

Feature Article

Disease Mongering: When Is the Line Crossed?

By John Mack

"Disease mongering" is a term that was coined by the late journalist Lynn Payer to describe what she saw as the confluence of interests by some doctors, drug companies, patient advocacy groups and media in exaggerating the severity of illness and the ability of drugs to "cure" them. (See "Defining Disease Mongering" for a more detailed definition.)

I first became aware of the disease mongering "conspiracy theory" through a series of articles published in the April 2006 issue of PLoS (Public Library of Science/medicine). The publication of these articles was timed in concert with the first-ever conference devoted to disease mongering in New Zealand ("Inaugural Conference on Disease Mongering").

The following examples of disease mongering were cited in the April, 2006 issue of PLoS:

- Restless Leg Syndrome (RLS)—Prevalence of rare condition exaggerated
- Irritable Bowel Syndrome (IBS)—Promoted as a serious illness needing therapy, when usually a mild problem
- Menopause—Too often medicalised as a disorder when really a normal part of life

The organization that hosted the Inaugural Conference on Disease Mongering, produced a mock video on a new "disease" called "Motivational Deficiency Disorder" and distributed it via YouTube. It's quite well-done (Figure 1, pg 4).

Experts Weigh In

Pharma Marketing News, hosted a live podcast interview of two experts in this area:

Neil H. Gray, Managing Partner, Healthcare Trends & Strategies, LLC. Neil has been working in the life sciences for 25 years, mostly on the service side. He has experience in a wide range of therapeutic categories and has worked with most of the larger and some of the mid-size pharmaceutical companies as well as some biotech companies. Neil's consultancy is focused on helping its clients better understand health care trends and supplying them with sensible strategies.

Alex Sugerman-Brozan, Director, Prescription Litigation Access Project, which is based in Boston, MA. This is a coalition of over 125

consumer, labor, healthcare and other advocacy organizations. The Project's primary mission is to challenge illegal tactics of the pharmaceutical industry by helping consumer organizations and labor unions and others participate in class action law suits. In addition, the organization is also a frequent critic of much of the marketing undertaken by the pharmaceutical industry and hosts the annual "Bitter Pill Award."

During the podcast, the following questions were put forward for discussion:

1. Is disease mongering a legitimate issue? That is, are some pharmaceutical marketers attempting to broaden the market for their products to stimulate sales?
2. What is the influence of DTC?
3. What is the impact of Disease Mongering on pharmaceutical credibility?

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Defining Disease Mongering

The problem of disease mongering is attracting increasing attention, though an adequate working definition remains elusive. In our view, disease mongering is the selling of sickness that widens the boundaries of illness and grows the markets for those who sell and deliver treatments. It is exemplified most explicitly by many pharmaceutical industry-funded disease-awareness campaigns—more often designed to sell drugs than to illuminate or to inform or educate about the prevention of illness or the maintenance of health. In this theme issue and elsewhere, observers have described different forms of disease mongering: aspects of ordinary life, such as menopause, being medicalised; mild problems portrayed as serious illnesses, as has occurred in the drug-company-sponsored promotion of irritable bowel syndrome (see pp. 156–174 in [2]; [4]) and risk factors, such as high cholesterol and osteoporosis, being framed as diseases.

The Fight against Disease Mongering: Generating Knowledge for Action; Ray Moynihan, David Henry;

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0030191>

RLS Foundation's Ties to GSK

(Adapted from a Pharma Marketing Blog post entitled "[Restless Pharma Marketing](#)".)

If you visit the RLS Foundation's Web site, it's a bit difficult to find out where it gets its money from. You have to dig down a few pages to learn that GSK and Boehringer Ingelheim are "Gold Level Sponsors." Both of these pharmaceutical companies market treatments for RLS.

Not that's anything wrong with that.

But an RLS Foundation November 15, 2005, Press Release announced the first RLS Foundation Science Award went to Ronald L. Krall, MD, Senior VP of Worldwide Development at GSK! That's a first! Pipe money into a foundation and viola! you (or a VP in your company) gets an award!

