

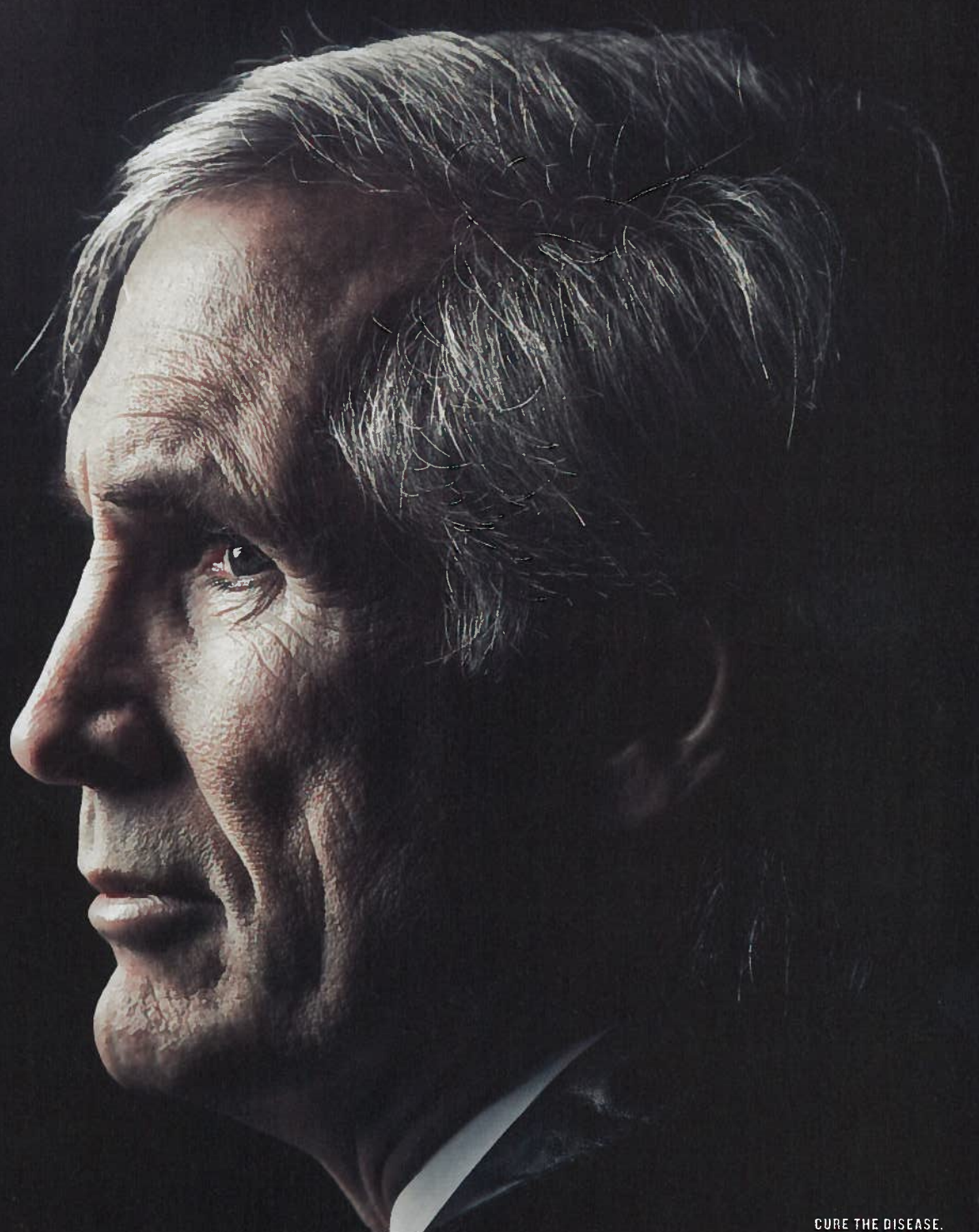
# ADVERSE REACTIONS

WE HAVE ONE OF THE BEST DRUG SAFETY PROGRAMS IN THE WORLD. IT TRACKS ALL PRESCRIPTION USE IN THE PROVINCE AND SAVES US \$500 MILLION A YEAR. YET THE B.C. LIBERALS HAVE HALTED ACCESS TO ITS RESEARCH AND FIRED EIGHT OF ITS WATCHDOGS. DID PHARMA NET DO ITS JOB TOO WELL?

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**CURE THE DISEASE.  
KILL THE PATIENT**

Last September, the Ministry of Health fired Victoria's Ron Mattson, alleging that he, a project manager with the Pharmaceutical Services Division, improperly distributed patient data.

