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BIOLOGIC DRUGS AND THE LAW

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"Canadian drug innovators have to follow an arduous process when filing for regulatory approval for traditional small molecules…"

Biologic drugs are much larger than the small synthetic molecules used to treat most conditions. "I can synthesize a small ingredient in a test tube and rest assured it's the same as the original," said Lesley Rapaport, president of LRR Patent Law Office in Toronto, speaking at the Face-to-Face Drug Plan Management Forum. With biologic drugs, "there's a cell doing the work, so you can't ensure exact duplication"—which is why the copycat biologics in current development will be called follow-on or subsequent-entry biologics (SEBs) rather than generics.

While Canadian drug innovators have to follow an arduous process when filing for regulatory approval for traditional small molecules, generic manufacturers "don't have to prove as much, so the process is abbreviated—although they have to wait until the patents for the original drug and a data-exclusivity period have expired," Rapaport explained.

Because SEBs "may differ more substantially from the original than small molecules do," Rapaport said it is unclear exactly how much information SEB manufacturers will be required to provide. In 2010, the Canadian government issued guidance documents to help address the following questions: What safety and efficacy data will SEB manufacturers have to show? What differences from the original will be sufficient to justify data exclusivity?

An audience member asked whether these regulatory uncertainties, coupled with high manufacturing costs, might deter pharmaceutical companies from the SEB category. "While there may still be a question mark in terms of profitability," said Rapaport, "several companies have taken an interest in pursuing this market. Stay tuned."

- Gabrielle Bauer

Best ways to save on your drug spend

Speaking at the Face-to-Face Drug Plan Management Forum, Steve Moffatt, senior vice-president of sales and marketing with Green Shield Canada, questioned plan sponsors' ongoing tendency to have their drug plans provide full coverage in today's financially constrained landscape. "On the one hand, it seems financially irresponsible," he said. "On the other hand, employers maintain that it's tax-effective compensation for employees, and plan members cling fiercely to their drug plans." So where is the "burning platform" for change?

As it turns out, the manufacturing sector has been leading the way. "The economic downturn of 2008 hit the sector particularly hard," Moffatt noted. By making modest changes in plan design, the sector was able to reduce its drug spend in the years since 2008—unlike other sectors, which saw a decline only in the rate of growth.

Specific changes included adjustments of co-pays, dispensing fee caps, generic substitutions and judiciously managed formularies for biologics. "Out-of-pocket expenses for plan members became much higher after the design changes," Moffatt said. Recognizing that "it's easier to implement plan design changes for younger people coming in," the sector focused on developing wellness programs to keep chronic diseases in check.

By communicating the economic rationale for dispensing fee caps to both members and pharmacies, one Green Shield client got buy-in and co-operation, said Moffatt.

Forewarned about the impending $9 cap, "many pharmacists dealing with the company decided to limit their dispensing fee to this amount," he said.

Moffatt advised targeting a 54% generic penetration rate, using such strategies as generic or therapeutic substitution and maximum allowable costs. Biologic drugs— defined as drugs manufactured by an organism such as a bacterium or yeast—are best managed through an approval process to "ensure they reach only the right candidates," he said. As for vaccines, "make a decision as to whether you're in or out, because a lot of new vaccine drugs are coming down the pipeline."

According to Moffatt, "bread-and-butter" conditions such as hypertension, diabetes, depression and gastrointestinal disorders account for 80% of total drug costs. "If people are trying a new drug, make it available on a trial basis, then increase your prescription period so you're not dealing with as many refills," Moffatt advised. Effectively managing these issues while staying the fiscal course also requires a hard look at plan philosophy, he said. "Figure out where your obligations lie and what you want the plan to achieve for your members."

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Changing lifecycles puts premium on insurance

As if the sandwich generation didn't have enough to fret about, they now have to worry about their new insurance needs, too. And many don't even know it.

The changing lifecycle of Canadians has implications not only for their personal finances and retirement savings, but also on insurance needs, according to a recent report by TD.

"People are living longer, supporting adult children and aging parents, and are more active later in life than previous generations—and that means they need more money to sustain their quality of life," says Dave Minor, vice-president, TD Insurance.

Thanks to medical advancements, more people are surviving critical illnesses and living longer. The average life expectancy is now 78 for men and 83 for women. As a result of these lifecycle shifts, critical illness insurance is becoming more important to protect a family's ability to earn income and save for the future, especially during prime income earning years.