Not only that, Dr. Richard Allen, a member of the RLS Foundation's Medical Advisory Board, proudly reveals in the press release that he had the "pleasure" of "collaborating" with the research team selected by Dr. Krall to do studies supposedly supporting the data on the prevalence of RLS in the US and in Europe.

A couple of other suspicious findings: Although the RLS Foundation Web site claims the organization was incorporated in 1992, the earliest press release available on the site is dated November 14, 2005, just one day before the press announcement of FDA approval of Requip in the US. Even the color scheme of the Requip.com and RLS Foundation Web sites match (blue and orange). Coincidence? Probably; there are so many sites with those colors!

To sum up the ties between the RLS Foundation and GSK.

- GSK is a Gold Corporate Sponsor of the RLS Foundation, which means it has given the foundation a good chunk of change (the amount is not revealed);
- at least one member of the Foundation's Medical Advisory Board has financial ties to a pharmaceutical company (GSK) with a treatment for RLS;
- the PR activity of the organization seems to have picked up right when that company's drug (Requip) hit the market;
- RLS Foundation's first RLS Foundation Science Award went to a GSK Senior VP.

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Is It a Legitimate Issue?

John: My question is this: Is disease mongering a legitimate issue? That is, are some pharmaceutical marketers attempting to broaden the market for their products to stimulate sales?

Neil: I think it is a legitimate issue. The issue has been heightened recently with the advent, growth, and reach of direct to consumer advertising. Restless leg syndrome is an example, and, in fact, was the issue that put me over the edge and I say “enough is enough!”

A new Epidemic



Figure 1: Scene from “Motivational Deficiency Disorder” video.
Source: www.diseasemongering.org

In terms of a definition I think “the selling of sickness that widens the boundary of illness and grows the drug market accordingly” adequately capsulizes the meaning.

You’ll never find me arguing against the industry’s efforts to improve communications between patients and physicians. That’s vital, especially as the population ages. The industry, therefore, needs to take a look at where it’s spending its dollars. The market will decide the fate of restless leg syndrome, but perhaps not before too many dollars and too much time is misdirected towards issues that are not critical to the nation’s health.

If the industry’s focus is to broaden the awareness of disease to encourage expanded dialogue between prospective patients, existing patients, and healthcare providers, this deserves support and positive recognition. Patients only can experience positive outcomes when they and their providers have determined they need treatment to alleviate symptoms or cure a malady. In point of fact, the industry can be and frequently is an enormous force for good by helping undiagnosed patients become diagnosed and cared for patients.

However, when the industry seeks to broaden or widen the boundaries of disease solely to stimulate more sales of an existing or future product, I think that action will correctly stimulate acute and displeasing scrutiny from industry critics. GSK’s Requip campaign makes me truly wonder about the science behind this problem, where it has been residing in the literature all these years, and how many patients are truly afflicted. I need to learn more here. And while I don’t pretend to chastise GSK for pursuit of what they feel is a market opportunity, “restless leg syndrome” truly makes me wonder where else they could have applied their assets. I suspect the market will determine whether Requip will prove beneficial to patients and stakeholders over time.

Alex: The most extreme definition of disease mongering would be creating a new medical condition to justify the development, marketing, and sale of a drug for its treatment. A much broader spectrum of activities by the drug industry, however, could be included under the term “disease mongering” if we included convincing people who are not sick that they have a medical condition that needs to be treated. In other words,

the condition can be a real medical condition, but the number of people who may have the condition is exaggerated. In addition, I would also consider disease mongering the attempt to convince people who really have a medical condition that they need a brand name drug for treatment as opposed to an equivalent generic drug or OTC medication or a lifestyle change. An example of the latter may be the promotion of insomnia medications.