# AFTER HALF A LIFETIME WORKING FOR THE B.C. MINISTRY OF HEALTH, RON MATTSON, 59, WAS INVITED INTO HIS BOSS'S OFFICE, FIRED, AND ESCORTED OUT OF THE BUILDING.

He's seldom had a full night's sleep since that morning last September, and he remains unsure why he was fired from his job managing pharmaceutical data and research from the provincial government's PharmaNet database. According to government investigators, he failed to protect the confidentiality of a specific set of records, but the data in question was anonymous and never even left his office, says Mattson, who is suing the government for wrongful dismissal and defamation of character.

Dr. Malcolm Maclure was sacked by the ministry in similar fashion. After two decades of award-winning scientific work for the ministry, Maclure, 60, who trained at Oxford and Harvard and holds UBC's prestigious chair in patient safety, received a phone call while overseas last summer informing him the ministry had removed him from his duties supervising research using PharmaNet data. The news seemed "difficult to believe," he recalls. But sure enough, his BlackBerry account was terminated, and a couple of days later his wife's email chimed with confirmation that he was amongst a group of alleged drug data violators purged while under investigation. Like Mattson, Maclure describes the charges against him as "vague." He has also sued the government for wrongful dismissal and defamation of character.

Dr. Bill Warburton, too, was fired in much the same way. An economist who used PharmaNet data to investigate the cost effectiveness of various pharmaceuticals commonly prescribed within B.C.'s billion-dollar government-funded drug plan, Warburton saw his contract terminated with scant explanation. Soon afterward, his wife, Dr. Rebecca Warburton—a University of Victoria health economist who, with Maclure, directed pharmaceutical research for the ministry—was fired, as were four others inside the government with access to drug data: Bob Hart, David Scott, Ramsay Hamdi, and Roderick MacIsaac. Rebecca Warburton is preparing to sue the government for abusing her reputation and inflicting pain on her family. MacIsaac, a researcher evaluating the safety and effectiveness of B.C.'s stop-smoking program, committed suicide in January.

"We figured that someone in the ministry got their wires crossed," Bill Warburton says about what started as an obscure misunderstanding but has ignited into a threat to province-wide medical safety. But after eight months of growing financial and emotional distress, he now believes he and his wife are ensnared in something far larger than a petty squabble over data management.

Alan Cassels, a UVic pharmaceutical policy analyst, sees distressing implications in the firings. "Most of the enterprise of drug policy research has ground to a halt in B.C.," he

says. "Many of the research leaders within the government are gone." The affected scientists were all closely involved in staging major studies of physician prescribing practices, and the safety of a wide array of drugs, he notes. MacIsaac's work, for example, was to assess smoking cessation drugs including Champix, which PharmaCare began paying for in September 2011. Warburton was investigating antipsychotic drugs that are often used with little medical supervision in old folks' homes and are attracting increasing scrutiny. Mattson and Maclure were deeply involved with a

major study of Alzheimer drugs that PharmaCare is funding pending the studies' outcome. Maclure was also investigating whether physician prescribing patterns are influenced by drug companies: in recent scientific publications he has probed the medical basis for the vast sums spent by the B.C. government and B.C. patients on drugs prescribed for diabetes, depression, and respiratory disease.

All of this research had the potential to seriously dent the international drug companies whose products were being investigated, Cassels says. "The Alzheimer drugs, especially, are expensive drugs with huge potential for market growth internationally that face important questions about effectiveness. The pharmaceutical industry really doesn't like people doing this kind of research because it's independent research, it's clean and hopefully objective, and they don't have control over the results. So you can imagine how much pressure there is to discredit it and perhaps even shut it down." Not surprisingly, no government official has publicly validated his theory.

So far, the government has revealed next to nothing about the results of the investigation into the confidential records, underway since last May. In September, Health Minister Margaret MacDiarmid issued allegations of misconduct in a terse press conference, saying that the RCMP had been asked to investigate. (When contacted by *Vancouver* magazine she and other ministry officials refused to expand on those comments.) In an interview with Victoria's CFAX radio in mid January, however, MacDiarmid did say, "While on one hand we don't believe that anybody is personally in jeopardy because names weren't attached, it's still highly personal information... It's only been used for research as far as we know, and we just haven't found anything to indicate that it's been used for other than research." For their part, the RCMP are saying nothing; Corp. Darren Lagan, a Mounty spokesman in Victoria, won't even confirm they are investigating.

