

The Ontario College of Pharmacists

Submission to the

Health and Human Services Task Force on Drug Importation

May 14, 2004

Rec'd 6/11/04

Established under the Pharmacy Act of 1871 the Ontario College of Pharmacists is the largest licensing and regulatory body for the profession of Pharmacy in Canada. The College's authority to regulate the profession of Pharmacy is vested within provincial health legislation, namely the *Regulated Health Professions Act* which grants self-regulating authority to 23 health professions in Ontario. With 10,000 pharmacists on the current register, the College regulates approximately 40% of the pharmacists in Canada. In addition, 3000 community pharmacies are currently accredited and regulated by the College with respect to operational standards.

The questions posed by the Task Force are excellent and comprehensive- indeed, much detailed consideration and research would be required before we could attempt to provide answers. This submission sets out the position of the College on the provision of pharmacy services, highlights some of the experiences we have had in our jurisdiction and addresses the issues that could challenge our ability to regulate effectively in the public interest.

It is the position of the Ontario College of Pharmacists that high quality cognitive standards of practice for pharmacists and operational standards for pharmacies must be met regardless of where the patient obtaining pharmacy services from Ontario resides. These standards include the pharmacist establishing a professional relationship with the patient and taking reasonable steps to enter into a dialogue on his or her drug therapy. In all situations where drugs are delivered to patients, the College's standards for packaging, shipping and delivery (and Canada customs rules and regulations for delivery outside Canada) must be met. The College's *Point of Care* symbol, which is included for your information, must, as a standard of accreditation, be prominently displayed in all accredited pharmacies and their related websites.

Ontario law does not contemplate *virtual* pharmacies and as such, Ontario pharmacies are accredited "brick and mortar" pharmacies- each of which is routinely inspected by College inspectors once every 3 years to ensure compliance with our requirements. Of the 3000 pharmacies currently issued certificates of accreditation by the College, records show that less than 300 have websites available to the public- the majority of these use their websites as another method of communicating with their patients and do not provide pharmacy services over the internet. The exact number of pharmacies in Ontario providing internet pharmacy services is not certain but we do know that any such practices are directed primarily to patients residing outside Canada and the College investigates each and every such operation as they become known to us through various means.

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Although the issue of cross border prescription sales gives rise to issues and potential issues, as regulators charged with protection of the public, our position remains grounded in the knowledge that Ontario has a safe and effective self-regulatory system that protects the public-whether they reside in Ontario or not- against practitioners (pharmacists and prescribers) and pharmacies that fall below our standards of practice. Furthermore, we believe this to be true across Canada and would suggest that the American public is not at risk if they obtain their pharmacy services from legitimate, licensed and accredited pharmacists and pharmacies in Canada.

This brings me to our primary issue of concern which is the increasing inability of regulators to protect the public against internet sites that purport to be but are not legitimate. An increasing number of websites exist that promote themselves as pharmacies located in Canada when in fact, they are not legitimate accredited pharmacy operations. In the spring of 2002, the Ontario College of Pharmacists, acting under the authority of the Provincial Offences Act, effectively closed down in Ontario an illegal operation selling drugs to the American public using the name *thecanadiandrugstore.com*. The College laid a total of fifteen charges under the Provincial Offences Act against the operation, its owner and operator who was not a pharmacist, including using the name "drugstore" which is a protected title under Ontario law. We also laid charges against an Ontario pharmacist, pharmacy, physician and a Canadian drug wholesaler for their roles in aiding and abetting this illegal operation. In June, 2003 the case was successfully prosecuted and I have brought copies of the press releases setting out the details of the charges and the results of this prosecution for your information.

The College's prosecutorial actions against *thecanadiandrugstore.com* was necessary but extremely resource-heavy, and underscores the importance of a cooperative, coordinated approach in pursuing rogue internet prescription drug sites. Furthermore, focusing our attention on the procurement of prescription drugs from bona fide, regulated and safe pharmacists and pharmacies based in Canada is in our opinion, not helpful and diminishes our effectiveness in protecting the public against potentially dangerous drugs obtained through the unregulated internet sites. Also as regulators, we cannot totally solve the problem unless there is an effective public education program on both sides of the border. The VIPPS™ program established by the National Association of Boards of Pharmacy, and the College's *Point of Care* program are examples of programs that offer assurances to the American public that pharmacy sites from which they seek their prescription services are both legitimate and subject to regulation.

While these programs are a good start, it is our view that much more needs to be done to inform the public of the importance of verifying the legitimacy of their health care providers.

Thank you for the invitation to present our position before you today.

