

## Big Bad Pharma

How Bad Drug Shortages, Bad Drug Supply Chain, Bad Manufacturing, Bad Ideas, and Bad Journalism Contribute to Pharma's Bad Reputation

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The drug industry is contending with a storm of unsavory media coverage documenting drug shortages in the U.S., drug counterfeiting, and recalls due to manufacturing faults. Some say bad journalism is heightening the “bad” news while ignoring the good that the industry does, which includes creating life-saving drugs and jobs.

### We Cured Cancer Dammit!

With regard to life-saving drugs, there can be little doubt that the industry deserves credit, although some drug company CEOs overplay the role of the industry and that generates bad press. Recently, for example, Marijn Dekkers, “outspoken” head of Bayer Pharmaceuticals, blamed ungrateful patients for not acknowledging pharma’s role in “curing” cancer.

“If you have cancer, you get a pharmaceutical product, and your cancer goes away,” said Dekkers in a *Wall Street Journal* interview. “You’re quick to call the doctor and [say] the staff at the hospital was great. But the pill that did it gets forgotten. We struggle with getting society to put value on what we do, and it becomes particularly important as we get under more pressure to develop the next pill” (for more, see <http://bit.ly/zaeakk>).

Compare that exaggerated scenario to reality: deaths from cancer, adjusted for the size and age of the population, have changed little since the 1950s, while death rates from heart disease and stroke have dropped significantly (see Figure 1, below). In this age of social media amplification of news sound bites and instant online collaboration, drug company executives—including CEOs—need to be extra careful about what they say to reporters.

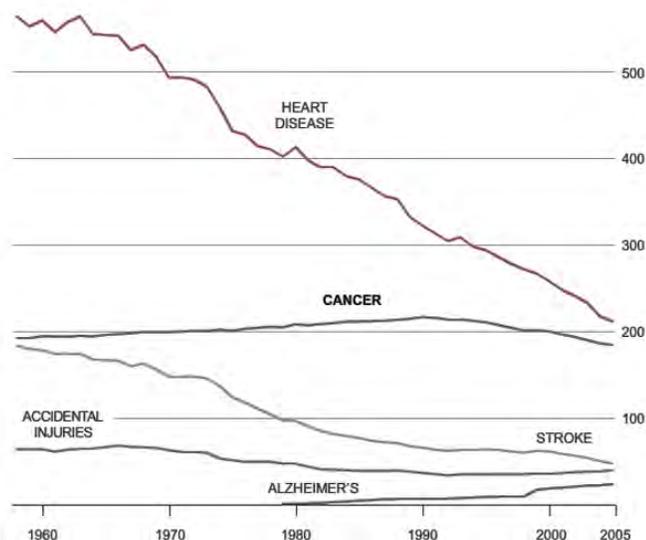


Figure 1. A Stubborn Disease. Source: NYT; <http://nyti.ms/xkvmN1>

### Creating Jobs

This election year every industry is bragging that it has the solution for creating jobs and turning the economy around. Every night, during the evening news, we are reminded by the oil industry, for example, that new oil and gas drilling will create thousands, nay, a million, new jobs in the U.S. “And that’s a good thing,” says the woman in the ads.

The pharmaceutical industry also reminds Americans that it creates jobs. PhRMA, the industry’s trade association in the U.S., churns out press releases that warn Americans that if the government passes such-and-such law or over-regulates such-and-such activity of the pharmaceutical industry, it will result in the loss of American jobs.

In a response to the President’s Fiscal Year 2013 Budget, for example, PhRMA stated “America’s biopharmaceutical industry is a key driver of economic growth; the President’s proposed budget would weaken our ability to innovate and create jobs. This is not an investment in America’s future and these proposals should not be considered” (see “PhRMA Statement on the President’s Fiscal Year 2013 Budget”; <http://bit.ly/zrAbM5>).

### Bad Reputation

However, when Americans were asked “Thinking about the role each of the following sectors played in the current state of the American economy, do you think each of the following sectors is a part of the problem, a part of the solution, or are you unsure?,” only 15% said the pharmaceutical industry was part of the solution, according to the 2012 Harris Poll Annual RQ survey. Fifty percent (50%) said the industry was part of the problem (see Figure 2, page 3). According to Harris, that puts the drug industry on the cusp of being a “malefactor”—an industry that Americans blame for economic woes.

