the Messenger

College of Physicians and Surgeons of Alberta

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College of Physicians & Surgeons of Alberta

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Registrar's Report

To pursue our vision of quality health care services provided by competent and caring practitioners we need to publicly demonstrate ethical conduct, fairness and accountability.

A series of articles on research ethics in the *National Post* and the Edmonton and Calgary papers confirmed the College of Physicians and Surgeons of Alberta – and, therefore, the profession of medicine in Alberta – is a national leader in protecting the public's and individual patient's interests when they are involved in research.

Two key issues emerged in the articles. First, is the quantum jump in clinical research that is occurring (with accompanying concerns about the role of pharmaceutical companies). The second is the issue of consent.

Clinical research has grown logarithmically, especially in the community. Pharmacy companies actively recruit practising physicians to enrol patients as research subjects for drug studies. In most provinces, the protocols for such research are outside the scope of academic or institutional research ethics boards. Therefore, with the exception of Alberta, when protocols are approved it is by for-profit ethics reviewers.

Is that a problem? Our own experience would suggest that it could be. Two trials, approved in other jurisdictions were rejected by the CPSA's Research Ethics Review Committee (RERC). In each case, detailed protocol review raised questions about the scientific validity of the study. In one, the study was to compare the efficacy of a new formulation of a standard drug. Instead of comparing the new formulation to the old one, the protocol compared the new formulation to a placebo, giving rise to the question: Is it research or is it marketing? Since physicians were to receive payment per capita for enrolling patients in the study, it becomes a very important ethical question.

I note parenthetically that rejection by the RERC can be appealed to the Council. While admittedly this can be a ponderous process, the College is working hard to make appeals more efficient.

The second issue identified in the series of articles is that of consent, and not just for the research trial. As mentioned, pharmaceutical companies seek enrolment of patients by their physicians. While it would seem innocuous for a physician to scan his/her charts for patients with the requisite demographics, it would be a violation of the *Health Information Act* to do so without the consent of either the patients themselves, or, where that is impractical, the approval of a research ethics board.

The CPSA has received protests about this process. In fact, we have been accused of "chilling the opportunity to do clinical research" in Alberta. However, as was so eloquently concluded in the newspaper articles, Alberta seems to have got it right, with the public interest as our paramount consideration. The public interest is not only clearly covered in the *Code of Ethics* (*Item 25. Ensure that any research … is approved by a responsible committee*), but also in the *Health Information Act*. The article by Dr. Flynne on page five of this *Messenger* explores this privacy issue further.

Other items of note in the issue include information on Butorphanol, on our regional tour, the 2003 complaint statistics, and an article urging specific consent for the administration of blood products. The latter is a consequence of the work of the provincial Policy Advisory Committee on Blood Services in Alberta, and underscores the importance of informed consent in the treatment world. The committee makes a compelling case for specific written consent for blood and blood product administration, and while the College has not met the specific wording of Justice Krever's first recommendation, the advice is offered here to emphasize the ethical obligation to obtain informed consent for any treatment.

Should the CPSA revisit this issue? What do you think? Your input on this, and/or any other issue, is welcome.

Dr. Bob Burns, Registrar
rburns@cpsa.ab.ca

Use of Medical Databases in Research Studies

The College's Research Ethics Review Committee has been increasingly concerned about the use of medical databases to search for suitable research subjects.

Under the *Health Information Act (HIA),* a Research Ethics Committee must review any proposed database search to determine whether the researcher must obtain the consent of identified individuals (those whose names and personal health information appear in the database). This applies equally to manual and electronic databases, and includes physician office medical records.

The Research Ethics Committee usually requires consent unless obtaining the consent is unreasonable, impractical or not feasible (*HIA*, Section 50(1)(iv)).

Physician researchers must obtain the review and approval of a Research Ethics Board before data matching is performed.

Researchers requesting that the Research Ethics Committee waive consent should include with their application a reasoned argument as to why such waiver should be considered.

Physician researchers must also obtain the review and approval of a Research Ethics Board recognized under the *HIA* before data matching is performed.

Physicians who are or likely to be engaged in research should review their database processes and consider the option of obtaining patient consent to use the data for research purposes. Patients must also be made aware that their consent can be withdrawn at any time.

Sections 48 through 56 of the *Health Information Act* govern disclosure for research purposes. A copy of the *Act* is available at http://www.qp.gov.ab.ca/documents/acts/H05.cfm.