Policy for Ontario Pharmacies Operating Internet Sites

(Council June 2001)

Any site selling drugs (Schedule I, II, or III) to the public through an Internet site must be an accredited pharmacy. As such, the pharmacy must meet all the requirements and obligations of all federal and provincial legislation. The designated manager is responsible for the operation and information posted on the pharmacy's website.

1. The following is not all inclusive but indicates some areas that must be addressed:
 - a. Authenticity of prescription orders;
 - b. Sale of Schedule II and III drugs - pharmacists must make the decision to sell Schedule II drugs and be available for consultation;
 - c. Tracking of deliveries;
 - d. Transmission (receiving and sending) of prescriptions must be in compliance with all federal and provincial legislation and Standards of Practice;
 - e. All Internet prescriptions must be recorded, filed, labelled and entered using the same filing system/computer as the regular pharmacy;
 - f. Pharmacists must comply with the Standards of Practice;
 - g. Website must be in compliance with federal and provincial regulations regarding the advertising of drugs, fees, and pharmacy services.

2. The home page of any pharmacy Internet site must identify the:
 - a. Website as belonging to or referring to a pharmacy accredited by OCP;
 - b. Accreditation number and owner;
 - c. Physical location of the pharmacy, including address and city/town;
 - d. Telephone number to contact the pharmacy;
 - e. Designated manager;
 - f. Hours that a licensed pharmacist is available for consultation.

3. Personal patient health information must be collected, recorded and used in a manner to protect confidentiality and privacy. The Internet site may wish to provide a confidentiality statement with regard to (but not limited to) insuring the security of personal health information.

4. The Internet site should provide a policy and procedure document for the public to explain the following:
 - a. Counselling patients on new and repeat prescriptions;
 - b. Counselling patients on over-the-counter medications;
 - c. Delivery policy;
 - d. Returns policy;
 - e. Complaints procedures.

5. The designated manager/pharmacy owner must inform OCP as per the legislation regarding change of information in the DPRA and Pharmacy Act, OCP By-laws:

- a. When a pharmacy is going to be conducting business over the Internet;
- b. The Internet address;
- c. Nature of the business (e.g. Rx, OTC or both, specialties);
- d. Phone number if different from the pharmacy.

6. Internet operation must be available for onsite inspection by OCP inspectors as it is considered a part of the accredited pharmacy.

7. Disclaimers. Pharmacists are reminded of liability issues and their professional responsibility regardless of disclaimers posted on an Internet site. It is recommended they seek legal advice.

Deanna L. Williams, R.Ph., B. Sc. Phm., CAE

Deanna Williams graduated from the Faculty of Pharmacy, University of Toronto in 1976.

She practised pharmacy in both hospital and community settings, and until 1992, was the pharmacist-owner of a small medical arts dispensary in Oakville, Ontario. In 1992, she joined the Ontario Ministry of Health as a Policy Coordinator with the Drug Programs Reform Secretariat where she worked towards the development and implementation of a new Ontario Drug Benefit program for seniors and clients on social assistance. Deanna joined the Ontario College of Pharmacists, the licensing and regulatory body for Pharmacy in Ontario in 1994. As the Deputy Registrar, and Director of Programs, she assumed responsibility for the College's program areas - Patient Relations, Pharmacy Practice, Continuing Education, Registration and was responsible for the development and implementation of the College's Quality Assurance program. Deanna assumed the position of Registrar of the Ontario College of Pharmacists on May 1, 2000.

Deanna is a guest lecturer in the Pharmaceutical Jurisprudence course for both University of Toronto undergraduate pharmacy students and foreign-trained applicants, and from 1992 through 1999 she was a teaching assistant in the Professional Practice course for fourth year pharmacy students at the Faculty of Pharmacy, University of Toronto. She has served as Chair of the Quality Assurance Working Group of the Federation of Health Regulatory Colleges of Ontario and has been an active participant in the Council on Licensure, Enforcement and Regulation (CLEAR) since 1995. Deanna has been the sole Canadian member of CLEAR's Board of Directors since 1999 and assumed the office of CLEAR President in September 2003. She also serves as Vice Chair of CLEAR's International Relations Committee, a member of its Training and Development Subcommittee, and is Vice Co-Chair of its overall Program Committee for 2003.

In addition to work activities, Deanna has also served on volunteer boards. From 1989 to 1995 Deanna served as an appointed member and Chair of the Halton District Health Council, one of twenty five advisory boards in Ontario established to provide advice to the Minister of Health on a number of health issues and priorities. She is an active member of the Canadian Federation of University Women where she has served as President of three local clubs over the past twelve years. In 1996, the Ontario Ministry of Education established School Councils as advisory bodies to the Minister of Education and Deanna served two consecutive terms as Chair of the School Council at Lorne Park Secondary School.