### Is Pharma’s Bad Reputation Deserved?

“All the companies have to do to figure out why their reputation is in the dirt, is look in the mirror,” said an anonymous commenter to a Pharma Marketing Blog post. That and sentiments like it prompted *Pharma Marketing News* to ask readers if they believed that drug industry’s reputation was deserved or not. The question was part of the “How to Earn Back the Public’s Trust” survey, the results of which were summarized previously (see “Pharma’s Bad Rep or Bad Rap”; <http://bit.ly/pm83-01>).

While a clear majority of non-industry respondents (ie, HCPs and the general public) said “Yes,” only a small minority of pharma and agency respondents were willing to admit that the bad reputation was deserved

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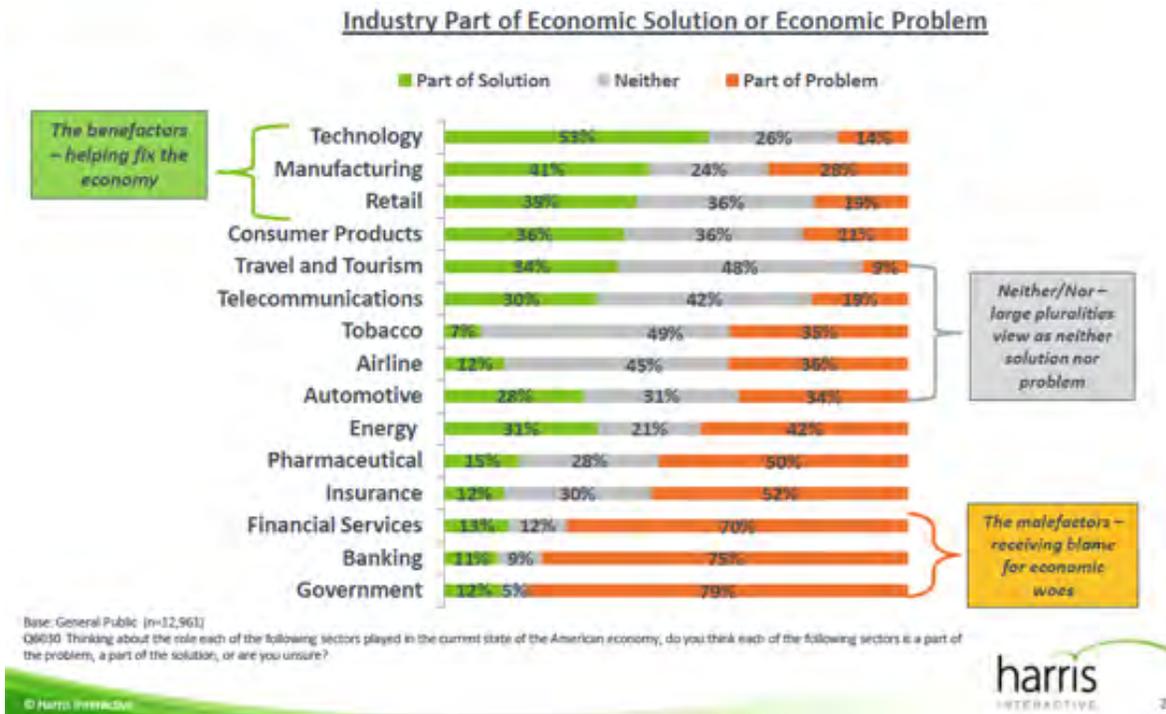


Figure 2. Industry Part of Economic Solution or Economic Problem. Source: 2012 Harris Poll Annual RQ survey; <http://bit.ly/xelJ2T>