Dr. Paul Flynne
Assistant Registrar

Payment Required when Applying for Research Reviews

Effective June 1, 2004, the College's Research Ethics Review Committee will require payment of the review fee before the review of research protocols can begin.

Investigators and/or sponsors will no longer be invoiced for this fee, and the study will only be processed for review if payment is included at the time of submission.

A fee schedule of review types is available on the College website (www.cpsa.ab.ca – College Programs – Research Ethics Review. Under the "Information" section, click "Fees").

The College's Research Ethics Review Committee has been operating since 1996 to ensure the highest ethical standards in human research studies. It is one of four Alberta bodies providing such services (others include Alberta Cancer Board, University of Alberta Health Research Ethics Board (Bio-Medical), and the University of Calgary Conjoint Health Research Board of the Faculty of Medicine).

Regional Tours Continue in 2004

After successful visits in Ft. McMurray and Edmonton last year, representatives from the College will be making tour stops in each of Alberta's nine health regions in 2004.

Council President Dr. Gordon Arnett, College executive and other council representatives will attend medical staff association meetings in each region.

In addition to addressing local issues, Dr. Arnett will talk about the roles and responsibilities of the College and any major initiatives currently underway. Dr. Arnett's brief presentation will be followed by a question and answer session.

The purpose of regional tours is to help put a 'face' to the College and create the opportunity for CPSA Council members and staff to hear Alberta physicians' questions, concerns and suggestions.

If you have a specific issue or question you would like addressed during the College's tour in your region, please contact Kelly Eby, CPSA Communications, (780) 412-2683, 1-800-320-8624 ext. 683, or e-mail keby@cpsa.ab.ca.

We look forward to your feedback and meeting many of you in 2004.

Regional Tour 2004
Mark your Calendar!

- **Palliser** (Medicine Hat) Thursday, March 18th
- **East Central** (Killam) Tuesday, May 4th
- **Peace Country** (Grande Prairie) Monday, May 10th
- **Calgary** (Calgary) Tuesday, June 1st
- **David Thompson** (Red Deer) Tuesday, June 17th
- **Capital** (Edmonton) Thursday, October 21st
- **Aspen, Chinook, and Northern Lights** - Fall 2004

For Your Information

Prescribing Anabolic Steroids

Physicians are reminded that anabolic steroids are no longer on the Alberta Triplicate Prescription Program (TPP). Please do not use the triplicate forms for anabolic steroid prescriptions.

May Council Meeting

Council of the College is holding a public meeting on May 28, 2004. Please call Nicola Clarke at **(780) 970-6227, 1-800-561-3899 ext 227** or e-mail nclarke@cpsa.ab.ca to reserve a seat and to receive a copy of the agenda. Seating is limited and reservations are required.

Messenger Via E-mail

More and more Alberta physicians are choosing to receive an electronic version of *The Messenger* rather than a hard copy in the mail. And we couldn't be happier. Receiving an electronic version is more timely, cost effective and environmentally friendly.

If you are not getting an e-mail from the College announcing a new issue of *The Messenger*, visit our website to register or update your current e-mail address (http://www.cpsa.ab.ca/updateemail/updateemail.asp)

You can also update your e-mail by contacting Karen Graves at (780) 970-6216, 1-800-320-8624 ext. 216 or e-mail kgraves@cpsa.ab.ca.

Consider the benefits of a paperless office. Contact the College to remove your name from the hard copy Messenger mailing list.

2004 Medical Directory

A copy of the College's 2004 Medical Directory is being mailed out to all physicians with this issue of *The Messenger*. (Physicians receiving *The Messenger* electronically will also receive a hard copy of the directory by mail.)

Physicians who do not receive their one complimentary copy of the Directory should contact Ms. Karen Graves at (780) 970-6216, 1-800-561-3899 ext. 216, or kgraves@cpsa.ab.ca.

Please allow Canada Post until April 30, 2004 to deliver your hard copy of the Medical Directory before contacting the College.

If physicians require additional copies, or if other parties are interested in obtaining the 2004 Medical Directory, it may be purchased based on the following 2004 rates.

Delivered Within Edmonton (each)

Directory	$75.00
Delivery	5.00
GST	5.60
Total	**$85.60**

Delivered Outside Edmonton (each)

Directory	$75.00
Delivery	8.00
GST	5.81
Total	**$88.81**

Picked-up at the CPSA Office (each)

Directory	$75.00
GST	5.25
Total	**$80.25**

Directories will be delivered to your 'College Mail' address. Allow until April 30, 2004 to receive your copy before contacting the College.

