- *Essential Psychopharma*Stahlogy -

Fixing Pharma and the Feds

What the pharmaceutical industry and the FDA can do to restore their reputations

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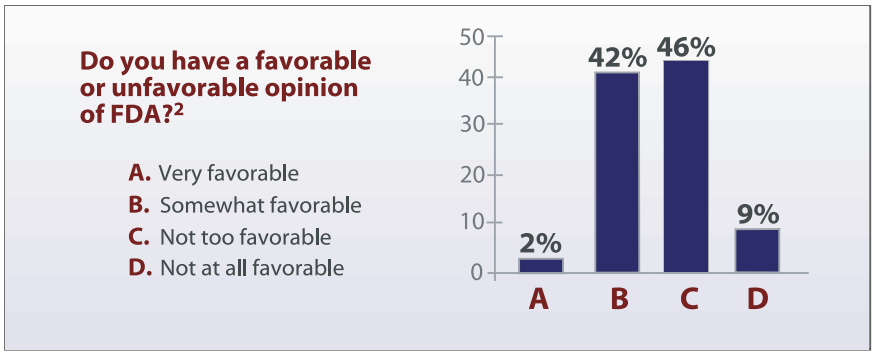
Most admired to most reviled?

Two decades ago, the pharmaceutical industry in general and several Big Pharma companies in particular consistently ranked as "America's Most Admired" companies. The go-go 80s and the greedy/corrupt 90s have taken their toll on the pharmaceutical industry's reputation (see figures 1–7), and now these companies rank with oil and tobacco companies as some of the least trusted companies of all. Top pharmaceutical executives are now facing criminal charges and some may actually have to serve time in federal prisons.

Figure 1



America's single-most admired company of the 1980s is now facing possible liquidation due to lawsuits about putting profits before people and bungling their communication of safety concerns, as they arose, for one of their multibillion dollar drugs.

What happened?

It's about making medicines

Looking back, we can perhaps trace how we got to where we are today. There was little serious drug development until after World War II and essentially no real FDA until the 1960s.

At first, many pharmaceutical companies were formed to make antibiotics, including penicillin, for our troops in World War II. As science advanced, treatments for hypertension, anxiety, and other disorders evolved from novel chemical synthesis of many new drugs. However, not all of them worked very well and not all of them were safe. It took the thalidomide safety disaster for Congress to create a real FDA, tasked with regulating both the safety and efficacy of medicines. This system worked very well at that time, and many companies were making not only important drugs, but high profits.

Low-hanging fruit

As the costs of drug development and marketing skyrocketed to over a billion dollars for each successful new drug, the pharmaceutical industry began to cherry pick the drug discovery opportunities. That is, the industry was no longer following the best scientific breakthroughs to fulfill the greatest unmet needs of patients. Rather, the industry began to go for the low-hanging fruit by doing this only for those opportunities that also promised billion dollar drugs. That meant pursuing symptomatic treatments for very common diseases that needed life-long chronic treatment. Vaccines that prevented illnesses and treatments for illnesses projected to generate less than a billion dollars in sales became far less attractive and were often dropped from drug discovery programs.

At first, this business strategy was no problem, as everyone seemed to be able to have their cake and eat it too. There were plenty of good scientific targets as well as multiple unmet needs for highly profitable chronic illnesses suffered by millions of patients. However, by the 1990s, this began to change as the treatments for depression, arthritis, high cholesterol, and many others flooded into the market, and the high-profit illnesses with the easiest drug development targets became fulfilled, and with multiple "me-too" competitors.

Its not a charity, brother

As the pharmaceutical industry began to weigh their options, those most interested in making short-term profits figured it out quickly. On the one hand, you could invest your money on high-risk, new mechanisms (such as substance P antagonists, CRF, corticotrophic-releasing factor antagonists, etc). On the other hand, you could invest in low-risk, low-innovation, patent extension gimmicks

Cont.

