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CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

GENERIC DRUG MAKERS CHALLENGE FEDERAL DATA EXCLUSIVITY RULES

THE ISSUE

In October 2006 the federal government published regulations that impose eight years of data exclusivity for brand-name drug companies. The new rules vastly exceed what is necessary for compliance with Canada's international trade obligations and, in doing so, overstep the regulatory powers granted by Parliament.

BACKGROUND

Data exclusivity extends a brand-name company's market monopoly over a product, and has nothing to do with the protection of research data or patents. Data exclusivity is independent of the patent system and operates to prevent a generic competitor from entering the market. The comparison necessary to demonstrate generic bio-equivalence rarely involves an examination of the brand-name company's data by Health Canada. Brand research data is also not supplied to generic drug makers.

On October 18, 2006, the federal government published a package of regulatory amendments to Canada's drug patent rules. As part of these changes, the federal government extended the ban on generic competition to eight years (an additional six months for paediatric drug products) – regardless of whether there are relevant patents on the brand-name products.

In the early 1990s, the Canadian Parliament approved legislation that allows the Government of Canada to make regulations necessary to comply with Canada's international trade obligations. Through international trade agreements such as the North American Free Trade Agreement (NAFTA) and the Trade-Related Aspects of Intellectual Property Right (TRIPS), Canada is required to provide five years of data exclusivity for brand-name pharmaceutical companies.

The Government of Canada's decision to extend the period of data exclusivity for brand-name companies oversteps Canada's trade obligations and, in doing so, the regulatory powers sanctioned by Parliament.

The social and economic impacts of the unfair extension of market monopolies cannot be ignored. Taxpayers, provincial governments and consumers are paying a steep price for this three-year extension – to the tune of more than \$100-million each year. Had this eight-year ban been in from 2001 to 2006, it would have added approximately \$600-million to prescription drug costs in Canada. It would also have blocked Health Canada's approval of lower-cost generic equivalents of blockbuster medicines such as anti-depressants Zoloft and Wellbutrin, and cholesterol reducer Pravachol.

The new rules are the federal government's response to lobbying from brand-name drug companies and pressure from the United States Trade Representative (USTR) to strengthen data exclusivity provisions. But in an interview with the U.S. publication *Inside U.S. Trade* published on October 27, 2006, the Office of the U.S. Trade Representative ***"acknowledged that the changes Canada made go beyond the five years of data exclusivity the U.S. had demanded."***

Canadians are left with changes that, on whole, do nothing but hand over millions of dollars to brand-name drug companies at the expense of their health-care system and domestic generic drug makers.

CGPA POSITION

On November 14, 2006, Canada's generic pharmaceutical industry launched legal action in the Federal Court of Canada challenging the October 2006 changes to federal regulations that provide brand-name drug makers with an eight-year ban on generic competition. The new rules exceed what is necessary for compliance with Canada's international trade obligations by three years and oversteps the regulatory powers sanctioned by Parliament. In November 2007, the Federal Court agreed to proceed with the case.