To place an order, complete the 2004 Medical Directory Order Form available on our website (http://www.cpsa.ab.ca/findaphysician/purchase_md.asp).

If you use the order form from your current 2003 directory please note the price changes for 2004 and submit payment accordingly. Pre-payment is required by cheque, VISA or MasterCard prior to shipping any directories.

Urgent & Emergency MRIs & CTs

Alberta physicians who request MRI or CT studies should be aware of local procedures to secure timely imaging studies for their patients.

Although scheduling rules vary among facilities and between regions, a conversation between the requesting physician and the radiologist is a common requirement.

Physicians should not direct a patient to a privately owned imaging facility for an urgent or emergency MRI or CT without first speaking to a radiologist and attempting to schedule the study in a public facility. By way of policy, Alberta Health and Wellness does not pay for privately funded diagnostic services.

The College understands the pressure on physicians to obtain timely tests, consultations and many other services for their patients. However, knowing the appropriate channels to access those services and for reporting access problems is an important professional responsibility.

Talk to a radiologist to schedule a study in a public facility before directing your patient to a privately owned facility.

2003 Complaint Statistics

The number of complaints lodged against Alberta physicians declined last year, as the College of Physicians & Surgeons received 593 complaints in 2003 compared with 698 in 2002. There are about 7800 physicians in Alberta.

The number of complaints each year are affected by a variety of factors including individual patient expectations, communication training and methods, high profile events and overall changes in the health care system. To see fluctuations from year to year is normal.

The goal of the College is to ensure that our complaints resolution process is fair, effective and open to both patients and physicians.

Following receipt of a written complaint, the College follows up with both the complainant and the physician to investigate and to determine if informal resolution is possible. Formal disciplinary hearings are infrequent, as the College prefers to take a remedial or quality improvement approach whenever possible. The steps of the complaints process are the same for each individual to ensure a consistent and fair approach.

Approximately half of the complaints submitted to the College in 2003 include a component related to the quality of care received. This could mean an incorrect or delay in diagnosis or treatment, procedural or counseling concerns, inappropriate or delayed referrals or issues related to physician follow-up. The second most common area of concern is practice management which encompasses physician availability, office management and communication. This trend is consistent with previous years.

Dr. Trevor Theman
Assistant Registrar

Total Complaints per Year

Year	# of complaints
2003	593
2002	698
2001	717
2000	660
1999	601
1998	771

Number of Physicians vs Complaint Statistics & Average Days to Close of Complaint

Totals	2003	2002	2001
Active registered physicians	7241	7144	6876
Number of complaints received	593	698	717
Number of physicians complained about	500	578	615
Complaints open at end of year	220	251	246
Average days to close of complaint			
• up to 4 months	69%	73%	73%
• 4-12 months	26%	22%	23%
• more than 12 months	5%	5%	4%

Summary of Complaint Natures

Nature	Number of complaints
Quality of Care	354
Practice Management	213
Medical Reporting	96
Third Party	38
Ethics	35
Systemic	5
Unclassified	10
TOTAL	751*

* some complaints are filed in more than one category as they involve more than one nature

Quality of Care: diagnosis-incorrect or delayed, treatment-prescribing, procedural and counseling, referral/consultations, follow-up.
Practice Management: physician availability, office management including finance, and communication
Medical Reporting: release of records, report completion and accuracy
Third Party: Independent Medical Examination, (WCB, and Non-WCB, all others)
Ethics: confidentiality, informed consent, advertising/self promotion, research related, and boundary violations including sexual, financial and other.
Systemic: access to human resources and technology, continuity of care and interdisciplinary issues.
Unclassified: all others.

2003 Physician Resource Statistics

Registration Information:

	2003	2002	2001	2000
Type of Registration				
Full Register	**5,323**	5,196	5,012	4,876
Special Register	**537**	488	431	365
Temporary Register	**8**	4	7	4
Courtesy Register	**1**	1	1	2
Total	**5,869**	5,689	5,451	5,247
Sex				
Female	**1,725**	1,649	1,541	1,457
Male	**4,144**	4,040	3,910	3,790
Specialist/Non-Specialist				
Specialist	**2,885**	2,807	2,667	2,547
Non-Specialist	**2,984**	2,882	2,784	2,700

