

Feds mum over legal protection for swine flu vaccine makers

By Steve Rennie (CP) – Sep 20, 2009

OTTAWA — The federal government won't say if Canadians who suffer harmful side effects from the new swine flu shot can take the vaccine maker to court.

The Public Health Agency of Canada will not reveal whether drug companies are shielded from H1N1 flu vaccine lawsuits in this country like they are in the United States.

"This is a complex issue which is currently being examined by the federal government," spokeswoman Nadia Mostafa said in an email.

"It raises legal questions involving federal/provincial and public/private sector jurisdictions. The federal government will provide additional details around this issue in due course, following appropriate discussions/deliberations."

That effectively throws a shroud over Ottawa's arrangement with pharmaceutical giant GlaxoSmithKline, which has a contract to produce 50.4 million doses of pandemic vaccine at its facility in Ste-Foy, Que.

Conversely, the United States has been open about its decision to protect vaccine makers, government officials and others from lawsuits over the vaccine.

Health and Human Services Secretary Kathleen Sebelius has granted legal immunity to "individuals and entities involved in all stages of 2009 H1N1 influenza vaccine development, testing, manufacture, distribution, prescribing, administration, and use," says a U.S. Health Department website.

That protection doesn't extend to harm caused by wilful misconduct.

GlaxoSmithKline was as tight-lipped as the Public Health Agency when asked if it was protected from Canadian lawsuits over its vaccine.

"GSK is discussing issues relating to potential liability exposure associated with pandemic preparedness products, including vaccines, in the context of its pandemic planning negotiations with all governments, including the Canadian government," company spokeswoman Michelle Smolenaars Hunter said in an email.

"The details of the contract negotiations with the Canadian government are confidential and cannot be discussed further."

Vaccine makers in the U.S. have been protected from lawsuits over the use of childhood vaccines since the 1980s. Instead, a federal court handles claims and decides who will be paid from a special fund.

The decision to protect vaccine makers came after the 1976 swine flu outbreak, when 40 million Americans were vaccinated in a national campaign.

But that scare never morphed into the deadly pandemic officials feared.

Instead it touched off a flurry of injury claims from Americans who suffered side effects from the vaccine - including about 500 people who developed a paralysing condition called Guillain-Barre Syndrome.

However, that syndrome was never conclusively linked to the 1976 swine flu shot, and experts don't think a repeat is likely.

Paul Harte, a medical negligence trial lawyer in Toronto, said it's very rare pharmaceutical companies are sued in Canada over flu vaccines.

Vaccines always carry some risk, he said, and as long as the public knows the risks companies are generally not held liable.

"The reality is that both pharmaceutical and medical negligence cases are relatively rare in Canada," Harte said.

"They are a tiny proportion of civil actions in Canada, and appear with much less frequency than in the United States."

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