She lives in the Toronto area with her family.



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NEWS RELEASE

CHARGES LAID AGAINST THE CANADIAN DRUG STORE INC. FOR OPERATING AN ILLEGAL INTERNET PHARMACY

ONTARIO COLLEGE OF PHARMACISTS ADVISES ALL ONTARIANS TO VERIFY LEGITIMACY OF INTERNET PHARMACY SITES BEFORE USE

May 14, 2002, Toronto — The Ontario College of Pharmacists recently laid charges under Ontario's Regulated Health Professions Act, the Drug and Pharmacies Regulation Act, and the Pharmacy Act against The Canadian Drug Store Inc., one of its Directors, an Ontario pharmacist, an Ontario pharmacy, an Ontario physician and a Canadian drug wholesaler.

The advent of the Internet has created new means for the public to access health and pharmacy services but it has also created new risks. There are many websites selling prescription and non-prescription medicines that have not been accredited as legitimate pharmacies by pharmacy regulators in either Canada or the U.S.

The Ontario College of Pharmacists urges all Ontarians to verify the legitimacy of Internet pharmacy websites prior to providing personal health information to or purchasing products from these sites. It also advises the Ontario public to ensure that they always receive drug counselling from, and have their prescriptions filled, by a licensed pharmacist.

You can call the Ontario College of Pharmacists at 1-800-220-1921 to confirm whether a particular website is operated by a licensed Ontario pharmacy. The College also advises anyone considering using a pharmacy website to first review information provided at its public education website www.worthknowing.ca. Furthermore, College policy requires that any Ontario pharmacy operating a website to display their pharmacy accreditation number and the College's Point of Care symbol (see below) to assure public confidence.

The public needs to know that some websites presenting themselves as online "pharmacies" or "drugstores" may be operating without a pharmacy license and dispensing prescriptions without the oversight of a licensed pharmacist.

1.0 In sum, a total of 15 charges have been laid under Ontario's Regulated Health Professions Act, the Pharmacy Act and the Drug and Pharmacies Regulation Act and allege that:

1.1 Through the Internet, The Canadian Drug Store Inc. and one of its Directors, William Shawn, have been unlawfully operating an unaccredited pharmacy without registered

pharmacists from a Toronto location filling prescriptions written by U.S. doctors for U.S. residents

1.2 Stephen Bederman, an Ontario registered pharmacist, the Director to the Ontario-accredited pharmacy Birchmount Pharmacorp, and a director of the company SB Enterprises Inc., has been involved with Mr. Shawn and The Canadian Drug Store Inc. in unlawfully supplying prescription and non-prescription drugs to U.S. residents.

1.3 A member of the Ontario College of Physicians and Surgeons, Dr. Stanley Gore, and Canadian Custom Prescriptives Inc. have also been involved with Mr. Shawn and The Canadian Drugstore Inc. in unlawfully facilitating delivery of prescription and non-prescription drugs to U.S. residents.

1.4 A drug wholesaler, Rep-Pharm Inc., has also been supplying medications that can only be sold to a licensed pharmacy, to William Shawn and The Canadian Drug Store Inc.

2.0 The offence periods vary for many of the counts but, generally, the offence period is from November/2001 to February/2002.

3.0 The charges are punishable with fines up to \$25,000 and, additionally, in the case of individuals charged with offences contrary to the Regulated Health Professions Act, 6 months imprisonment.

4.0 The first appearance at the Old City Hall courts is scheduled for June 11, 2002.

Established in 1871, The Ontario College of Pharmacists licenses and regulates all Ontario pharmacists and community pharmacies. Pharmacy as a self-regulated profession is one of 21 regulated health professions in Ontario regulated by its College, which is established to oversee the profession under the Regulated Health Professions Act. The College's primary role is to ensure pharmacists provide Ontarians with high quality, ethical pharmaceutical care. It sets the requirements to enter the profession, establishes and enforces the profession's standards of practice and ethics, and ensures the continuing competence of all practicing pharmacists. The College also sets and enforces the operational standards for community pharmacies, including pharmacy-owned/operated websites.