Location

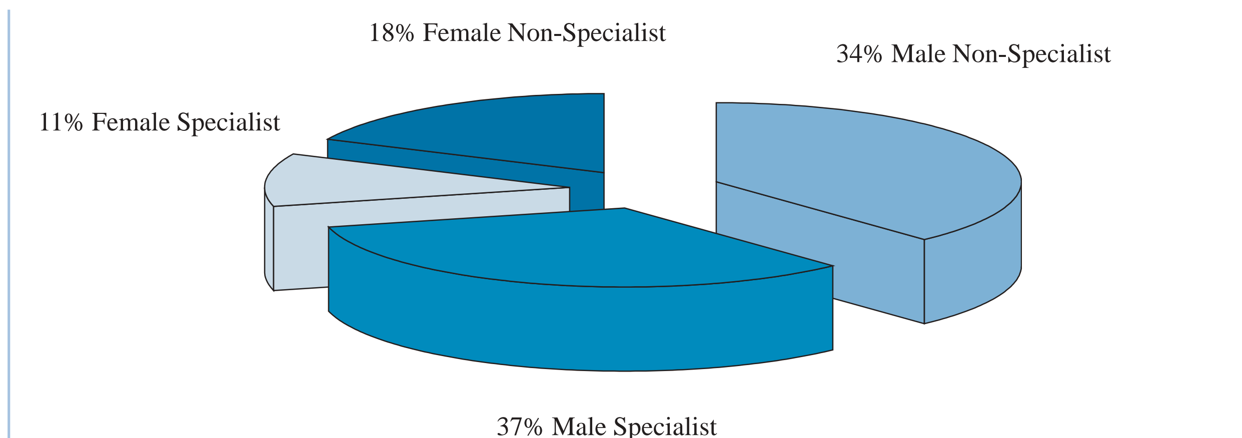
* 2003 statistics are not compared to previous years due to boundary changes effective April 1, 2003 which combined Alberta's 17 health regions into 9.

	2003	2002	2001	2000
RHA 1 Chinook	**225**			
RHA 2 Palliser	**116**			
RHA 3 Calgary	**2,358**			
RHA 4 David Thompson	**364**			
RHA 5 East Central	**106**			
RHA 6 Capital	**2,331**			
RHA 7 Aspen	**165**			
RHA 8 Peace Country	**139**			
RHA 9 Northern Lights	**53**			
Location Unknown	**12**			
Total	**5,869**	5,689	5,451	5,247
Other Registrants				
Full Register, out of province	**416**	442	464	453
Educational Register	**1,511**	1,455	1,399	1,319
Total	**1,927**	1,897	1,863	1,772
Grand Total, All Registrants	**7,796**	7,586	7,314	7,019
Retired				
Retired, in Alberta	**459**	453	454	462
Retired, out of province	**126**	115	96	88
Total Retired	**585**	568	550	550

Changes in Physician Workforce:

Increases	**2003**	2002	2001	2000
New Registrants				
University of Alberta	**63**	60	80	52
University of Calgary	**43**	36	37	34
Other Canadian Universities	**131**	148	162	135
USA	**0**	3	4	1
Other	**137**	131	106	121
Restored to Register	**52**	51	46	51
Returned to Province	**40**	30	24	40
Total	**466**	459	459	434
Decreases				
Left Alberta	**-103**	-91	-103	-114
Retired	**-33**	-29	-31	-35
Voluntary Erasure	**-57**	-23	-50	-32
Removed from the Register	**-66**	-56	-49	-45
Deceased	**-9**	-11	-13	-14
Total	**-268**	-210	-246	-240
Net change during each year	**198**	249	213	194

Workforce Breakdown:



About Butorphanol (Stadol NS®)

The College is printing this article as part of an ongoing educational series to raise physicians' awareness of medications not on the Triplicate Prescription Program yet prone to abuse or misuse in the future. The Program may add this drug to its list of monitored drugs under the TPP if funding for the addition can be found.

Introduced in the US in 1970 as an injectable agent, Butorphanol was later modified and reintroduced as a nasal spray in 1989 under the trade name of Stadol NS®. As an agonist/antagonist, the drug was initially advertised as having little or no abuse potential. Today, butorphanol is prescribed for individuals with migraine and other headaches. Its effectiveness is largely a result of the rapid nasal absorption property giving rapid onset of analgesia. The drug is not recommended for ongoing chronic usage.

Since butorphanol's introduction, there has been controversy concerning the drug's abuse potential. Despite continued silence from the United States Food and Drug Administration surrounding butorphanol's abuse/addiction potential, reports indicate that there are ten new cases of addiction and abuse per month occurring in the U.S.