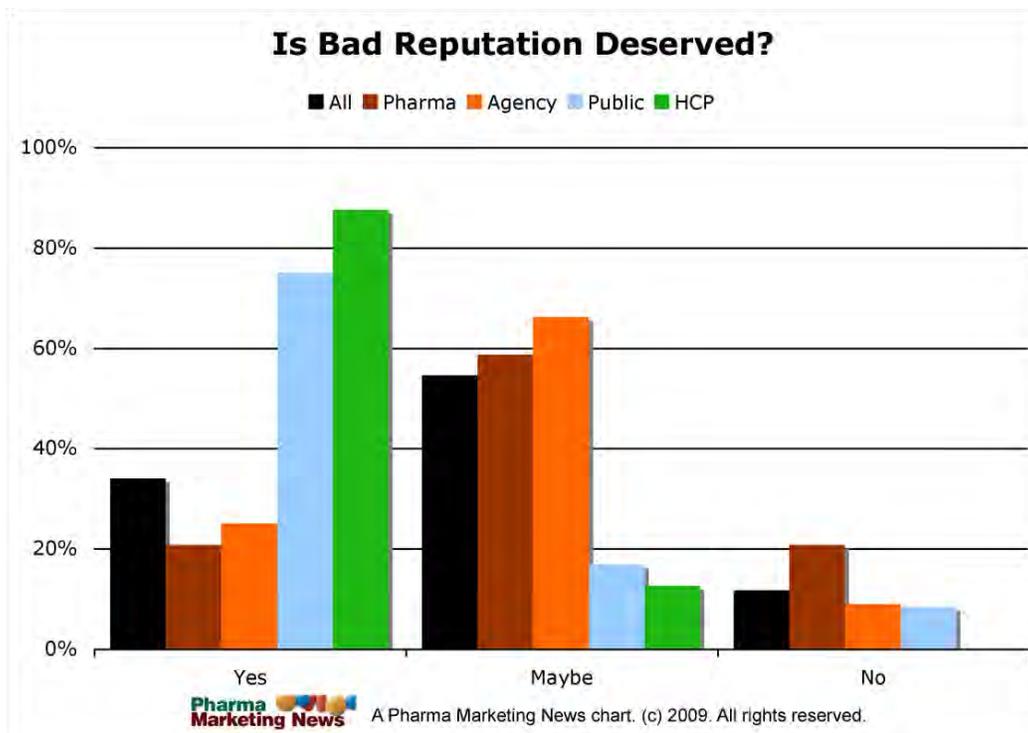


Figure 3. Question: In general, do you believe the industry's bad reputation is deserved? Source: "How to Earn Back the Public's Trust" survey; <http://bit.ly/pmnsurveytrust>

(see Figure 3, page 3). "Maybe" was their most popular choice. Among all respondents, 98% who are unsupportive of the industry said "Yes," whereas only 28% of supportive respondents agreed.

Of course, the drug industry can be both part of the solution and part of the problem. It depends on whose problem/solution you are talking about.

Pharma is part of the solution for white-collar workers who work within industry, have Rx medical coverage, and can afford prescription drug co-pays. Blue-collar workers and retired folk who depend more on government "safety nets," however, may see high drug prices and the drug industry's antipathy toward Medicare rebates as part of the problem. The latter are not among the typical U.S. pharma work force especially as the drug industry ships more and more blue-collar manufacturing jobs overseas to countries like China.

### Outsourcing Will Grow

Over 75% of respondents to the PMN "Predicting the Future of the Drug Industry Survey" agree with the statement:

"Pharmaceutical and biotech companies will continue to increase their outsourcing of clinical trials and related drug development. Outsourcing will account for more than 50% of R&D spending by 2019."

Learn more about this survey and the results here: <http://bit.ly/PMNsurveyPredict>

### Drug Counterfeiting

It can be argued that by exporting drug manufacturing—and also clinical trials—to countries like India and China, the U.S. pharmaceutical industry also endangers our drug supply. This link between overseas drug manufacturing and counterfeit or tainted drugs in the U.S. was suggested in a recent news story about counterfeit Avastin:

"Most Americans don't question the integrity of the drugs they rely on. They view drug counterfeiting, if they are aware of it at all, as a problem for developing countries. But the latest incident, which follows the appearance of other fake drugs in the U.S.—including counterfeits of the weight-loss treatment Alli and the influenza treatment Tamiflu—suggests it is a growing risk, especially as more medicines and drug ingredients sold in the U.S. are made overseas (see "Roche warns of fake cancer drug in US"; <http://bit.ly/zl5lUb>).

At the 2010 Annual Public Relations & Communications Summit at Pfizer Headquarters in NYC, Chris Loder, Pfizer's Head of US Media Relations, cited World Health Organization data that says 1% of worldwide sales of Rx drugs are counterfeit. Loder claimed that number is between 10 and 50 percent in "developing" nations. Pfizer defines counterfeit as "products deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product."

Loder spoke of Pfizer's all out campaign to bring attention to the counterfeit drug problem, which obviously hurts sales, especially of Pfizer's flagship drug, Viagra. But it's also a safety issue: "Counterfeit medicines are a risk to patient health and safety," said Loder. "That's the one message we send."