**O**n average, every person in B.C. spends \$575 a year on pills, which puts pharmaceuticals on par with the forestry industry—although with exponentially greater growth potential: government spending on the PharmaCare Plan—which pays for drugs for seniors and people with disabilities, and administers programs like the smoking-cessation regimen MacIsaac was reviewing—has increased roughly 30 percent since 2005, and the number of pills popped in the province is growing about 10 percent every year. The number of registered pharmacists in B.C. has risen by 23 percent over the past five years, in part because the variety of pills available to

**FIRST. DO NO HARM**

Nobody has suffered more delays and barriers to access to the PharmaNet data than UBC prof and Therapeutics Initiative lead investigator Colin Dormuth



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patients is so vast: more than 8,000 drugs are approved for use in the province, and PharmaCare covers over half of them based on detailed appraisals of their medical validity.

Provincial officials tasked with managing this vast pharmacopeia walk a fine line. Asserting budget and safety concerns in the face of pressure from the famously aggressive, powerful international companies presiding over the trillion-dollar global pharma industry requires enormous sensitivity. Deciding what drugs to include within the provincial drug plan, and how much to pay their manufacturers, is a high-pressure task that sees officials barraged with competing pressures from pharmaceutical companies, physicians, patients, and a plethora of public watchdog groups. Yet thanks to the 1996 creation of the PharmaNet database, which researchers use to help inform government healthcare policies, British Columbia has one of the most successful (and unsung) drug safety regimes in the world. PharmaNet uniquely includes records of every prescription filled in the province, so B.C. captures better data on pharmaceutical consumption than any other province or state in North America, explains Steve Morgan, a UBC drug policy researcher who has published a series of studies in recent years that validate the tens of millions of dollars invested in the program.

Among the findings that Morgan and his UBC colleagues have gleaned from the data is that 80 percent of the increase in drug expenditure between 1996 and 2003 (a period during which per capita expenditure on prescription drugs more than doubled) was explained by the use of new, patented drugs (dubbed "me-too" drugs) that copy cheaper existing drugs. Because the me-too drugs cost as much as four times more than the older drugs they mimic, they substantially raise pharmaceutical makers' profits. But few systematic benefits to patients are gained, Morgan emphasizes. "The rising cost of using these me-too drugs at prices far exceeding those of time-tested competitors deserves careful scrutiny," he and his colleagues concluded in a warning that sent a chilly message to the industry.

## THE FIRED AND SUSPENDED SCIENTISTS WERE ALL CLOSELY INVOLVED IN STAGING MAJOR STUDIES OF PHYSICIAN PRESCRIBING PRACTICES, AND THE SAFETY OF A WIDE ARRAY OF DRUGS

In his latest paper, Morgan revealed that while prescriptions were filled during 63.5 percent of pregnancies in B.C., "evidence on safety is limited for many of the medicines most frequently filled in pregnancy"—an unwelcome finding for the manufacturers of the drugs in question. And a 2011 study offered even broader advice to health policymakers. Based on a probe of pharmaceutical data alongside other healthcare data, he forcefully disputed the widely held belief that B.C.'s aging population is inflicting unsustainable costs on the system. After drilling into the data, he concluded that population aging contributes less than one percent per year to spending on medical,

hospital, and pharmaceutical care. A major cause of health cost inflation, he suggested, is the rising price of pharmaceuticals.

Important as such revelations are for patients and taxpayers in B.C., perhaps the biggest endorsement of the PharmaNet data comes from the simple fact that B.C. has the lowest per capita drug costs in Canada. Based on data from the Canadian Institute of Health Information, B.C. has succeeded in reducing spending on pharmaceuticals by as much as \$500 million a year since 2008. A good deal of this massive restraint on payments to pharmaceutical companies has been guided by revelations scientists have teased from PharmaNet.

**T**here are few people who know more about B.C.'s passion for pills than Bob Nakagawa. A pharmacist by training, Nakagawa directed the Ministry of Health's Pharmaceutical Services Division from 2006 until last April, when he left the ministry to become registrar of the College of Pharmacists of British Columbia. (He was council president for the College in the late 1980s when he played a leading role in coaxing the province to establish the PharmaNet database.)

During his tenure running the ministry's pharmaceutical programs there were three highly publicized data scandals, including one that involved millions of personal files, yet while running the branch that governs PharmaNet Nakagawa never heard a word about the recent troubles that led the ministry to fire Malcolm Maclure, the Warburtons, and the rest. (He does acknowledge that according to his replacement in the branch, Assistant Deputy Minister Barbara Walman, the investigation began when he was still in charge.) And the news that Maclure was singled out "absolutely shocked" him, Nakagawa recalls. "I've known Malcolm for many years," noting that the two men helped structure B.C.'s drug pricing regime—a topic on which Maclure enjoys commanding international status.