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NEWS RELEASE

THE CANADIAN DRUG STORE INC. PLEADS GUILTY

July 17, 2003, Toronto — The Ontario College of Pharmacists announced today the resolution of its prosecution against The Canadian Drugstore Inc.; Rep-Pharm Inc.; Stephen Bederman, who is an Ontario registered pharmacist, the Director to the Ontario-accredited pharmacy Birchmount Pharmacorp, and a director of the company SB Enterprises Inc.; and Dr. Stanley Gore, an Ontario registered physician, and his company Canadian Custom Prescriptives Inc.

The Canadian Drugstore Inc. (which is not an accredited pharmacy in Ontario) plead guilty on June 23, 2003 to one offence contrary to the Regulated Health Profession Act, 1991 (RHPA), and four charges contrary to the Drug and Pharmacies Regulation Act (DPRA). The charges alleged:

1. Between November 26, and December 16, 2001 The Canadian Drugstore unlawfully performed the controlled act of dispensing or selling a drug to a patient, contrary to section 27(1)(a) of the RHPA, 1991
2. Between November 15, and December 31, 2001, The Canadian Drugstore unlawfully:
 - 2.1. Established or operated an unaccredited or unlicensed pharmacy, contrary to section 139(1) of the DPRA
 - 2.2. Owned or operated a pharmacy (The Canadian Drugstore) when none of the company's directors were pharmacists, contrary to section 142(1) of the DPRA
 - 2.3. Operated a retail business with the designation "drug store" when the business was not an accredited or licensed pharmacy, contrary to section 149(1) of the DPRA
 - 2.4. Dispensed a prescription without the written authorization of a Canadian doctor, contrary to section 155(1) of the DPRA

The Ontario Court of Justice fined the company \$20,000. This fine amount was part of an overall disposition which:

1. Included a \$125,000 payment by the Canadian Drugstore Inc. to the Leslie Dan Faculty of Pharmacy, University of Toronto to establish the Ontario College of Pharmacists' Professorship in Pharmacy Practice
2. Took into account a \$155,000 loss to The Canadian Drugstore Inc. resulting

from a February, 2002 College of Pharmacists' seizure, under warrant, of prescription drugs which The Canadian Drugstore had in its possession

The Canadian Drugstore Inc. advertised on the Internet that it was a source of low cost Canadian drugs to American patients. American patients would fax their prescriptions, written by their U.S. doctors, directly to The Canadian Drugstore who would then arrange for the prescription to be co-signed by an Ontario doctor. (This practice directly contravenes current policies of both the Ontario College of Pharmacists and the College of Physicians and Surgeons of Ontario.)

The co-signed prescription would then be faxed to an Ontario pharmacy for filling. The filled prescriptions were returned to The Canadian Drugstore Inc. who then delivered the prescriptions to their American patients by parcel post.

Rep-Pharm Inc, a drug wholesaler, pleaded guilty to the offence of wholesaling drugs for a retail purpose to a retail operation other than a pharmacy, The Canadian Drugstore Inc., contrary to section 160(1) of the DPRA. Rep-Pharm was fined \$5,000. Rep-Pharm admitted in Court that it had erred in that it did not realize that the three drugs in question were scheduled and restricted to sale only to an accredited pharmacy, therefore could not be sold to The Canadian Drugstore.

The Ontario College of Pharmacists requested that all outstanding charges under the DPRA and RHPA against pharmacist Stephen Bederman, Birchmount Pharmacorp operating as Pharmasave, and a related company, SB Enterprises, be withdrawn. As a result of their alleged involvement in The Canadian Drugstore Inc. scheme as suppliers of prescription drugs, Bederman and Birchmount Pharmacorp will be the subjects of a December, 2003 hearing before the Discipline Committee of the Ontario College of Pharmacists.

The College further requested the outstanding charges against Dr. Gore and his related company, Canadian Custom Prescriptives, be withdrawn. As a result of his alleged involvement in the same scheme, Dr. Gore has been referred by the College of Physicians and Surgeons of Ontario to its Discipline Committee for a hearing and determination.

Advice to the Public

The Ontario College of Pharmacists urges all Ontarians to verify the legitimacy of Internet pharmacy websites prior to providing personal health information to or purchasing products from these sites. It also advises the Ontario public to ensure that they always receive drug counselling from, and have their prescriptions filled, by a licensed pharmacist.

Please call the Ontario College of Pharmacists at 1-800-220-1921 to confirm whether a particular website is operated by a licensed Ontario pharmacy. The College also advises anyone considering using a pharmacy website to first review information provided at its public education website www.worthknowing.ca. Furthermore, College policy requires

that any Ontario pharmacy operating a website display their pharmacy accreditation number and the College's Point of Care symbol (see symbol at www.worthknowing.ca) to assure public confidence.

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