### Drug Supply Chain Safety

PhRMA maintains that "the most common means for counterfeit drugs to enter the United States is through purchases made on illegal online pharmacy websites operated by criminals in countries that have known counterfeiting problems" (see <http://bit.ly/w3EFZN>).

Yet according to Allan Coukell, director of the Pew Charitable Trusts' medical group, counterfeit Avastin "isn't something that was ordered over the Internet, or sold on a street corner. It illustrates that it's possible to sell a fake drug into a legitimate distribution system." Coukell was quoted group in a recent *Washington Journal* article (<http://wapo.st/wJb5MI>).

While there are no known cases of someone being poisoned by counterfeit Viagra, it is a certainty that Americans died from a tainted drug entering the supply chain via legitimate means. In 2007 and 2008, for example, "up to 149 Americans died ... after taking heparin, a blood thinner, contaminated during the manufacturing process in China," according to a "Drug Safety and Accountability" bill in (re)introduced in Congress in 2011. Also according to that bill, "up to 80 percent of the active ingredients in drugs used in the United States are made overseas, many in countries where regulatory oversight does not meet the standards of the United States."

It wasn't the active ingredient in Heparin that caused the problem, it was a contaminant that was deliberately added to heparin batches that were processed in China from pig's intestines by the American pharmaceutical firm Scientific Protein Laboratories. The contaminant mimics the in-vitro properties of heparin, but is much cheaper than heparin, which is obtained from pig intestine. It seems that there was a shortage of pigs in China at the time, perhaps due to efforts to curtail swine flu.

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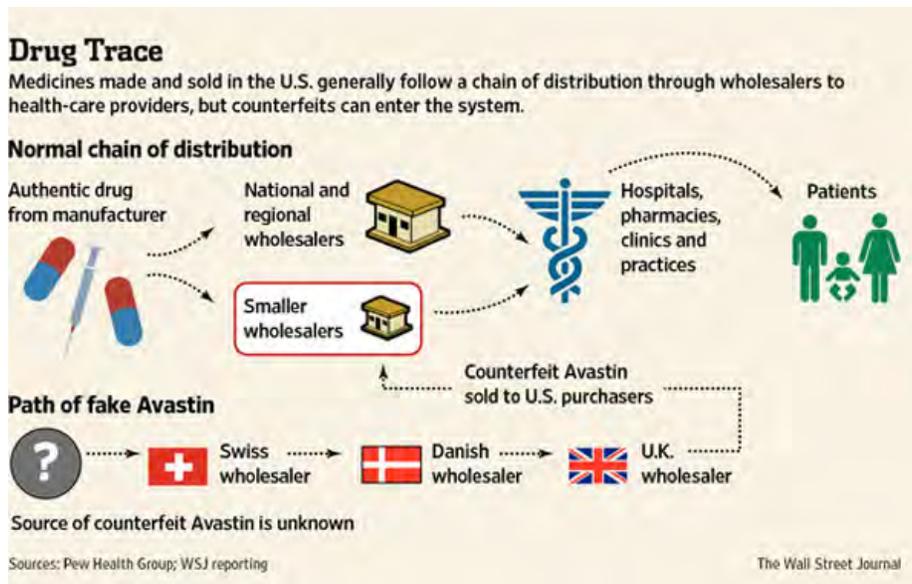


