

Natural Health Products: The Gap between Perceptions and Reality

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Citation info: UBCMJ. 2015; 7.1 (11-12)

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Emily is a 49-year-old female who takes a number of prescription medications, including warfarin. She has noted feeling “down” over the past several weeks, and, while motivated to do something to improve her quality of life, she is reluctant to add to the number of medications she already takes. She hears about a herbal product named St. John’s Wort (SJW). Unlike prescription antidepressants, which are synthetically-derived chemicals, she understands that SJW comes from a plant, and she believes that this herbal product presents a safer, more natural option for managing her depressed mood. After some deliberation, she heads to her local pharmacy, purchases a bottle of SJW, and begins taking it that day.

The above scenario, with obvious variations for indication and product choice, likely plays out countless times every day across Canada. A given patient self-selects a natural health product (NHP), either in a pharmacy, on the internet, or in a health food store, under the assumption that a natural, plant-derived product always presents a safer alternative to synthetically-derived prescription drugs. We know this is a common scenario because the NHP industry consistently records annual sales topping a billion dollars in Canada.¹ However, as the above scenario plays out, there are a number of assumptions here that are not supported.

To a chemist, there is no difference between SJW and the prescription drugs that a patient, such as Emily, could potentially take for a given condition. SJW is a chemical derived from the lovely flower, *Hypericum perforatum*. However, when analyzed by a chemist, it has a chemical structure not unlike an antidepressant synthesized in the laboratory, and though

it is a naturally-derived substance, SJW should not automatically be assumed to be safer than its synthetic counterparts. In fact, there are a number of plants capable of causing great harm to humans and a number of synthesized drugs that can do the same.

A pharmacologist, too, would draw no distinction between SJW and synthetic prescription drugs, including those in its therapeutic class. Although SJW has a variety of molecular targets in the body, its key mechanism in treating depression is believed to be inhibition of reuptake of neurotransmitters, such as serotonin—this is the same mechanism by which many of the widely-used antidepressants work.² Much like other antidepressants, SJW elicits side effects and importantly, in Emily’s case, it is an inducer of cytochrome P450 enzymes and p-glycoprotein, an intestinal efflux pump that is increasingly implicated in a number of important drug-drug interactions.^{3,4}

One of the clear distinctions between SJW and other antidepressants is that it can be readily obtained without consulting a health care provider, most notably a physician or a pharmacist. There are a number of options that might have proven beneficial for Emily, all with far less risk of harm than SJW. If she is suffering from mild depression, non-pharmacological interventions include psychotherapy, exercise, phototherapy, and a review of her current medications to ensure that none are responsible for her symptoms.^{5,6} In opting for what Emily believes to be a natural intervention—that she might perceive as “non-pharmacological”—she has unwittingly chosen a path that is the opposite of what she was intending. Perhaps more concerning, when patients

with more severe depression self-select products like SJW, they are less likely to be assessed or followed by a physician, and therefore, lack the supports they might need to monitor their clinical status and to ensure that they are not at risk of self-harm or of harming others.

Finally, to an evidence-based practitioner, what distinguishes NHPs from their synthetic counterparts is the general lack of evidence supporting their efficacy or safety. SJW is one of the most studied NHPs and it is generally accepted that SJW is likely superior to placebo for mild to moderate depression. However, there is still some uncertainty about this and about its associated harms because studies of SJW are heterogeneous in both design and results.⁷ For the majority of NHPs, the evidence is lacking.⁸⁻¹⁰

The question is, then, why — well into the 21st century — do we still have such a gap between perceptions of NHPs and reality? Though there is no easy solution to this problem, there are clues as to why it exists. With rare exceptions, NHPs are not patented in the same way that conventional pharmaceuticals are. This patenting process forms the basis of our current system for reviewing and approving pharmaceuticals, most notably because of the exorbitant expense associated with the process. Much of that expense is due to the (hopefully) well-designed, double-blind randomized controlled trials that lie at the heart of the drug approval process. The incentive for pharmaceutical companies to undergo this expensive and arduous process is the promise that they retain market exclusivity for their product for a number of years after approval. NHPs typically cannot be guaranteed the same promises of market

exclusivity, because in most cases, these molecules were not patented upon discovery and have not been modified in a significant enough manner to justify patent protection.

In 2004, the government of Canada did attempt to improve this system with the NHP regulations, which were intended to address key issues, such as quality control, standardization, contamination, proof-of-benefit, and safety.¹¹ A manufacturer, after having met the requirements of this process, receives a natural product number (NPN), analogous to the drug identification number assigned to “conventional” drugs approved for sale by Health Canada. The NPN is intended to provide some reassurance to the consumer that the product they are purchasing has met the above standards. However, enforcement of these regulations has been an issue,¹² and these changes have done little to assist with scenarios such as Emily’s. The evidence upon which NHPs are used, with respect to both efficacy and safety, is still generally shaky at best, and they still fall under the radar of most practitioners,¹³ despite the clear need for their use to be more closely documented.

Although there are no easy solutions to issues with the use of NHPs, there are simple steps that can be taken to try to reduce the risk of harm from taking these agents. The first involves improved enforcement of existing legislation. The challenge facing enforcement is the sheer number of manufacturers with products

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for sale and the availability of these products via the internet. As studies have suggested, even the seemingly simple goal of ensuring quality control has been a challenge.¹⁴ Given the resources that might be required to improve enforcement, perhaps a system that sets a much higher bar for manufacturers to achieve a NPN would provide an incentive for a few manufacturers to invest additional resources in their products. Alternatively, a system could be developed to provide guidance to consumers as to which manufacturers and products far exceed the standards. From the public perspective, Canadians need clear guidance as to the efficacy and safety of a given NHP, rather than having to rely on claims made by manufacturers.¹⁵ NHPs that have known safety issues or are widely considered as substitutes for proven remedies should not be sold anywhere other than a pharmacy. Ideally, patients would be required to consult with a pharmacist before purchasing such a NHP; however, this might not be practical, and some patients might resist discussing their health concerns in a pharmacy setting. Thus, another option would be to better educate patients by changing the terminology we use to refer to NHPs. This is because NHPs, like SJW, are, in reality, drugs derived from natural sources. The terms that we currently most often use to refer to these chemicals (i.e. “natural health products”, “herbals”, etc.) stand in stark contrast to the terminology we use to refer to prescription drugs (i.e. “drug”, “synthetic”, “pharmaceutical”, etc.), and it is thus no wonder that the public views them so differently. A more informed consumer might be the most efficient way to bridge the gap between perceptions of NHPs and reality.

disclosures

The author does not have any conflicts of interest.

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