play a relatively minor role in a dynamic and complex pharmaceutical marketplace – where they are but one means drug companies use to promote their products. It is also still feasible that DTC ads play a larger role than researchers or market analysts have yet been able to grasp.

There is suggestive evidence both ways, and some of the evidence has been interpreted both ways. Companies' DTC ad spending is dwarfed, for example, by spending on ads to doctors and the retail value of the free drug supplies (called samples) doctors get from companies and give to their patients. Companies spent \$2.8 billion in 2001 on DTC ads versus \$4.7 billion on doctor detailing and over \$2 billion on educational events aimed at physicians. Doctors gave patients \$10 billion worth (had they been sold) of free samples.

Based on this kind of data alone, some analysts suggest that DTC ads are still a small piece of the drug promotional pie. But others, including us, have noted that the retail value of free samples vastly overstates the actual cost for their manufacture and distribution. Thus, if you remove the \$10 billion retail value of such samples, spending on DTC ads is a sizable and growing portion of all prescription drug promotion.

Moreover, we would suggest that there is a natural synergy between free samples and DTC ads. With physicians acting as intermediaries, patients are asking for drugs they see advertised and they are receiving samples of most of those drugs *in the doctor's office*, along with a prescription. That synergy may be creating a multiplier effect wherein DTC ads plus a growing supply of free samples in doctors offices are reinforcing each other, leading to more prescriptions filled, higher costs, but also, notably, potentially higher compliance.

On the other hand, physician detailing – which is designed to be a person to person marketing interaction – clearly has far greater efficiency than DTC ads and may still be far and away the principle force driving the recent growth in the volume of drugs prescribed.

DTC ads' "hit rate" has also been widely discussed. Surveys show that vast majority of adult Americans have seen a DTC ad. Remarkably, a quarter to a third of people who said they had seen an ad for a prescription drug also said they had talked to their doctor about one, and between 12% and 25% of that group specifically asked to be prescribed a

drug they saw advertised. In one large survey, half of those that made such a request got the drug. In another, 71% got it.

The bottom line here is that about 4% to 6% of the U.S. adult population – 8.5 million to 12.6 million people in 2001 – appear to have gotten a prescription for a drug (and likely a free sample) as a *direct result* of a DTC ad. Putting that in context, however, there were 823.5 million physician visits in 2000, with over half the adult population of 211 million people having at least one visit. (According to a recent study, doctors in 1999 prescribed 146 drugs for every 100 office visits, up from 109 drugs per 100 office visits in 1985.)

So depending on how you look at it, and how much faith you put in the responses of people to telephone surveys, DTC ads are either causing a substantial new demand for prescription drugs or doctor visits in which a drug request is made still are only a small component of all visits.

Other evidence of DTC ads' effect comes from analysis of the prescription volume and sales of advertised drugs compared to non-advertised drugs. Research we conducted found that in 2000 doctors wrote 25% more prescriptions for the 50 most heavily (DTC) advertised drugs (aggregated) compared to 4.3% more scripts for all other drugs combined. Sales of the top 50 most heavily advertised drugs rose an aggregate 32% from 1999 to 2000 compared to 13.6% for all other drugs combined. Increases in the sales of these 50 drugs heavily advertised accounted for almost half (47.8%) of the overall \$20.8 billion rise in spending on drugs in the retail sector from 1999 to 2000.

Such research is highly suggestive but, again, proves no direct cause and effect link between DTC ads and increasing drug use and spending. For example, it bears keeping in mind that newly approved drugs that also happen to be heavily promoted may experience sharp increases in use and sales in their first two years on the market – especially if they represent true clinical breakthroughs. Indeed, the more powerful evidence of the potent effect of DTC may lie in older drugs that experience 20% or more increases in sales for several straight years after the launch of a DTC ad campaign. We believe, for example, there is strong circumstantial evidence that sales of the three prescription oral antihistamine drugs Claritin, Allegra and Zyrtec – all approved in the early to mid 1990s – have been substantially boosted by heavy DTC ad campaigns from 1998 to 2000.