Many of these marketing strategies along the spectrum, up to and including disease awareness, are problematic. Yes, it is vital to raise the public’s awareness of a variety of serious and

chronic conditions, but *who* is doing the awareness raising is absolutely key! Pharmaceutical companies, of course, have an extraordinary vested interest in the growth of a particular market and should not be our trusted source of information about diseases.

HCP Co-conspirators

John: There are other stakeholders who benefit from the types of disease mongering practices you've mentioned. What about complicity by some in the medical community? Doctors who treat these conditions also have a vested interest in expanding the definition of condition or enlarging the audience that may have the condition.

Neil: Is there collaboration between the industry and healthcare providers to engage in some form or another of disease mongering? The answer is unequivocally "yes." We're going to see a lot more of this. The leverage of the pharmaceutical industry and the desire to improve symptoms of patients may entice some healthcare providers into collaborative efforts that they might not have otherwise joined based solely on clinical data.

Alex: The healthcare provider's role has been thoroughly compromised by the onslaught of marketing directed at them by the industry. No public health message could possibly compete with the 90,000 or so Pharma sales representatives that descend upon HCPs every day!

Neil: I disagree. It takes two to tango. Physicians need to be more circumspect with regard to pharmaceutical detailing. Simply pointing the finger to at industry as the catalyst for all perceived irregularities addresses only half the problem.

Alex: Yes, everyone has a role to play here, including consumers, providers, and pharmaceutical companies.

One of the best examples of how marketing creates a totally inappropriate and costly result is the enormous success of Nexium. Clinically, Nexium has no benefit over Prilosec—the OTC version of the medication, which is available for about one-seventh of the price. Yet, in 2006, AZ estimates it Nexium sales were \$4.6 billion. Every dollar of that is the result of a prescription written by a doctor who could have written a prescription for a generic or OTC Prilosec. They did this for a variety of reasons—patient demand, formulary coverage, and maybe even pharmaceutical marketing targeted at them. So in that equation, everyone has a role to play and can change it. No one gets off the hook. But, unfortunately, the industry has been the primary driver of

inappropriate prescribing whether it's for diseases of questionable reality or diseases that are simply oversold or upsold.

Patient Advocate Co-conspirators

John: What about patient advocacy groups? I know the pharmaceutical industry has created these groups from scratch (see "RLS Foundation's Ties to GSK", pg. 3), but they also work with existing organizations.

Neil: This, like many things, has the potential for doing good as well as doing harm. In the cancer community, for example, better funding of patient groups creates more awareness of the benefits of early diagnosis. There also has been the creation of advocacy groups that are questionable in scope and focus.

Alex: Disease advocacy groups run the gamut from those that steadfastly refuse to take any money from the drug industry to those that are pre-existing and independent but that do accept industry support, and finally, on the other extreme end, those that are wholly owned subsidiaries that are created out of whole cloth and which are aptly called the astroturf lobby. The line between these categories is often blurred.

Active support of a patient advocacy group by a pharmaceutical company with a vested interest in the disease state implicitly calls into question the credibility and independence of that advocacy group.

Neil: I think it's fair to say that the industry finances a major share of disease research. There is a need to bring advocacy groups into the dialog to reach the right patients for research subjects and to communicate the results of research to members. I don't think this lessens the legitimacy of the organization as a patient advocate. Where it does get out of hand is when created advocacy groups seek to steer public opinion one way or the other on a product focus. Advocacy groups cross the line when they engage in pharmaceutical-sponsored lobbying.

Does DTC Foster "Disease Mongering?"

John: Disease mongering may be a natural outgrowth of DTC advertising, which tends to broaden its audience as much as possible to justify the expense or meet sales goals. Erectile dysfunction DTC ads, for example, over the years have featured younger and younger men, which may be an attempt by marketers to "grow the market" for these drugs.

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The Viagra ads began by featuring Bob Dole, who was 76 at the time (1999). Levitra started out with Mike Ditka (age 65), while Viagra shifted to Joe, who is maybe 45 or 50. The Cialis guys in the bathtub and convertible also look about 45 to 50. But the new Levitra guy looks thirty-something. His wife—or is it just his "gal?"—is stunning and looks even younger!