Figure 2

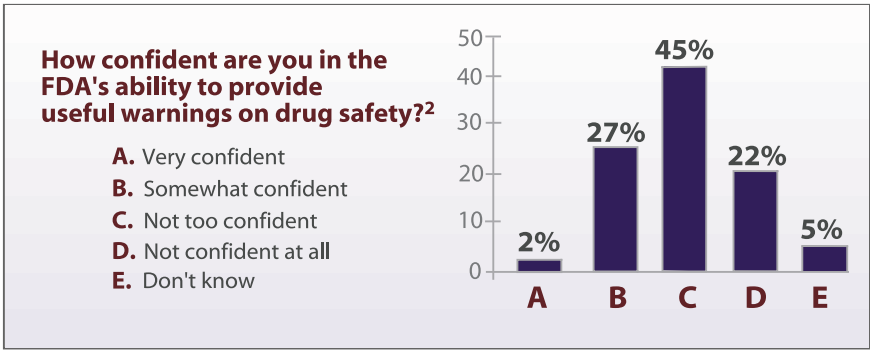


Figure 3

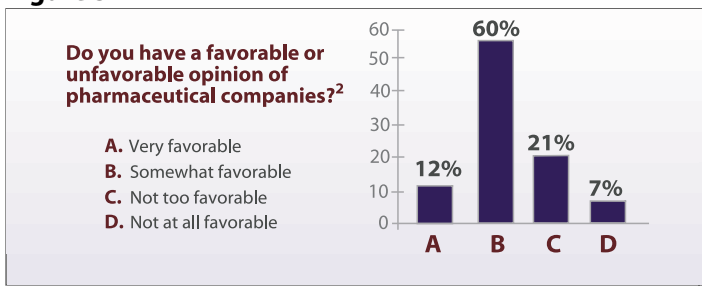
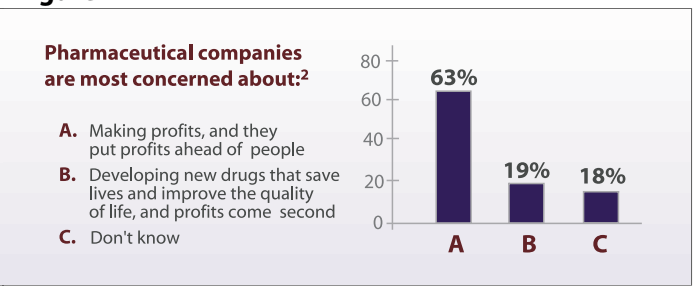


Figure 4



such as controlled-release formulations, active enantiomers, and active metabolites of known drugs.

Going for the latter was what fulfilled the unmet needs of Big Pharma executives and stockholders to make more short-term profits, but did not really address the highest priority, unmet needs of the patients, nor did it exploit the best available science. In what was a reversal of the way the system is supposed to work, as the new products became less innovative, the pharmaceutical industry became more profitable. At the same time, the public became more involved in choosing their own drugs because the FDA started to approve consumer advertising. Seeing high profile Big Pharma on primetime television every night and during major sports coverage every weekend created high expectations of being able to choose your own great drug, with little or no risk. However, once payors found out the cost of such drugs, they became skeptical about the value of these expensive new drugs, often perceiving them as having little or no benefit over much less expensive generics.

Skyrocketing costs for drugs that often were marginally innovative were associated with soaring Pharma stock prices, exorbitant executive salaries, huge budgets for Madison Avenue ads, and the deployment of a hundred thousand Pharma sales reps costing $100,000 each. Was this value for money? The stage was set for punishing Pharma and the Feds for any unforeseen side effects. And when these unforeseen side effects inevitably occurred, there was a precipitous collapse of the reputations of both Big Pharma and the FDA.

Cover your backside

When antidepressants were found to increase suicidality in children, antipsychotics to increase risk of death in the elderly, and anti-inflammatories to increase cardiovascular events, the FDA was excoriated for not protecting the public. Pharma companies were skewered for not publishing their data and sued for hiding their results and putting profits before people.

The FDA, seeking to regain the public's confidence and to appear to be managing the appropriate communication of risks of medicines, reacted (some would say over-reacted) by creating a series of austere warnings for an ever-increasing number of drugs. Although this may have taken the heat off the FDA and even to a certain extent, off Pharma, it put the heat squarely on the backs of prescribers.

Indeed, a recent poll of high prescribers of psychotropic drugs shows that they have little confidence in the FDA's ability to provide useful warnings on drug safety. These psychopharmacology experts also do not hold a highly favorable overall opinion of the FDA (figures 1 and 2).

These opinions of high prescribers of psychotropic drugs are actually more negative for the FDA than they are even for Pharma (figure 3).

It's about the patient, stupid

It has been said that it can take at least seven years to make a reputation, but only seven seconds to lose one. For Pharma and the Feds to rebuild their reputations over the next several years, they might remember that it's about the patient.

That is, for the FDA, it should not be about appearing to look good to critics while communicating science so badly that patients are afraid to take drugs and prescribers are afraid to prescribe drugs. Actions by the FDA that unnecessarily burden prescribers with more legal liability and the need to spend even more time than is reasonable—in an already time-constrained practice—to explain, monitor, and reassure about taking drugs, means that fewer patients are likely to get treatments. As a matter of fact, prescriptions for antidepressants in children and for atypical antipsychotics in the elderly have fallen since the new warnings.

Perhaps a better solution would be for the regulators to take a role in helping to communicate the truth to patients, namely, that all drugs have risks as do all illnesses, and the practice of medicine is to balance risks with benefits, not to reinforce the notion that one can find treatments with all benefit and no risk.

For Pharma, it should not be about maximizing short-term profits and having "ease of drug development" drive drug discovery and marketing efforts, but about following the best science to fulfill the most glaring unmet needs of patients. There may be something wrong with a system, for example, where most drugs for bipolar disorder are studied and approved for the manic phase of that illness, when most of the disability and unmet medical need is in the depressed phase of that illness.

