Pharmas-co-dependence exposed

Would it be time to say, "No thanks"?

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Family physicians need to understand the lengths to which the pharmaceutical industry goes to influence them and how this hampers their professional independence, reduces the effectiveness of their prescriptions, and impoverishes the public health care system. Hence, the title of this article. *Pharmas* refers to pharmaceutical companies, *co* refers to collaboration or cooperation, and *dependence* refers to our reliance on funding from the pharmaceutical industry. Marketing by the pharmaceutical industry influences our institutions' scientific, editorial, educational, therapeutic, regulatory, and budgetary priorities; it also influences their relations with the media. The world of pharmaceuticals is in crisis, and our prescription profiles betray our involvement in this crisis.

Failure to innovate

Most "new" products brought to market since the 1990s have not substantially improved on the medical benefits provided by older, less costly drugs whose risks were well known. These new products are "me-too" drugs, new formulations, pharmacologic innovations, expanded indications, and products using new routes of administration or processes of manufacture. Most do not represent genuine therapeutic advances or meet those needs perceived by family physicians. They do, however, increase drug consumption. Technologic innovation does not equal therapeutic progress.

The industry's response: aggressive marketing

The sheer size of the pharmaceutical companies enables them to wield enormous political power through lobbying and to maintain legions of medical representatives who court physicians. Investment in advertising that targets prescribers is disproportionally greater than true innovation; opinion leaders are generously encouraged; continuing medical education is often sponsored; multicentre clinical trials are sponsored with ready-made protocols; and medicalizing and medicating the population is encouraged. The very notions of health and evidence-based medicine are biased by market-driven objectives.

The industry stakes its territory, associating itself with a multitude of medical and scientific activities and offering to fund drug agencies, advertising agencies, publishers, institutions, societies, associations, organizations, foundations, and so on. The road gets slippery[1,2] when promotion and education, commerce and science, and business and health care get too close: their values are simply different.

Opinion leaders

Transparency International, a non-governmental organization, recently proposed a code of conduct in its 2006 *Global Corruption Report*.[3] This code was endorsed by the editors of *Lancet*.[4] Among the specific recommendations made to physicians were the following: do not promote health products in which you have a financial interest, and do not join the list of speakers of a health products company. Conflict of interest can arise when collaboration goes beyond research and turns into marketing when physicians become paid consultants or paid speakers.

Even though it only takes direct aim at certain opinion leaders who take payment in exchange for repeated presentations and overly enthusiastic interpretations of certain clinical trials, this was the first time that an international non-governmental organization had explicitly assigned a meaning to the "co" in pharmas-co-dependence that tarnishes the image of integrity and independence of our medical institutions.

New products

All too often, so-called innovations are presented in a way that exaggerates anticipated benefits, minimizes known and unknown risks, fails to mention direct and indirect costs, and downplays nondrug alternatives and established products. The new products are always costly, often unnecessary, and sometimes dangerous.

New indications

Sometimes, the innovation is a new indication that has yet to become well established and that entails with substantial economic consequences. In preventive pharmacotherapy, we are witnessing a constant lowering of the thresholds of normalcy and target values that sometimes leads to alarmist screening followed by prescriptions whose usefulness is practically negligible or even negative.

We see public health campaigns that logically can only end in visits to physicians and prescriptions for

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medications. These campaigns are organized by disease mongerers, increasingly perceived as controversial, and will soon deserve to be called "preventive hounding."

Regulation

Permissiveness and lack of a transparent approval process. Knowledgeable observers have lost confidence in the drug industry and in drug agencies, which are authorizing products and indications that do not carry substantial medical benefits or whose efficacy is only marginally superior to that of placebo or has only been demonstrated on surrogate end points.

Approval is granted without face-to-face comparison with the standard treatment. Approval is granted even if the sample studied is not representative, its effectiveness is not clearly established, safety is not sufficiently documented, and even if the direct and indirect costs far outweigh what few benefits it might offer.

Permissiveness and lack of transparency in pharmacovigilance. A recent investigation into the United States Food and Drug Administration confirmed that there are serious shortcomings in its mission to protect the public. An Institute of Medicine report on drug safety[5] is troubling; it recommended sweeping reforms and new regulations. In Canada, the former Director of Health Canada's Health Products and Food Branch recently expressed the same concerns—that pharmacovigilance is being neglected in favour of the approval process by both the authorities and the promoters.

Publication of trials

Regardless of the internal validity, external validity, or power of trials submitted for approval or published, their interpretation tends to favour a new product over existing products when they have been funded by its promoter. Meta-analyses suffer from the same bias. Unfavourable results are not always published. From semantic confusion to statistical manipulation, scientific spinning is increasingly being aired in the best learned journals.

Meaningful prescribing

Prescriptions have no pharmacologic benefit beyond their placebo effect unless several conditions are met to insure clinical benefit. Prescribers have to review patients' medical and pharmaceutical histories, make diagnoses, and make the right ones. They must have sensible, valid, and quantified therapeutic objectives and then choose the best therapeutic approaches, the correct pharmacologic classes, the right products, the right dosages, and inform patients adequately. Over the longer term, prescribers must monitor compliance, response, tolerance, and persistence of indications and the objectives and readjust the treatment or discontinue it accordingly. Prescribing is serious matter.

Initial training and continuing medical education

To offset inadequate funding, we have allowed the drug industry to sponsor most continuing medical education events. If we leave the funding of continuing medical education in its hands, the industry will offer continuing product information, not continuing medical education.

Society needs well-informed physicians whose sources of education and information are rigorous, independent, transparent, and free from bias, distortion, and disinformation. We need physicians who write fewer and better prescriptions, with caution and restraint, and who avoid inappropriate prescriptions that create avoidable, sometimes fatal, reactions and their ensuing avoidable costs. We need physicians who know how to identify products prescribed "under influence" for nonpriority indications, and who limit their therapeutic arsenals to a selection of well established products they have learned to use judiciously.

Where do we start to make changes?

With training. Medical teachers have begun to avoid situations in which marketers just use them, the way they are using learned journals. We need to prevent sponsors from influencing the selection of topics, presenters, and bottom lines. We need to present nonpharmacologic approaches, well established products, validated indications, and the information that family physicians actually need. We can question the attribution of credits to sponsored continuing medical education events.

With practitioners. Students, physicians, academics, consumers, publishers, and educators from all over are calling for healthier drug policies. Some are highly critical of the ways in which drug companies promote their products and court physicians, and believe, as we do, that it would be preferable to refuse drug samples, paid meetings, paid surveys, and visits from pharmaceutical representatives. Others are critical of direct-to-consumer advertising, tolerated in disguised form, that turns prescribers into pushers.

With our institutions. "The pharmaceutical industry must now be called to order. The industry has shown itself to be sufficiently resilient to adapt to change if society insists on it."[6] We need a new pact, a renegotiation of the rules of the game, new laws to regulate the relationship between the industry and the state, and a new code of ethics to govern the relationship between the industry and the medical profession.

Conclusion

Family physicians have the right and the obligation to receive their education and information in an environment free from the influence of marketing strategists. As

first-hand witnesses to polypharmacy, family physicians can help to reduce the unwanted side effects and extra costs associated with new products and indications when their usefulness is questionable. They need to cast a critical eye on what they learn about new products when the learning comes gift-wrapped. They should learn to say, "No thanks!"

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