Some marketers might defend this as a typical marketing tactic of appealing to a younger demographic than might be the typical consumer of the product, but I suspect that expanding the market is the main motivator in this case.

Pharma Marketing News surveyed readers and Web site visitors on this issue. Seventy-four percent (74%) of respondents Strongly agreed/Somewhat agreed with the statement "Disease mongering is a natural outgrowth of DTC advertising."

One respondent had this to say: "It is hard to argue that some people may benefit from drugs to treat these diseases. The problem with disease mongering is that it attempts to broaden the market for these conditions to many people who would be better served by behavioral modification and non-drug therapies. Another unspoken issue associated with disease mongering is its role in generating buzz through public relations, publicity, and word-of-mouth. Many diseases have been mongered so companies can own a condition for which their drug can be talked about. An example is the use of antidepressants to treat 'shoppaholics.'"

Neil: The opportunity for disease mongering is either subliminally or overtly fostered by a climate that encourages "envelope pushing" by industry through direct-to-consumer advertising.

It seems to me that responsible advertisers, with strong leaders and ethical corporate cultures (of which they should not be bashful) understand and use DTC as a long-term investment that touches and communicates their products, values, people, and intentions. Those who run astray in this arena might be driven more by short-term measures, stakeholder pressures, or priorities. This is where the notion of leadership emerges...and it takes a host of leaders (both industry and FDA-based) to weigh carefully the short-term benefits vs the long-term implications of overly aggressive DTC. We'll hear more on this, I'm sure, in 2007 as the FDA's Division of Drug Marketing, Advertising, and Communications within its Center for Drug Evaluation and Research staffs up.

Disease Awareness or Disease Mongering?

John: Even disease awareness marketing, which was promoted by PhRMA's DTC Advertising Guidelines and is being used more by the industry (approx. 9% of the 2006 DTC budget vs 6% in 2005), is cited as an example of disease mongering by critics: "[Disease Mongering]" is exemplified mostly explicitly by many pharmaceutical industry-funded disease awareness campaigns—more often designed to sell drugs than to illuminate or to inform or educate about the prevention of illness or the maintenance of health." (PLoS, see page 19 for sources)

A case study may be found in the Erectile Dysfunction (ED) market where there have been a spate of disease awareness ads that talk about the potential causes of ED: high blood pressure, diabetes, and high cholesterol. On the one hand, these ads are more educational than previous ED ads were. On the other hand, the new ads may be an attempt to widen the potential market for ED drugs by including all men with high blood pressure, high cholesterol, and/or diabetes.

Take DA Out of Marketing?

John: With more emphasis on disease awareness, is there a danger that we will see more disease mongering of the sorts we have mentioned? Given the penchant of marketers to cross the line, should disease awareness, non-branded, advertising be taken out of the hands of the marketing department just as CME has on the physician marketing side? I note with interest that Centocor public relations produced a disease awareness "Drug-umentary" (see "Innerstate: A Review of the First Disease Awareness Documentary Film" in this issue), which may be a harbinger of things to come.

Neil: That's an interesting notion. I do see the pendulum swinging towards medical affairs departments having more of a say in these matters. Your idea may enhance the credibility of the information presented.

Alex: As long as DA remains in the hands of marketing, it is advertising and not a public service announcement. Just as we needed to define what we mean by disease mongering, we also need to define DA. What I have seen of DA primarily promotes pharmaceutical therapies and does not at any length or in any detail other possible interventions whether lower-cost drugs, or other medical or lifestyle interventions. That would be true disease awareness.

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DA tends to track what is likely to offer return on investment for the company sponsoring it. If we are really serious about DA as a public health priority, then it should be separate from the industry altogether.