"He is the researcher in the world," Nakagawa says before adding that he's nonplussed as to why MacDiarmid fired Maclure: "From the outside looking in, we're not hearing very much," he laments. "People seem to think its nefarious pharma pressure. I don't know."

Tensions over the use of the PharmaNet data had been mounting for years, but in 2008 conflict openly flared after the provincial government—eager to encourage pharmaceutical research investments—established the industry-dominated Pharmaceutical Task Force to investigate the work of UBC's Therapeutics Initiative, the province's leading drug research team. According to the nine-person force—five with ties to the drug industry, including Russell Williams, Canada's top pharmaceutical industry lobbyist—the Therapeutics Initiative (which won international plaudits by issuing early warnings about Vioxx, a drug named in 27,000 lawsuits for injury or death) needed "replacing or reconstituting." The task force was especially anxious to eliminate the Therapeutic Initiative's role in determining what drugs should be covered by PharmaCare—a recommendation the government quickly implemented, notes the co-managing director of the Therapeutics Initiative, UBC professor Jim Wright.

Seeking to put the situation in perspective, Nakagawa notes that many researchers express frustration with the ministry's unwillingness to grant scientists access to data—a point

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recently underscored by Elizabeth Denham, B.C.'s information and privacy commissioner. Last June, Denham met with a group of PharmaNet experts, including Dr. Bruce Carleton, a UBC pharmacology professor who, as chair of the Ministry of Health's Data Stewardship Committee, has significant influence over who gets drug data and for what purpose. In a report on the meeting's outcome, Denham concluded there is a "real and systemic" problem: "Researchers in British Columbia are simply not getting access to the health data they need to conduct medical research. This is unacceptable." Even more pointedly, in a passage that seems to address Carleton's role chairing the province's data committee, she complained of "data stewards with no efficient processes to approve data access requests and inefficient administration."

When it comes to delays and barriers in getting access to PharmaNet data, no one has suffered more than Colin Dormuth, the scientist who serves as lead investigator for the Therapeutics Initiative. Dormuth is highly prolific: over the past year alone he has published (often in collaboration with Maclure) a dazzling series of studies spotlighting key safety problems in pharmaceuticals, including acne medication, opioids, antibiotics, statins, heart drugs, and medications used to treat ADHD in children. Much of this prodigious output has been fertilized by Dormuth's participation in a national collaboration known as the Drug Safety and Effectiveness Network. Funded with a \$30 million federal grant, DSEN represents the biggest national investigation into drug safety in Canadian history. As a British Columbian, Dormuth had critical, direct access to PharmaNet data that would significantly boost DSEN's scientific significance.


But for reasons he describes as "utterly mystifying," that access to de-identified data was suspended last summer, and remains so. Although Carleton did not respond to an interview request placed through both his own office and the UBC press office, a source who spoke on condition of anonymity says Carleton threatened to block Dormuth from data access during a meeting about DSEN—

after the two competed to serve as the network's B.C. member. So, rather than using free data from B.C., Dormuth has been required to spend over \$100,000 of taxpayer money to purchase data from the U.S.

It's a situation that Dr. David Henry, CEO of Toronto's Institute for Clinical Evaluative Sciences, Canada's pre-eminent centre for science-based health policy development, describes as extremely distressing. "The most comprehensive data in Canada has been denied to us," he says, noting that the B.C. government has failed to respond to repeated inquiries from alarmed scientists across Canada—an attitude in keeping with its refusal to release information about its data-sharing agreements requested by the B.C. Freedom of Information and Privacy Association last summer. He is equally alarmed by the B.C. government's attack on Maclure, whom he calls a "world-leading scientist" who is "straight as a die." He describes the B.C. government's savaging of Maclure as "very distressing to us in the scientific community," citing the names of key scientific leaders from across the country.

For his part, Dormuth, like Elizabeth Denham, strongly questions the ministry's stewardship of the PharmaNet data. "There's a culture where people's instinct to safeguard the data is being promoted to the point of irrationality. They are extremely reluctant to let scientists use the data," he says. Given that the B.C. public has invested tens of millions in gathering this data—including the 2008 construction of a \$30 million data centre for PharmaNet in Calgary—Dormuth argues the public is entitled to have any barriers to research on drug safety and costs removed, and removed quickly. Michael Law, a UBC drug policy researcher, agrees. "Since it is produced using public money and it is a public resource, I think it should be available to researchers that want to do important work on drug safety."

A data stewardship committee that overprotects the security of the data and a government that conducts witch hunts that demolish scientific careers may wind up not protecting the public at all, but leaving us exposed to ever more drug safety disasters. **vw**



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