Narcotic drugs rely on the way they utilize various receptors in the brain to mediate analgesia. The most potent of these receptors is the mu receptor. Other receptors include kappa and delta receptors. Butorphanol utilizes the kappa and mu receptors. Its action at the mu receptor includes activating some receptors while blocking others at the same time. It is this effect that produces the theoretic safety from addiction and abuse, as mu receptor agonists are the drugs most frequently implicated in narcotic addiction. The kappa activity of the drug produces most of its analgesic effect.

Butorphanol is an opioid analgesic with kappa agonist and mu mixed agonist and antagonist properties. The drug is rapidly absorbed through the nasal mucosa producing a rapid analgesic effect.

Since the drug blocks the mu receptors, use of butorphanol in an individual already using narcotics may precipitate an acute opioid withdrawal syndrome (i.e., this may occur when butorphanol is used to treat a headache in an individual using a long acting opioid to treat chronic back pain).

"Street pharmacologists" have long recognized that the most desirable drugs for addiction purposes have the following characteristics: rapid absorption, easy administration, euphoric effect and short half life. This is the reason that smokable drugs are very popular.

The street value of an addictive drug increases as these properties can be built into the drug's pharmacology. An example of this is the differential in desirability between coca leaves which are chewed, cocaine powder which is taken intranasally, and crack cocaine which is smoked. There has been a marked increase in the availability of smokable narcotics over the last few years for this very reason.

Although not smoked, butorphanol is rapidly absorbed. Absorption via the nasal mucosa is very rapid when compared with oral absorption. Butorphanol also has a reasonable euphoriant action via the kappa and mu receptors. The half life of butorphanol is very short, lasting for between 60 and 90 minutes.

The short half life of a drug often leads to a need for reuse. This may lead to compulsive use characteristics of those individuals susceptible to addiction.

Butorphanol should be avoided, or at least used with great care, in individuals with either a family or personal history of addictive illness and/or where addiction screening tools are positive.

Dr. Ian Forster
LifeMark Health Institute

Signs of addictive problems with butorphanol:

- increasing tolerance and dose escalation coupled with craving,
- drug seeking behaviour, and
- reduction in functionality.

Should these symptoms supervene, the drug should be stopped and the patient should be carefully re-assessed. An analgesic with a long half life should be substituted where appropriate.

Informed Consent for Transfusion

In response to communication with the Policy Advisory Committee on Blood Services in Alberta, the College is printing this article to help reinforce the importance of obtaining appropriate informed consent when blood and blood products are administered.

For those of you who may be experiencing deja vu, no, we haven't time warped back into the mid 90's and the time of Krever. However, the issue of informed consent for transfusion has become a topical and somewhat controversial subject again due to the emergence of transfusion transmitted West Nile Virus and the recent possible human case of variant Creutzfeldt-Jakob Disease (CJD) transmission in Great Britain.

To many of my colleagues outside of transfusion medicine, the issue of informed consent for blood transfusion seems excessive in view of the many more invasive and potentially harmful therapies we expose patients to without a specific, written consent (i.e. chemotherapy). I don't necessarily disagree, but the fact that the public and the media perceive blood transfusion as a significant risk generates heightened awareness and concern about transfusion therapy. While not necessarily well informed or logical, the concern is real and deserves our consideration. Physicians must also remember that in Canada we have gone through a public inquiry that makes very specific recommendations for transfusion consent (Table 1).

What are we actually referring to when we talk about informed consent? Informed consent is the process of communication between the patient and their physician during which information about transfusion indications, risks and benefits is provided. The patient must have the opportunity to ask questions and then make a choice. Informed consent is not a specific document or patient signature, rather these are the tools used to document the patient's decision. The essential elements of informed consent include:

- the indications for the transfusion,
- possible risks,
- possible benefits,
- alternatives available to the patient,
- potential consequences of not receiving the blood transfusion.

To facilitate this process for Alberta physicians, in October of 2002 the Alberta Medical Association published a clinical practice guideline (CPG) entitled ***Guideline for Red Blood Cell and Plasma Transfusion: A Summary***. What is extremely useful is the provision of not only a risk table for transfusion associated risks (updated Canadian risk figures are pending publication on the website) but a table of risks of daily life to help the physician and patient put these risks into the proper perspective. This CPG and an accompanying patient brochure are available on the AMA website (www.albertadoctors.org).

