

Escalating MS drug costs in the US

Puzzling, troubling, and suspicious

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The medical profession and the pharmaceutical industry might seem to have the same motivation: their goals frequently align in health care, and both focus on alleviating the burden of patients' conditions. However, the ethical system of the physician is directed at the best interests of the patient; the ethical system of the pharmaceutical industry is a business ethic, focused on and directed at profit. Keep this in mind as you read Hartung et al.¹ as they document the “alarming” escalation of the costs of drugs for patients with multiple sclerosis (MS) in the United States.

When the first disease-modifying therapy (DMT) appeared in 1993, everything changed for patients with MS, their families, and their neurologists. Long considered an incurable or at least untreatable disease, it was now possible to alter the outcome of the disease. This increasing sense of hope sparked greater interest, a growing army of researchers with more funding, and more clinics and clinicians dedicated to the care of people with MS. It was hoped these expensive new drugs, with short-term benefit in reduced relapses and fewer MRI lesions, would lead to long-term reduction in the progression of disability.

It was not a surprise that first-generation DMT prices were high, but patients and insurers adjusted to the annual costs in the range of \$9,000–\$12,000. Prices were expected to increase with inflation, but decrease with production efficiencies, patent expiration, and entry of generics (which is expected to happen in a free-market world). When more effective DMTs appeared, we were not surprised that they had higher price tags. What was not expected was the skyward escalation of the prices of all DMTs.

Hartung et al. describe the escalating prices of first-generation and newer DMTs and compare the prices paid by 5 public sector health care insurance agencies: US Medicaid, US Veterans Administration (VA), United Kingdom, Australia, and Ontario (Canada). Comparable prices for private sector insurers are not reported.

A company marketing a new drug has some power to set the price, but this power is moderated by

competition with other therapies and the bargaining power of insurers, acting on behalf of many or all persons within a health care system. The disturbing escalation of DMT prices in the United States is clearly related to the political prohibition of US Medicare to negotiate prices with the pharmaceutical industry. What has happened defies common sense, logic, and the expected rules of the marketplace. Since Food and Drug Administration approval, and with increasing product competition, Betaseron has gone from \$11,532 to \$61,529, Avonex from \$8,723 to \$62,394, glatiramer acetate from \$8,292 to \$59,158, and Rebif from \$15,262 to \$66,394. These price increases, and emerging evidence that long-term outcomes are less than anticipated, undermine the cost-effectiveness of MS DMTs. These counterintuitive increases suggest the possibility of collusion among the manufacturers, but the authors say they do not have evidence.

What justification does the pharmaceutical industry in the United States offer for the remarkable increase in the costs of these drugs? Well, they do not have to explain, as they are allowed to set prices in a black box, based on the business ethic of maximizing profit, supported by a bizarre law that prevents US Medicare (the US federal government social insurance program) from negotiating prices directly with the pharmaceutical industry. That this is arbitrary and “just because they can” is shown by comparisons with other countries, such as Canada, Australia, and the United Kingdom, where the costs of the same drugs are one-half to one-third as much. What is even more striking is the contrast within the United States, where the same drug covered by Medicaid (insurance programs funded by the federal and state governments and administered by the states) may be 2 to over 4 times higher than to the federal VA system (for armed service veterans), which is permitted to negotiate prices (Betaseron is \$49,146 via Medicaid, but \$10,583 via US VA).

There are wider implications of the pharmaceutical industry grabbing as many public sector health care dollars as they can. Health care systems have

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limited resources, and any out-of-control escalating component may deprive other areas of support. The “tragedy of the commons” is not just that one person or group commands more of the resources, but that this process eventually destroys the commons.

Hartung et al. ask if the pharmaceutical industry is too big to fail. We think it will survive as long as its therapies improve health outcomes and represent value for money. But like big banks, pharma cannot be free to ravish the marketplace unfettered. There is a need at times to grab the big banks or big pharma by the lapels and make it clear that they are seriously out of line and are hurting people. The answer, “business is business,” must be balanced with a sense of morality when addressing patients with serious and life-threatening illness. The use of generic drugs in MS, which is expected to limit the rising drug costs, is unlikely to become widespread in the near future, because of the more stringent requirements for biosimilars than for small molecule agents; drug

companies have developed strategies that delay their release or make it as ineffective as possible.

The ethics of medical professionalism requires physicians to be advocates for their patients. Hartung et al. ask that neurologists become concerned and initiate a national conversation on this issue, which is relevant also to conditions other than MS, such as cancer and hepatitis C. We cannot just be concerned—our professional ethic requires us to act.

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1. Hartung DM, Bourdette DN, Ahmed SM, Whitham RH. The cost of multiple sclerosis drugs in the US and the pharmaceutical industry: too big to fail? *Neurology* 2015; 84:xxx–xxx.

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