Researchers document the ills of marketing illness

It’s harder and harder to be well,” says Dr. Steven Woloshin. For years, he and his collaborator, Dr. Lisa Schwartz, have studied the effects of, as he puts it, shrinking “the boundaries of health.”

In 1999, the physician-researchers published one of the earliest papers on this topic. In it, they calculated the number of Americans who would be labeled “diseased” or “sick” under several proposed changes in the definitions for diabetes, high blood pressure, high cholesterol, and overweight. They found that by relaxing the thresholds for these conditions, 85.7 million more Americans would have at least one chronic condition, and 75% of adult Americans would be considered diseased.

Harms: Such expansions of disease definitions are worrisome, they say, because “the extent to which new ‘patients’ would ultimately benefit from early detection and treatment” is often unknown. And diagnosis and treatment are not without harms, physical and psychological.

Their latest paper on the subject was published in the April issue of PLoS Medicine, the journal of the U.S. Public Library of Science. The issue included seven articles on “disease mongering”—the expansion of disease definitions to increase the market for a treatment or drug. Schwartz and Woloshin’s article focused on restless legs syndrome (RLS). RLS is defined by four criteria: 1) the urge to move the legs due to an unpleasant feeling in them; 2) onset or worsening of symptoms when at rest; 3) relief from movement; and 4) symptoms that occur primarily at night and interfere with sleep.

Between 2003 and 2005, the drug company GlaxoSmithKline (GSK) ran an RLS awareness campaign and funded several studies on RLS and its treatment with the drug ropinirole. GSK also supported the RLS Foundation, a nonprofit advocacy group.

In 2005, the Food and Drug Administration approved ropinirole for treatment of RLS. Sold by GSK as Requip, ropinirole had already been approved to treat Parkinson’s disease. After gaining approval for RLS, too, GSK spent $27 million advertising the new use, according to the Washington Post, and sales of Requip rose 34%, to £156 million (about $270 million).

Saga: To examine the media’s role in the RLS saga, Schwartz and Woloshin studied all the articles on RLS in major newspapers from late 2003 to late 2005; there were 33. Almost two-thirds used RLS prevalence figures from GSK and the RLS Foundation—that it affects 12 million Americans, about 10% of the adult population. But these estimates “overstate the prevalence of clinically meaningful disease,” say the researchers. Those figures are from a study that used only one of the four criteria to define RLS and that included people with leg symptoms from other causes, such as diabetic neuropathy. Schwartz and Woloshin estimate the actual prevalence of RLS to be well below 3%.

While almost half the articles (15) mentioned ropinirole, only five noted its side effects. It has several, including nausea (40% with ropinirole versus 8% with placebo), dizziness (11% versus 5%), and, ironically, sleepiness (12% versus 6%). One-fifth of the articles mentioned the RLS Foundation but “none reported that the foundation is heavily subsidized” by GSK. From 2001 to 2006, the firm donated at least $850,000 to the foundation.

Huge: “It is easy to understand why the media would be attracted to disease-promotion stories,” say Schwartz and Woloshin. “The stories are full of drama: a huge but unrecognized public health crisis, compelling personal anecdotes, uncaring or ignorant doctors, and miracle cures.

“The problem lies in presenting just one side of the story. There may be no public health crisis, the compelling stories may not represent the typical experience of people with the condition, the doctors may be wise not to invoke a new diagnosis for vague symptoms that may have a more plausible explanation, the cures are far from miraculous, and healthy people may be getting hurt” through unnecessary treatment.

The bottom line for Schwartz and Woloshin, who are based at the VA in White River Junction, Vt., is giving the public balanced information, which they do in a regular column they write for the Washington Post. “Otherwise,” says Woloshin, “we may be harming people.”

Jennifer Durgin