Figure 4: How Fake Avastin Entered U.S. Drug Supply Chain

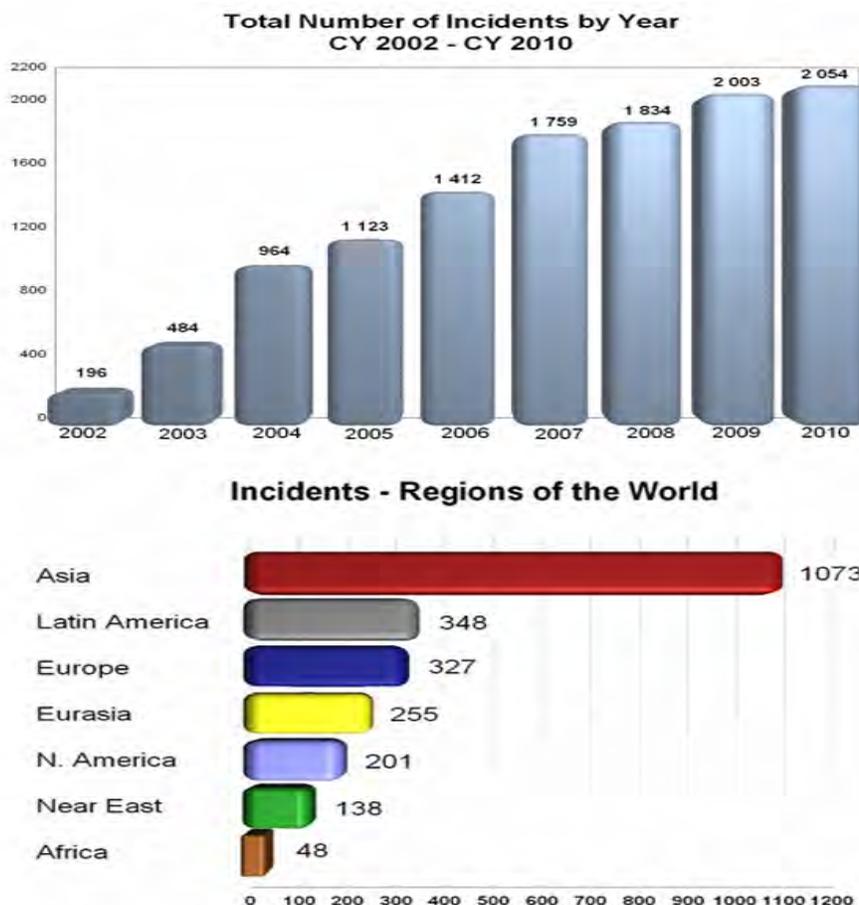


Figure 5: Counterfeit Drug Incidents. Top: yearly totals of counterfeit drug “incidents” logged by the Pharmaceutical Security Institute (PSI). Bottom: geographical distribution of incidents in 2010.

So, yes, counterfeiting was the problem, but not counterfeiting done by renegade "bad guys" selling product through the Internet, which Loder focused on as the main problem. It was contamination at the facility responsible for producing product for sale in the US. And the product found its way into the normal drug supply chain unnoticed by regulatory authorities.

A *Washington Post* article noted that "For more than a decade, public safety advocates have called for a tracking system that would enable everyone from manufacturers to wholesalers to doctors to verify the authenticity of prescription drugs through electronic tags or barcodes. But bickering between those parties over the cost and scope has stalled the effort."

In response to a letter from U.S. Senator Michael Bennet (D-CO) pushing for the FDA to consider a uniform pedigree standard as a component of a comprehensive solution to drug safety and drug shortage problems, the FDA said:

"We agree that implementation of a uniform pedigree or track-and-trace system may help further secure the integrity of the drug supply chain by providing transparent and accurate information on the origin, source, and handling of a drug throughout the supply chain," Jeanne Ireland, assistant commissioner for legislation, wrote in the letter. "...A robust track-and-trace system may help protect consumers from threats posed by illegal or substandard products, which may result from a drug shortage situation, in addition to providing accountability and transparency of the supply chain."

PhRMA, however, continues to insist that the U.S. drug supply chain is "one of the most secure supply chains in the world" (<http://bit.ly/xbue2B>). Although PhRMA says it is committed "to work with ... private partners and government officials on ways to prevent diverted and counterfeit medicines from being introduced into the legitimate supply chain," it has been silent regarding implementing a tracking system that has helped other countries develop an even more secure system than exists in the U.S.

### Americans' Attitude Regarding Drug Safety

Aside from counterfeiting being a risk to public health, another message that consumers should be getting is that the drug supply chain can also be a risk to patient health and safety. Yet, they may not be getting that message.

According to a Pew Prescription Project poll ("American's Attitudes on Prescription Drug Safety"), Americans are confident that drugs produced and sold in the US are safe, but those produced in China and India are not (see Figure 6, above right). American's

were divided about the adequacy of the government's effort to secure the safety of drugs produced in the U.S.; 42% said the government should do more, whereas 45% said the government is doing the right amount.