Effect on Industry Reputation

John: Disease mongering brings into question the motivation of pharmaceutical companies, whether the prime motivation factor is profit or meeting real unmet medical needs. A recent PricewaterhouseCoopers survey shows that a substantially higher portion of consumers than pharma execs believe the primary motivator in developing new drugs is sales potential rather than unmet medical need (see Figure 2).

Pharma Marketing News surveyed readers and Web site visitors on this issue. Eighty-five percent (85%) of respondents felt that sales or profit potential was an extremely important factor influencing pharmaceutical companies about which drugs to develop and bring to market, whereas only 33% felt that an unmet medical need was extremely important in influencing the decision.

Do you think some of the marketing practices critics characterize as disease mongering is hurting the drug industry's reputation?

Alex: For much of the past decade, the industry has been its own worst enemy. It has generated most of the bad news and critics such as myself are merely responding to what has surfaced in the media, which unfortunately is not even the full story of what goes on in company boardrooms and doctors' offices. We are so critical because the industry is vitally important to the health and well-being of people. The trust in the industry by the public has been violated and people are very, very angry about that. It's going to take a long time for the industry to rebuild its credibility and it needs to start now by stopping ridiculous marketing campaigns that are causing people to roll their eyes.

Neil: I think it would help if the industry focused its priorities more on the long term rather than on the short term benefits.

NOTE: Pharma Marketing News surveyed readers and Web site visitors on the impact of disease mongering on pharma industry credibility. Sixty-seven percent (67%) of respondents Strongly agreed/Somewhat agreed with the statement "Disease mongering is a major factor in the loss of pharmaceutical industry credibility."

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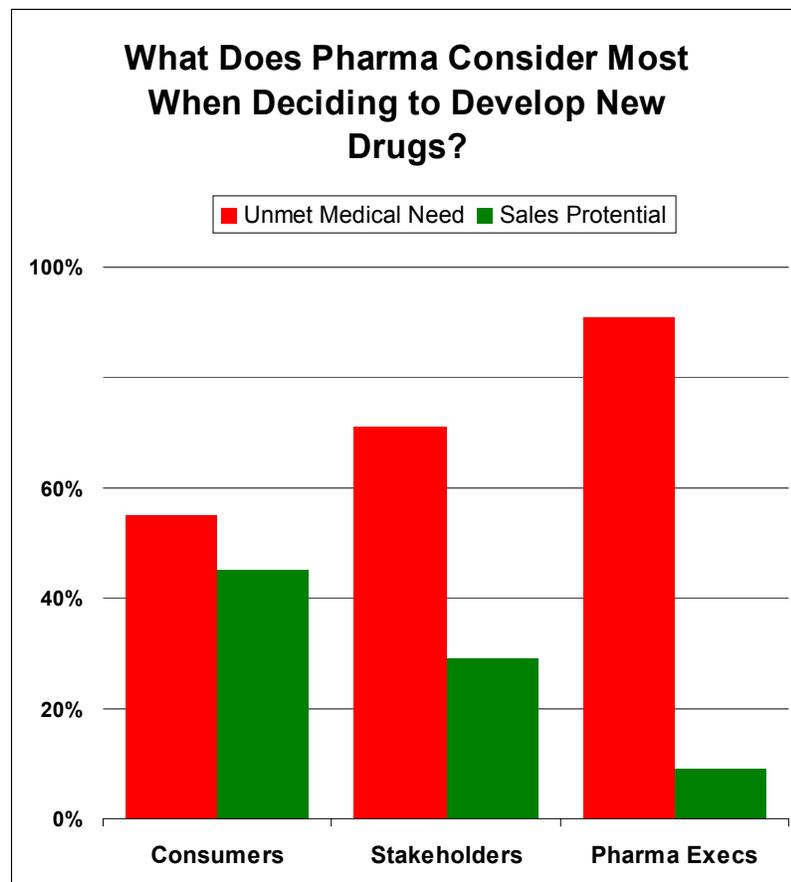


Figure 2: Source: "Recapturing the Vision: Restoring Trust in the Pharmaceutical Industry by Translating Expectations into Actions."