Another lifestyle change that impacts insurance needs is the fact that many families are choosing to have children later in life. According to Statistics Canada, the number of women giving birth in their 40s has more than doubled in the last few decades.

"Many young and healthy Canadians put off buying life insurance until they start planning for a family," says Minor. "But the reality is, even if you're postponing having children until later in life, sooner rather than later is the best time to purchase a policy."

The earlier you start a life insurance policy, the better your premiums will be given your younger age, and it reduces the risk of being declined for coverage due to health issues, he added.

High youth unemployment and increasing post-secondary education costs mean many young people are financially reliant on their parents until their late 20s. This can translate into higher-than-expected household expenses, including additional life insurance coverage to mitigate any disruption in household income and even an increase in home insurance coverage that may be needed for the extra valuables in the home.

These issues could add multiple layers of stress, both financial and emotional, to households already straining under a debt level that is equivalent to around 150% of personal disposable income.

Worse yet, a report by TD Economics found that over the past decade, while average debt-loads in Canada increased at twice the pace of income, the debt-loads of those 65 years and older grew at three times the rate and contributed as much as half to the overall debt growth.

"Life insurance is frequently used to cover debts and protect the estate assets in case of death, sometimes even paid for by the beneficiaries to help manage the cash flow of the insured," says Minor. "Term insurance is a good option for this objective as it is generally inexpensive and provides a pre-determined pay out to the designated beneficiaries."

- Vikram Bahrat

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Handling mental illness in the workplace

The Centre for Addiction and Mental Health estimates that mental health conditions are responsible for approximately 30% of all disability claims and 70% of the associated plan costs.

Employers dealing with these costs—and the related lost productivity—are understandably focused on getting employees who are dealing with mental health issues back to work as quickly as possible, in a suitable state to fulfill their duties. Achieving this requires three crucial elements: early identification and diagnosis of mental health concerns; an effective treatment plan; and a return-to-work strategy that enables the employee to gradually ease back into work life.

Identification and diagnosis

According to research published in the *Journal of American Medicine,* an estimated 40% of mental health-related cases are misdiagnosed or underdiagnosed, resulting in incorrect or insufficient treatment. Further, more than 50% of cases do not receive treatment at all. This is disturbing when you consider the impact that psychological illness can have on an individual's ability to function, both in and out of the workplace. Clearly, the ability to identify a psychological illness early is paramount.

Those in supervisory roles who are in close contact with employees on a daily basis can come to understand their employees' unique personality traits. With appropriate training, supervisors are ideally positioned to identify changes in employee behaviour that may signal the onset of mental health concerns. A properly trained supervisor can also effectively separate workplace issues such as harassment from those with psychological roots (e.g., a clinical mental illness, such as depression).

For example, according to the Canadian Mental Health Association, between 2% and 3% of Canadians may have seasonal affective disorder (SAD), though many may not realize it. A trained supervisor may recognize that an employee with a high number of absences in January and February—and who lacks concentration and misses deadlines during the winter months—may be

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HANDLING MENTAL ILLNESS IN THE WORKPLACE CONT.

affected by SAD. That employee could then be prompted to seek appropriate care, begin treatment and return to a fully functioning state.

Treatment plan
Treatment is another key component in effective psychological claims management. It is often left to the family physician to identify problems and initiate treatment while waiting for a formal appointment with a specialist. Too often, this means losing precious time through suboptimal prescriptions or inappropriate treatment. Employers should include wording in their benefits plan booklets to ensure that a

specialist diagnosis is required for mental illness claims.

Back-to-work strategy
Effective diagnosis and treatment are essential to understanding an employee's psychological and cognitive capabilities and how they align with the demands of a particular job. This understanding can help an employer to develop an effective transitional back-to-work plan. An individual who is recovering from an episode of depression, for example, may have a decreased ability to concentrate. A progressive, time-limited back-to-work plan—which could include short, specific tasks with written step-by-step instructions for each—and an environment with minimal disruptions can help the employee work his or her way back into a regular routine.

Mental health issues will likely remain a key concern for workplace productivity and claims management. However, the implementation of a pragmatic approach to identification, treatment and recovery can help to minimize the long-term effects and improve outcomes for employees and employers alike.

- Liz R. Scott

Christy Insurance Agencies Ltd.

#19 –636 Clyde Avenue
West Vancouver, B.C.
V7T 1E1

Phone: 604-913-2474
Fax: 604-922-9534
Email: info@christyinsurance.com

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