sponse to these challenges that may determine the future of Nepal in this time of crisis.

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Summary Basis of Decision in context

In their analysis of Health Canada's Summary Basis of Decision (SBD) initiative, Joel Lexchin and Barbara Mintzes[1] raise important issues about transparency, but they do not discuss the unique Canadian legal context within which manufacturers submit their information for review.

The confidentiality of drug submissions is anchored in Canadian common law, federal statutes and international trade obligations. Drug manufacturers can usually argue successfully that data kept in trade confidence by the manufacturer and submitted to Health Canada in confidence are excluded from disclosure under the Access to Information Act. The recent Federal Court of Canada decision in the Singulair case[2] may impose further limits on the release of review information under access legislation. In the interests of public disclosure, Health Canada has appealed that decision.

With some exceptions, the North American Free Trade Agreement and the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights also require member countries, including Canada, to take steps to protect data filed with a national authority as a condition for market authorization.

Lexchin and Mintzes contend that the US Food and Drug Administration (FDA) routinely posts detailed information submitted by the drug company, along with FDA reviewers' analyses. In fact, the FDA ceased publication of Summary Basis of Approval documents in 1994, opting to publish hundreds of pages of review information, with confidential commercial information severed. The FDA was subsequently criticized by the US inspector general for not providing summary information;[3] that criticism was based on concerns about the readability of the full reviews for many segments of the public.

The SBD provides concise public information on the quality, clinical efficacy and safety elements of a drug submission, including summaries of clinical trial design and premarketing adverse events. Our consultations indicate that this is a major step forward, particularly for consumer associations and health care providers.

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[The authors respond:]

Diane Gorman maintains that Canadian federal statutes prevent Health Canada from releasing clinical information about safety and efficacy without the consent of the company submitting the data. In doing so, she ignores a section of the Access to Information Act that allows the release of such information if it "would be in the public interest as it relates to public health."[1] To our knowledge, Health Canada has never chosen to use this clause to disclose information.

Health Canada's Science Advisory Board examined whether the North American Free Trade Agreement created a barrier to disclosure of premarket clinical trial data and concluded that "Measures to require transparency for the protection of the public are not a violation of this treaty obligation."[2]

Ms. Gorman points out that the FDA stopped posting Summary Basis of Approval documents in 1994, but that was because of the workload involved, not because of the North American Free Trade Agreement. The redacted review information still contains detailed reports of methods and results of the clinical trials that the companies performed. As we pointed out in our commentary,[3] that information is not available in the SBD.

Finally, Ms. Gorman says that Health Canada's consultations show that consumer associations and health care providers find the SBD a major step forward. She fails to mention the statement issued by those attending the Health Canada SBD consultation, who endorsed the goal of transparency but stated firmly that "the model for a Summary Basis of Decision put forward at this consultation does not meet these common goals." Groups signing the statement included the Canadian Organization for Rare Diseases, Doctors for Research Integrity, the Hospital Employees Union, the Society for Diabetic Rights, Women and Health Protection, PharmaWatch and the BC Persons With AIDS Society.

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Training pediatricians

A recent item in the CMA Bulletin[1] discussed a proposal from the Royal College of Physicians and Surgeons of Canada (RCPSC) to reduce the number of PGY-1 training programs from approximately 30 to just a few "generalist competency" training streams. This proposal has been presented as an alternative to the "common PGY-1 year," previously discussed as a model to improve medical students' flexibility in deciding on a career path.

The Residents Section of the Canadian Paediatric Society (CPS), representing over 500 pediatric residents in Canada, has a mandate to examine and ensure the quality of pediatric training in Canada. In a recent survey, members of the Residents Section expressed interest in the common PGY-1 year and emphasized the importance of retaining 4 years of pediatric training to allow proper development of the skills of Canada's pediatricians.[2] Allowing for additional flexibility in residency training while encouraging residents' interests in a given specialty during their first year of training might also accomplish the goal of preventing early and later-regretted career decisions. We are therefore pleased that pediatric training will be represented in the new RCPSC model and we look forward to examining the proposal in detail. The goals already identified[2] remain the same: increased flexibility for residents and medical students while maintaining the depth and quantity of pediatric residency training. We continue to oppose any move to shorten training in pediatric specialty rotations. We believe that the medical treatment of children presents unique challenges, disease processes and training goals and that few of these goals would be met during rotation through adult specialties. As such, maintaining a PGY-1 year with focused pediatric rotations and improved flexibility for those residents who wish to transfer to or from a program may represent the ideal solution.

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Tintin in *CMAJ*

The article by Antoine Cyr and associates[1] is a fascinating perspective into the enigmatic delayed development of Tintin. The researchers must be commended for such insightful extrapolation from the limited source material. One wonders about Asterix and Obelix and the possible glandular or other systemic deficiencies that might be contributing to their sizes, body masses and apparent halted development. Perhaps the toxicity of cartoon ink should be independently evaluated.

Brent L. Hay
Calgary, Alta.

Reference
1. Cyr A, Cyr LO, Cyr C. Acquired growth hormone deficiency and hypogonadotropic hypogonadism in a subject with repeated head trauma, or Tintin goes to the neurologist. *CMAJ* 2004;171(12):1433-4.

DOI:10.1503/cmaj.1050008

Enfin une étude transcendante qui permet de soulager mes angoisses existentielles[1]! Enfin j'aurai compris pourquoi je vois douloureusement les ans s'égrener alors que Tintin est gratifié de cette éternelle jeunesse ... Mes parents ne me tapaient pas sur la tête, et leurs stratégies pédagogiques, orientées du bas vers le haut sur mon postérieur, ont-elles eu l'effet de me faire pousser plus rapidement (j'ai commencé à me raser à 13 ans).

Je souhaite ardemment que les augustes chercheurs de cette étude s'attaquent à une autre source d'inconfort planétaire : le secret de la Caramilk!

Yves Lambert
Centres jeunesse de la Montérégie
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Référence
1. Cyr A, Cyr LO, Cyr C. Acquired growth hormone deficiency and hypogonadotropic hypogonadism in a subject with repeated head trauma, or Tintin goes to the neurologist. *JAMC* 2004;171(12):1433-4.

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I read the article by Antoine Cyr and associates[1] with a growing sense of perplexion. For such an eminently qualified research group to miss the nub of the mystery is astounding. The obvious causes of our hero's "Peter Pan-ism" needed no such study, but the greater mystery did: How could Tintin's dog Milou live for 50 years (350 years in canine terms), especially after being shot at least 10 times?

I await the results of further investigation.

Craig D. Baker
Lincoln, England

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With Hergé's approval, Frederic Tuten wrote *Tintin in the New World*,[1] wherein Tintin meets the seductive Clavdia in Peru. One night, "sighs float to the ceiling ... a blue glow emanates from the bed center ... two animals collide and adhere." Tintin is cured!

Young coauthors Antoine Cyr and Louis-Olivier Cyr might wait a few years before trying this book, but I bet their more senior coauthor Claude Cyr