Interaction: Insurance Coverage of Drugs and DTC Ads

Health insurers and managed care plans cover more of the costs for prescription drugs than they did a decade ago – sharply lowering the financial barrier to the purchase of drugs and creating “coverage-induced” demand.

In 1990, private insurance paid 25% of the total national tab for prescription drugs. In 2000, insurers and health plans paid 44% of the bill. (Government paid 22% and consumers themselves paid 34%, down from 59% in 1990.) In fact, notably, the rapid growth of managed care coverage of drugs – usually with low co-pays – between 1995 and 2000 overlaps with the advent of the growth in DTC drug advertising. Such

coverage is one of the factors that make teasing out the independent effect of DTC ads difficult.

In particular, managed care plans teamed with a new industry – pharmacy benefit managers (PBMs) – to make access to drugs quite simple. Most insured Americans now have a drug card that permits them to fill prescriptions at drug stores and pay co-pays that range from \$5 to \$30. In addition, mail order and internet access to and sales of prescription drugs are exploding, after years of being promoted by PBMs. Both require a prescription of course and some internet channels are questionable. But consumers have become much more active participants in their health care choices in general and it's not hard to imagine that, reinforced by DTC ads, they could become more assertive (with doctors) about getting access to some medicines.

Viagra may be an indication of future trends for some heavily promoted “lifestyle” drugs. Most insurers now cover it with an appropriate diagnosis, though the coverage may be limited. Anecdotal accounts would suggest that (1) men are pressuring their doctors to prescribe the drug and (2) many men are paying for it on their own through various channels without a doctor visit or diagnosis. It is widely available over the internet. So promotion of drugs to consumers has effects both inside and outside insurance coverage.

There is little doubt that improved access to drugs and DTC ads are having an additive effect. The challenge now for insurers, beset with rapidly rising drug costs, is to preserve the beneficial easier access to needed medicines while constraining inappropriate prescriptions fed in part by outsized consumer demand.

Characteristics of DTC Promoted Drugs

First and foremost, only patent-protected brand name drugs are being advertised to consumers. Generic manufacturers have not yet engaged in this form of marketing, primarily because it is quite expensive. (Indeed, they do limited marketing to doctors as well.) It is an open issue when generic firms will begin to promote selective drugs directly to consumers, as DTC ads become a more established phenomena and as more “blockbuster” generics come to market in the next decade.

Research we conducted in 2001 found that 22 of the top 50 most heavily advertised drugs in 2000 were also on the list of the 50 best selling drugs that year – drugs such as Prilosec, Lipitor, Prevaids, Vioxx, Paxil, Prozac, Claritin and Viagra. In general, companies are marketing to consumers their “blockbuster” drugs. With a few exceptions, they are also heavily promoting the same drugs to doctors.

This makes sense. These are the drugs that will yield the most revenue and profit – in part because they are expensive medicines priced at a premium (most are recently approved) but also in part because they can be potentially taken by tens of millions of people.

In addition, companies use a DTC marketing approach for drugs to treat conditions that consumers understand and may be used to self-treating. Thus, drugs to treat allergies,

pain, arthritis, GI upset and ulcers, asthma, diabetes, high cholesterol, depression and high cholesterol have been widely promoted.

Interestingly, the number of drugs being advertised to consumers has held fairly steady over recent years. In 2001, companies promoted 105 drugs to consumers, up from 103 in 2000 and 92 in 1999.

The central question here is whether there will ever be anything but an economic driver for DTC drug ads. That may sound naïve. But the pharmaceutical industry proclaims loudly that DTC ads serve an educational function as well as a marketing function. If that's true, then will we over time see more ads for non-blockbuster drugs? In 2000, 12 drugs that were advertised to the public had sales on less than \$150 million. In most of these cases, the low sales were because the drug had just been approved. But in a few cases, the drugs were not targeted at large markets. For example, several HIV/AIDS drugs have been selectively marketed to consumers in areas with high HIV incidence (such as New York and San Francisco).