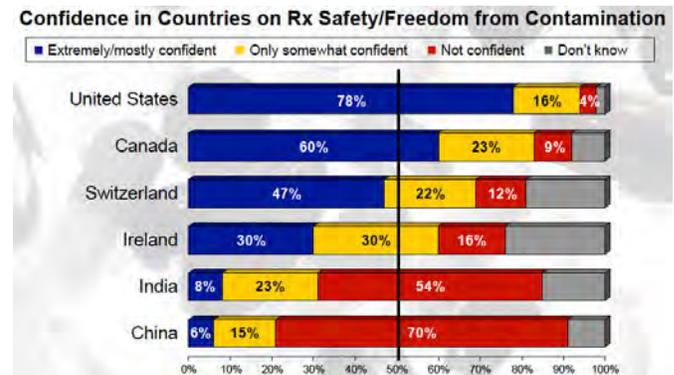


Figure 6. Confidence in Countries on RX Safety. Source: Pew Prescription Project poll, April 2010.

Perhaps the poll did not tell respondents that up to 80 percent of the active ingredients in drugs used in the United States are made overseas.

The story about how drug companies may or may not be monitoring the drug pipeline for adulterated—counterfeit or not—products is NOT being told. Perhaps this is because the PR people cannot think of dramatic images such as dead rats and sleazy criminals to represent the problem with drug supply chains. Or perhaps focusing on the supply chain hits too close to home.

### Drug Shortages

Also in the news lately is the nation's shortage of life-saving drugs such as methotrexate, a drug used to treat children's leukemia among other maladies. In a letter to Congressman Carney, author of H.R.3839 ("Drug Shortage Prevention Act of 2012"), the American Society of Health-System Pharmacists (ASHP) said "prescription drug shortages have created a public health crisis forcing clinicians to scramble to find life-saving medications for their patients."

As reported in the *Chicago Tribune*, "the FDA says the main reason for the shortages is manufacturing deficiencies leading to production shutdowns. Shortages also are resulting from companies halting production of drugs with low profit margins, companies consolidating in the generic drug industry and supplies of some ingredients shrinking" (see <http://trib.in/zOjhwe>).

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"This dramatic rise in the extent, duration and severity of shortages is occurring in an environment that is characterized by a near absence of communication between drug manufacturers and the Food and Drug Administration (FDA)," said the ASHP in an article titled "Can the United States Ensure an Adequate Supply of Critical Medications?" (find it here: <http://bit.ly/Avguk1>).

"This lack of transparency is a significant barrier to efforts to address drug shortages, and it represents a real and growing danger to patient safety. FDA has worked diligently to address this issue, but this work is hampered by the agency's inability to require reporting of information that could be instrumental in minimizing the impact of a shortage or averting it all together."

#### Lack of Patient Support Via Social Media

Not only is there a "lack of communication" between drug manufacturers and the FDA, there is a lack of communication between drug companies and their patients regarding this issue. That leads to more bad press and adds to the industry's bad rep.



Twitter and other social media can be effective in supporting patients when there is a problem with drugs (see, for example, "Use of Twitter for Patient Support"; <http://bit.ly/pm92-01>). Yet the pharmaceutical industry has not been very pro-active in reaching out to support patients via social media. Despite using social media to push out positive news about their companies and products, pharmaceutical companies whose products are in

short supply have not used these channels to communicate with patients.

Boehringer and Novartis—which own companies whose CEOs received letters from various cancer groups pleading for help alleviating the drug shortage caused by their troubled manufacturing processes—have posted positive tweets about their commitment to cancer patients, while completely ignoring the cancer drug shortage issue. Here are some recent (February 2012) tweets:

- @BoehringerUS: "@WHO estimates that 84 million people will die of cancer between 2005 and 2015 without intervention. #WorldCancerDay"
- @Boehringer: "@martin\_dudziak Very true. We are also committed and believe in continued research & clin trials as a major key factor in fighting cancer!"
- @MylanNews: "Mylan Committed to Expanding Access to High Quality, Affordable #HIV/AIDS Treatment. Company Honors #WorldAIDSDay"

- @Novartis: "Novartis continues to research ways to control tumor growth in advanced #breastcancer"

The Rx drug industry is betting its future on developing complex biologics to treat major diseases such as cancer. If the current crisis is any indication about how successful they will be in (1) manufacturing biologics and (2) using social media to inform the public about the products and support patients who depend on these products, then, it is not likely that they will succeed.

#### Bad Journalism or Bad Pharma?

All this bad news about the pharmaceutical industry could be blamed on bad journalism, which was a topic addressed Rich Meyer on World of DTC Marketing Blog. Meyer went on a bit of a rant against "bad journalism" and how pharma is often misrepresented in the news media (see "Bad journalism paints unfair picture of pharma industry"; <http://bit.ly/yrlvJa>).