My recommendations for an approach to consent for transfusion would be to first emphasize the need for giving the transfusion and the consequences of not being transfused. Then proceed to discuss the risks in terms of three broad categories. The first category, which is often the most overlooked, are the risks associated with the transfusion event itself. These include allergic, febrile and hemolytic reactions as well as reactions that may be of higher risk to specific patient groups. Volume overload, transfusion associated acute lung injury and iron overload would be considered the latter. The second group of risks is the infectious risk of transfusion. While the events in this category are several fold less likely to occur, it is these risks that the public are most concerned about and as such constitute a "material risk". The third category is the group of unknown or theoretical risks. Although, significant effort and cost has gone into improving the safety of the blood supply, the West Nile situation highlights that there is never a "zero-risk". After discussing the risks, potential alternatives to transfusion should be mentioned in the context of your patient's clinical condition. In many situations, there may not be appropriate alternatives while in others autologous donation, hematinic therapy, antifibrinolytics and perioperative cell salvage techniques may all be appropriate. The final step is then the documentation of the patient's decision in whatever format is recommended in your facility or health region.

Just as we must obtain consent before an invasive procedure, so must we do so before blood transfusion therapy. While the process itself is not standardized across the country it is considered standard of care. Ultimately, this dialogue with our patients contributes to better informed patients and better care.

Table 1 - 1995 Krever Commission Interim Report's six recommendations:

1) That the licensing bodies of the medical profession require in their

Continued on page 12

standards of practice that the treating physician obtain the informed consent of the patient to the administration of blood and blood products, in such a way that patients in Canada, barring incompetency or an emergency surgical procedure, will be informed of the risks and benefits of, and alternatives to, allogeneic blood transfusion.

2) That risks, benefits, and alternatives be presented in language the patient will understand and in a manner that permits questions, repetitions, and sufficient time for assimilation.

3) That the discussion between the physician and the patient take place well in advance of the surgical procedure or blood therapy to enable the patient to employ some of the alternatives to an allogeneic blood transfusion, such as the advance deposit of autologous blood, and to allow the patient to participate in a meaningful way in the decisions relating to the administration of blood and blood products.

4) That the treating physician document in the patient's medical chart that he or she has discussed the risks, benefits, and alternatives of blood transfusion with the patient.

5) That after treatment, patients be informed by the treating physician about the particular blood component or blood product and the quantity thereof that was administered to them in the procedure; and that this information be communicated both to patients who gave prior informed consent to the administration of blood or blood products and to patients who, because of a medical or surgical emergency, did not have the opportunity to consent to the receipt of a blood transfusion.

6) That information on the blood and blood products be recorded in the medical chart of the patient and on the discharge summary, and that it be included in the reporting letter written by the attending physician or surgeon to the referring physician.

Dr. Susan Nahirniak
Medical Director of
Capital Health Transfusion Services

Letters ...

Cost of Medical Education & Challenges Ahead

As differential fees are causing tuition to skyrocket, we need to find ways of changing the pace of increase. Medical students provide an essential service to the hospital system during their final years of medical education, as they see patients and generate differential diagnoses. During this time, we need to decrease the tuition they pay. Even more so, residents are front-line: running codes, seeing patients, and being first-call at the various hospitals. Creative and forward-thinking ways, such as 100% tuition reimbursement and interest-free student loan status during residency, must be sought.

If we don't decrease the cost of medical education, we risk decreasing diversity that we now enjoy and we risk adversely influencing medical students in their career choice. There will be an adverse effect on residents and medical student well-being, as they struggle with family, debt, learning, and clinical service work. As a profession, we serve where the need is: in the hospital, in the community, in the inner-city, overseas with volunteer organizations. Imagine that diversity disappearing, as residents struggle to pay off their debts and are less inclined to advance the humanitarianism of the profession. These aforementioned effects are merely the tip of the iceberg and you can let your mind wander about more possibilities.

What about loans to finance the cost of medical education? Although it may seem that our ability to handle debt is infinite, it really isn't. We can increase student loan amounts, open lines-of-credit, or have our parents take out a second mortgage, but eventually we have to pay it back. Worse yet, interest rates are at some of their all-time lows and this creates an artificial environment for financing debt. If interest rates start rising, we will feel the negative consequences on a much larger scale.

We must be vigilant to decrease the overall cost of medical education with a front-end and back-end approach. We need to tackle this by decreasing tuition and by finding ways of creatively addressing student loan repayment, and we definitely need to do this before interest rates start to rise. It would be shameful if we had major psychological or financial barriers to decrease accessibility to those who are capable, but cannot afford it. It would be shameful if we lost our human touch.

Calvino Cheng, MD
President, Professional Association of
Residents of Alberta

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