New media (special interest publications, the internet) may allow more targeted prescription drug marketing in the future. Many companies have web sites for their major drugs. Will they use the internet to market to specialty audiences? It's not yet clear. Privacy issues loom large in this form of marketing. But many marketing analysts believe the industry will eventually find ways to overcome privacy issues to carry out large scale targeted marketing of prescription drugs on the web.

Evidence on the Effects of DTC Ads -- Beneficial or Harmful?

As cited above, surveys show that a large portion of the public has been motivated to ask their doctor about a drug they have seen advertised. The pharmaceutical industry cites that as evidence of a beneficial effect of DTD ads. The industry also cites preliminary evidence that many people are specifically prompted to see a doctor after seeing an ad, also a beneficial effect.

There is no doubt that DTC ads have some beneficial effect – prompting doctor visits, increasing awareness of new medications and medical conditions, and leading some patients to get drugs they need.

What's not clear from the surveys or research to date, however, is what portion of doctor visits or requests for drugs prompted by DTC ads are appropriate and necessary – and what portion are not. We simply have no read on that. Common sense and a faith in a discerning, intelligent public might lead us to believe that the majority of visits, doctor-patient drug conversations and drug requests are beneficial. But it is quite feasible that ads for some drugs could generate a fairly large volume of inappropriate demand. Viagra may serve as an example here, again. So might ad campaigns for drugs to treat depression, anxiety, pain or obesity. It's not hard to imagine that segments of the public would be induced to seek a drug inappropriately to treat self-diagnosed “symptoms” of these conditions.

So what is the harm in that? Putting cost (of unnecessary visits and drugs) aside, the harm would be if a patient gets prescribed a drug they do not need. More research is urgently needed to assess this issue. It is the core public health issue with respect to DTC ads in our view. Are they inducing inappropriate demand? If so, what is the magnitude of that? Are doctors complying with patient requests? If so, how often? Are certain categories of drugs more amenable to this misuse than others?

Almost certainly both beneficial and harmful effects will be found. But in what balance? We don't know. And we do not currently have enough information to make a judgement about the balance of DTC's beneficial versus harmful effects. Indeed, thoughtful observers of this issue do not yet agree on what magnitude of harmful effect would be needed to spark concern about drug ads or a reevaluation of whether they should be allowed.

We would also advise that research be directed at learning to what degree DTC ads foster a belief that prescription drugs are safer or more effective because they are advertised in mass media.

Consumer Protection Issues

The issues raised by DTC drug ads are serious. They involve questions of public health, corporate responsibility, advertising ethics, and consumers' capacity to understand and process complex medical information.

We think the FDA and Agency for Healthcare Research and Quality (AHRQ) should collaborate to fund a series of studies to further define and measure the impact of DTC ads. An advisory group should be convened to help frame the key research questions.

We believe the FDA should direct more resources into monitoring the content of DTC ads to assure that a fair balance of information is presented. We support the FDA's recent efforts to measure consumer response to DTC ads. We strongly favor a continuation of that activity.

We support the FDA's current efforts to gauge the legal issues surrounding DTC drug advertising. We strongly believe that the FDA plays a critical role in regulating prescription drug advertising, marketing and promotion and that that role is appropriate given the FDA's purview over drug approval.

Enforcement Role of the FTC

In the last decade the FTC has undertaken important reviews of antitrust and competitive marketplace dynamics in the health care industry. It has also engaged in enforcement activity in this area. More recently, the FTC has studied closely the effect of patent issues on the balance of competition in the pharmaceutical industry. DTC ads for prescription drugs are a new force in the pharmaceutical industry that bears watching in this context. Generic firms are of course not precluded technically from advertising their products. But as a practical matter, they do not have the resources to do so. Virtually all DTC ads are for patent protected brand name drugs.

The FTC could play a useful role were it to commit to monitoring the impact of DTC advertising on competition for market share between brand and generic drugs – in general and in some specific therapeutic categories of drugs (e.g. – antibiotics).

In addition, we would strongly urge the FTC to study the issue of generic biologics. Currently, the FDA has no rules to guide it in the approval of generic versions of biologically-based (biotech or genetically engineered) drugs. Congress would be aided as it tackles this issue by the FTC's examination of the impact of this problem on competition in the pharmaceutical industry.