



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce & Industry, Govt., of India)

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Marni Soupcoff: How cheaper drugs for everyone leads to hardly any drugs for anyone

While the House of Commons has unanimously passed an NDP motion to require drug companies to notify Health Canada in advance of potential shortages, such warnings don't address two potential underlying causes of the country's current dearth of drugs: overzealous regulation and short-sighted sole-sourcing.

The sudden slowing of production of some medications at Sandoz Canada's Boucherville, Que., plant in February — combined with a subsequent fire that temporarily ground production to a halt at the same location — has left Canadian emergency rooms, intensive care units and operating rooms in the lurch.

Sandoz is the only supplier for approximately 90% of the injectable drugs the nation's hospitals use every day — in surgeries, emergency treatment and intensive and palliative care. The result has been an unnerving, if not yet critical, shortage of painkillers, anesthetics and other drugs.

But the Sandoz bottleneck did not start at home. It was the regulatory tentacles of the United States Food and Drug Administration (FDA) that sparked the initial slowdown (we can only assume the fire was God's work) when the agency warned the company about manufacturing deficiencies in Boucherville. Sandoz, whose Quebec plant also produces drugs for the U.S. market, responded with voluntary operational upgrades that necessitated pulling back on production.

This was not an isolated incident. For several years now, the FDA has been intensifying its enforcement of quality control measures on pharmaceutical companies — a move that sounds unimpeachable. Who wouldn't want to ensure the safety of drugs we count on to restore our health? Yet many government skeptics, such as Walter Olson, of the libertarian Cato Institute think-tank in Washington, D.C., believe the agency's stepped up enforcement is far exceeding what safety requires — and is creating record drug shortages in the United States, as well.

"In particular," Mr. Olson wrote of the FDA last year, "it now proclaims zero tolerance, barbed by tough fines, for many technical infractions whose actual impact on patient risk is at best doubtful, and it is unafraid of shutting down production lines again and again for retooling until its regulations are satisfied to the letter." He pointed out that there were then 246 drugs considered to be in shortage in the United States.

John C. Goodman, president and CEO of the National Center for Policy Analysis, a non-profit free-market research organization based in Dallas, Tex., has similarly criticized the FDA for "forcing

H.O.: 101, Aditya Trade Centre, Ameerpet, Hyderabad – 500038

Tel: 040-23735462/23735466, Fax: 91-40-23735464

Email: info@pharmexcil.com



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manufacturers to abide by rules that are rigid, inflexible and unforgiving” — a practice he believes is contributing to the difficulty of getting life- saving drugs to the patients who need them.

Of course, whether or not the FDA has become dangerously overzealous would be of much less consequence to Canadians if this country had more than one supplier to turn to for the vast majority of its injectable medications. But in the search for cost containment and less expensive drugs, the provinces have been moving toward a bulk purchasing model. Either on their own, or by joining a large group purchasing organization, they enter into agreements to buy drugs in large quantities to get a lower price per item. It reduces the governments’ overall pharmaceutical costs, but tends to result in far fewer suppliers.

“It’s a winner-takes-all approach,” says Mark Rovere, associate director of the Health Policy Research Centre at the Fraser Institute. Which is fine so long as the “winner” is able to deliver the goods. But there’s no incentive for other companies to invest in the infrastructure necessary to step in should the winner falter. Hence, when Sandoz slowed production to focus on revamping its plant, there were no other big pharmaceutical companies set to jump in and start producing the scarce injectables — or (even less likely) with the needed products already sitting around, gathering dust on their shelves.

How did this happen?

“A lot of it is rooted in the national pharmacare issue,” Mr. Rovere says, referring to the decades-long push for universal government coverage of Canadians’ prescription drug costs. The longing for a centrally planned, collectivist approach led to a focus on, as he puts it, “How do we get cheap drugs for everyone?” Bulk purchasing “does result in cheaper drugs,” he says “but it has unanticipated consequences.” Consequences such as the cancellation of non-essential surgeries and the rationing of painkillers.

HealthPRO Canada is a national health care group purchasing organization that buys drugs for 255 Canadian hospitals and health authorities. Its own promotional material does a good job of capturing the company’s dominance on the scene: “HealthPRO brings together the most significant purchasing power ever assembled within our country’s public health care system.”

In February, HealthPRO released a statement saying that it had made changes to its contracting strategy in order to address concerns about ongoing drug shortages.

The announcement explained that the new plan “strives to strike the right balance between competition, purchasing power and a more reliable supply chain” and requires its suppliers to, among other things, provide “correction plans for drug shortages lasting more than 60 days for hospital-specific items.”

That can’t hurt. But given what a dramatic impact depending on barely more than one source of

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injectable drugs has proven to have on the country's supply of medication, bolder changes are surely in order.

Rather than focusing on adding reporting requirements to companies such as Sandoz, Canada would do well to learn its market lessons from this incident.

First, use the results of the FDA's purported regulatory nitpicking as a cautionary tale. Second, remember the complexities and distortions that arise when the focus shifts from the individual to the universal (cheaper drugs for everyone somehow leads to hardly any drugs for anyone). Finally, and of most immediate importance, when purchasing drugs on behalf of a province — or becoming a member of a purchasing group that will do the same — do your best impression of a truly responsible and self-interested buyer by naming rational conditions that will protect you in the future.

One of these conditions might be: Never accept a deal that results in an entire class of drugs being supplied by a single source. It'll come back to bite you if you do.

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