Inverse benefits due to drug marketing undermine patient safety and public health

January 13 2011

Drugs that pharmaceutical companies market most aggressively to physicians and patients tend to offer less benefit and more harm to most patients — a phenomenon described as the "inverse benefit law" in a paper from the University of Texas Medical Branch at Galveston.

Published online Thursday, Jan. 13 in the *American Journal of* Public Health, the article explores recent withdrawals of blockbuster drugs due to safety concerns and finds a clear pattern of physician-focused marketing tactics that ultimately exposed patients to a worsening benefit-to-harm ratio. Potential patient safety and public health implications include unnecessary exposure to adverse side effects, high medical costs and competition for scarce resources.

"This is not a random occurrence, but rather a repeating, planned scenario in which drugs, discovered with good science for a specific set of patients, are marketed to a larger population as necessary, beneficial and safer than other alternatives," said co-author Dr. Howard Brody, a professor and director of the Institute for the Medical Humanities at UTMB Health. "Marketers are just doing their jobs. However, the reality is that for most new drugs, safety and efficacy are scientifically proven for only a small subset of patients. It's time for physicians to take a stand and not prescribe them so readily."

The inverse benefit law, coined by the authors and inspired by Hart's inverse care law (1), is manifested in marketing techniques commonly deployed to extend a drug's use beyond the proper evidence base. Brody

and co-author Donald W. Light, a professor at the University of Medicine and Dentistry of New Jersey, identify these strategies and illustrate the "law" with recent examples:

- Guidelines that reduce diagnostic thresholds and rely on surrogate endpoints – as seen in the steady lowering of blood glucose levels at which diabetes should be diagnosed to support glitazone drugs. Or relying on statins to lower cholesterol versus having a proven impact on the hard endpoint of decreasing heart disease incidence.

- Exaggerated safety and efficacy claims – as many as 140,000 cases of serious coronary disease in the U.S. might have been caused by rofecoxib, a COX-2 inhibitor, that was broadly marketed as safer and more effective than standard nonsteroidal anti-inflammatory drugs.

- "Disease mongering" – Osteopenia, once considered a non-disease state in patients who had not lost enough bone density to be diagnosed with osteoporosis, has now turned into a disease itself, in hopes of convincing physicians and patients that biphosphonate drug treatment will prevent their "disease" from progressing.

- Encouraging unapproved uses – three of five prescriptions for antipsychotics are for off-label use, even though 75 percent of those prescriptions lack evidence of benefits but expose patients to harm. Recent examples include gabapentin and olanzapine.

"While we looked only at marketing directed toward physicians, direct-to-consumer advertising plays a critical role in driving demand for a drug by patients who fall outside the group that might truly need it, and pressuring physicians to prescribe it more readily," said Brody.

"European countries are now debating whether to join the U.S. and New Zealand in allowing DTC advertising and we hope that our work could help inform that discussion."

Brody and Light recommend a series of remedial actions, including: restrict writing usage guidelines to groups free of commercial conflicts of interest; independently fund and design trials focused on safety and efficacy; and create a neutral agency (e.g., a branch of the National Institutes for Health) to conduct drug trials, including comparative effectiveness research to improve evidence-based prescribing.

The authors point to recent efforts such as the National Physicians Alliance's Unbranded Doctor Campaign and The Physician Payment Sunshine Act as positive steps toward a safe marketplace where physicians and patients access valuable, effective drugs.

"There is an unintended, but direct conflict between pharmaceutical marketing and public health," said Brody. "Physicians should approach commercial marketing by pharmaceutical companies with a critical eye. Future reform polices should look to reduce, minimize and limit these practices. Patients can also play an important role by being more skeptical of drug ads … and remember, the most important directive in them is to 'talk to your doctor'."

More information: (1) Hart JT. The Inverse care law. Lancet. 1971;1 (7696); 405-412.

Provided by University of Texas Medical Branch at Galveston