Pharma could get cracking on a change in business strategy soon, before they lose the residual good will that still does exist, especially among prescribers. That is, despite all the current problems, a poll of high prescribers of psychotropic drugs shows that they still have a somewhat favorable impression of Pharma

Figure 5

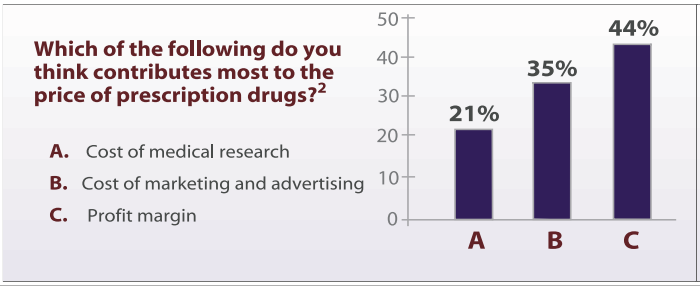
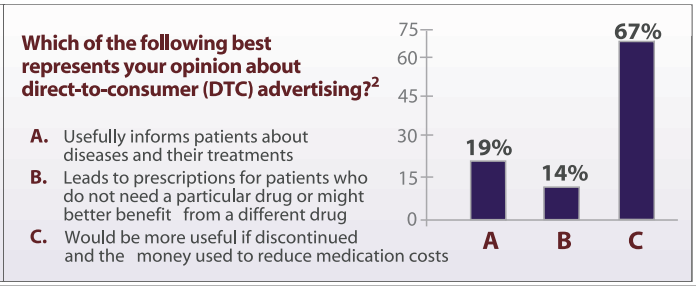


Figure 6



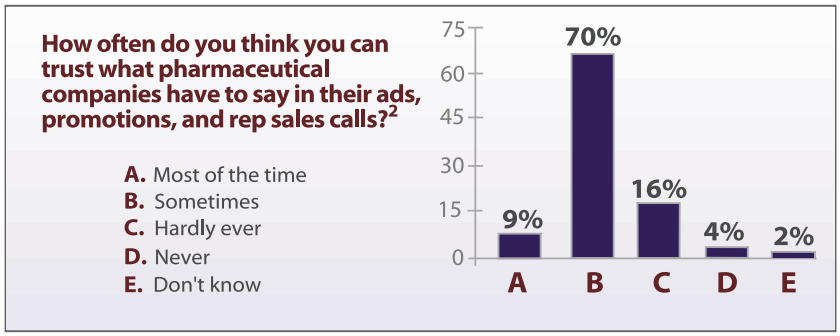
(figure 3), better in fact than their impression of the FDA (figure 2), and better indeed, than the general public's impression of Pharma in a recent survey by the Kaiser Family Foundation (1).

Some hints on what to do to get back more of the goodwill and advocacy of prescribers is suggested by their opinions in figures 4–7. Since prescribers, like the general public, think that Pharma puts profits ahead of patients (figure 4), and that the real cause of high costs of prescription drugs is the cost of making high profits and of marketing, and not of research (figure 5), Pharma could once again pursue more of the glaring unmet medical needs that exist and spend less effort on highly profitable but marginal innovations and gimmicks that merely extend prior art.

Interestingly, prescribers feel that it would be better if TV ads and over-the-counter marketing efforts were discontinued and the money saved used to reduce drug prices (figure 6). Thus, Pharma could rethink its direct-to-the-consumer strategy. Should the drug that a patient receives depend upon what he demands from his or her physician, and that depend, in turn, upon whether the patient saw the movie (and its ads) on one channel rather than a football game (with its different ads) on another channel?

Finally, a poll of high prescribers of psychotropic drugs shows that they only trust Pharma sales reps some of the time (figure 7). If reps are interested in increasing their own drug's market share at the risk of not getting the best drug to each patient, it will be hard to believe what they have to say.

Figure 7



The bottom line—It's about the patient, stupid. Patients want their prescriber, their regulators, and the pharmaceutical industry to work together to discover and deliver safe and effective medication for the illnesses that they have. At the same time, they want the system to work in a way that selects a treatment for them that is the best option for their unique set of circumstances, and not what is best for their prescriber, the sales rep, the regulator, or Pharma.

TAKE-HOME POINTS

1. Both the pharmaceutical industry and the FDA have taken serious hits to their reputations recently.

2. The pharmaceutical industry could get back to discovering beneficial medications and be less worried about short-term profits. Having scientists and medical professionals rather than legal and marketing professionals resume top leadership roles in Pharma might restore the right value systems to the industry.

3. The FDA could remember to put effective communication to consumers and prescribers above bureaucratic self-preservation. Thus, approving drug labels that may satisfy lawyers and politicians, but may confuse or scare consumers and disenfranchise prescribers, may not be the way to go.

4. Rather than serving their own short-term interests, all could remember that it's about following the best science to serve the unmet needs of the patient.

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