The drug industry has consistently blamed the news media for painting an "unfair picture" (see, eg, Figure 7, below). The news media, however, more often than not publishes "good" news about the industry and often reporters merely quote verbatim from drug company press releases (see, for example, "The Cymbalta Buzz Machine is at Full Throttle!"; <http://bit.ly/xtlfir>).

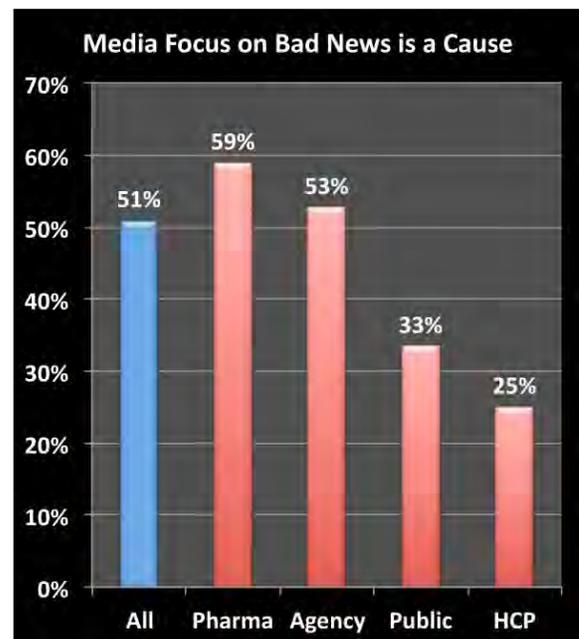


Figure 7. Media Focus on Bad News is a Cause of Drug Industry's Bad Rep. Percent of survey respondents who agree. Source: "How to Earn Back the Public's Trust" survey; <http://bit.ly/pmnsurveytrust>

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In a more recent example of how pliant the news media often are, Boehringer Ingelheim (BI) was chastised by the British Prescription Medicines Code of Practice Authority (PMCPA) for distributing a press release and briefing material for spokespersons that would in effect encourage members of the public to ask their health professional to prescribe a specific prescription only medicine. In fact, several news articles went even further and made some great marketing statements that BI could never make, such as referring to Pradaxa as a "super pill" and a "revolutionary drug." The stories also dissed the competition (warfarin) by referring to it as "rat poison" (see "BI Masters the Art of WOM through Its 'Parrots,' er, Spokespersons"; <http://bit.ly/zLSsOm>).

These are news stories about pharma products and not about the pharmaceutical industry itself, which is what Meyer was focused on. Getting news media to publish positive stories about products is very important to pharmaceutical companies. As for stories about the industry itself, well that's why there exists the PhRMA trade association, which counterbalances negative stories in the press and competes with news media to influence lawmakers. PhRMA has a tremendous budget and the industry shouldn't worry too much about the sort of "bad press" Rich is talking about, IMHO.

#### Is News Media to Blame?

Some time ago, Pharma Marketing hosted the survey "How to Earn Back the Public's Trust," which asked respondents if they agreed that the press is the main culprit for pharma's bad public image because news media report mostly bad news about the industry and not the good that it does.

Only 51% of survey respondents agreed strongly or somewhat (63% of pharma respondents agreed; see Figure 7, page 7). While that was a majority, even more respondents agreed that other issues are at fault: such as "lack of transparency regarding negative clinical data" (81% agree) and "high costs of prescription drugs" (81% agree).

Meanwhile, in an FCC Journalism Report, "complaints abound from seasoned reporters who lament the growth of 'press release reporting' and the lack of time they have to check out the veracity of information contained in a press release. Twenty eight percent of health reporters said that they personally get story ideas from public relations firms or marketing outreach somewhat or very often" (see "New FCC Journalism Report Paints Bleak Picture of Health Coverage"; <http://bit.ly/xykkAS>).

A March 2009 Survey of American Health Care Journalists (AHCJ) found that just under half (44%) of staff journalists participating in the survey say that their organization sometimes (34%) or frequently (10%) bases stories on news releases without substantial additional reporting (see "Academics Exaggerate, Journalists Regurgitate. What About Bloggers?"; <http://bit.ly/zcokYK>).

IMHO, this is "bad journalism," but of a type that tends to paint a more rosy picture of the pharmaceutical industry and the good it does.

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