Over the counter and into trouble

My recent involvement in promoting CMA's *New Guide to Prescription and Over-the-Counter Drugs* had me hunting for drugs in the drug store. It was an invaluable experience for me as a physician. If you have not been in a drug store recently, then get to one STAT and walk down the aisles in your patient's shoes.

Over-the-counter drug packaging has been changing drastically, and physicians have not noticed. "Line extension" is here, and the brand names that are part of medical language are no longer the drugs that we think they are.

Line extension is when a drug company takes an old, well-recognized brand name, adds a number, a few letters or a phrase and applies the name to an entirely different drug. Some examples are Anacin 3, which is acetaminophen, and the drugs pictured in Fig. 1.

Drug packaging falls under the Food and Drugs Act. Of particular interest is section 9 (1) of the act, which states that "no person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety."[1]

According to the Bureau of Pharmaceutical Assessment, the federal agency that oversees these drugs, line extension is legal. However, as a representative of the bureau pointed out, it is extremely difficult to change the guidelines for manufacturers unless there have been complaints and harm has been proven.

It seems that there have been no complaints. There is no consumer watchdog group to comment on the increasing number of similar names appearing on the counters.

Spend some time in the drug store soon. Imagine that you are the patient with high blood pressure whose physician just told her to "pick up brand X." Take a good look at the packages on those shelves. Do you feel confident that your patient will buy the drug that you recommend?

Fig. 1: Can you tell the difference? From left to right, Benadryl allergy formula contains diphenhydramine, whereas Benadryl decongestant/allergy contains diphenhydramine plus pseudoephedrine; Chlor-Tripolon regular contains chlorpheniramine, whereas Chlor-Tripolon N.D. (non-drowsy) contains loratadine and pseudoephedrine; Claritin skin itch contains loratadine, whereas Claritin Extra allergy and sinus contains loratadine plus pseudoephedrine.

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Reference
1. *Food and Drugs Act*, RSC 1985, F-27.

Consent for circumcision

I read with interest the article "Bioethics for clinicians: 1. Consent" (*Can Med Assoc J* 1996;155: 177-80), by Dr. Edward Etchells and associates. Unfortunately, the issue of consent for one of the most commonly performed operations in North America — the circumcision of infant boys — remains unclear.

A report by the Committee on Bioethics of the American Academy of Pediatrics casts doubt on whether a physician can ethically perform circumcision on newborns.[1] Neither informed consent nor patient assent apply because a newborn is not competent. Parental permission is acceptable only in situations in which medical intervention is clearly and immediately necessary. Nonessential treatment that can be deferred without substantial risk should be delayed until the child's consent can be obtained.[1] Clearly, neonatal circumcision is nonessential, and it is not recommended by the Canadian Paediatric Society.[2] Even if informed consent could be obtained, studies show that the consent process for neonatal circumcision is nearly always incomplete.[3,4]

Etchells and associates state, "Un-

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der common law, treating a patient without his or her consent constitutes battery, whereas treating a patient on the basis of inadequately informed consent constitutes negligence." Since a newborn cannot give consent, does neonatal circumcision constitute battery? Does the incomplete consent process in neonatal circumcision constitute negligence?

Respect for a patient's autonomy must apply to the weakest among us; otherwise, no one's autonomy can be assured.

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References

1. American Academy of Pediatrics Committee on Bioethics. Informed consent, parental permission, and assent in pediatric practice. *Pediatrics* 1995;95:314-7.
2. Fetus and Newborn Committee, Canadian Paediatric Society. Neonatal circumcision revisited. *Can Med Assoc J* 1996;154:769-80.
3. Christensen-Szalanski JJ, Boyce WT, Harrell H, Gardner MM. Circumcision and informed consent. Is more information always better? *Med Care* 1987;25:856-67.
4. Ciesielski-Carlucci C, Milliken N, Cohen NH. Determinants of decision making for circumcision. *Cambridge Q Healthc Ethics* 1996;5:228-36.

[Three of the authors respond:]

A neonate is incapable of providing consent. As we state in our article, incapacity is not an exception to the requirement for consent, and substitute consent should be sought. If circumcision were performed without substitute consent, this would constitute battery.

In most cases, substitute consent is provided by the neonate's parents. Dr. Howe states that "parental permission is acceptable only in situations in which medical intervention is clearly and immediately necessary." He cites the Committee on Bioethics of the American Academy of Pediatrics, which also suggests that "the pediatrician's responsibilities to his or her patient exist independent of parental desires or proxy consent," and that providers of care to neonates "have ethical and legal duties to their child patients to render competent medical care based on what the patient needs, not what someone else expresses."[1]

These statements suggest that the authority to provide substitute consent for a neonate lies with the clinician rather than the parents. However, this view is inconsistent with existing Canadian legal, ethical and professional standards. The authority to provide substitute consent lies with the parents. Some limits to parental authority have been established through law or professional policy. For example, the Supreme Court of Canada has ruled that parents may not subject their children to nontherapeutic sterilization,[2] and the College of Physicians and Surgeons of Ontario, in its policy on female circumcision, excision and infibulation, states that "the performance of any of these procedures by a physician who is licensed in Ontario will be regarded as professional misconduct."[3] However, there are no established limits to parental authority in regard to consent to male circumcision. The Fetus and Newborn Committee of the Canadian Paediatric Society has recommended that circumcision of male newborns not be routine but that the decision be made based on the social rather than the medical concerns of the parents.[4]

Howe cites a study that showed that parents were unaware of all of the risks and benefits of circumcision. The same study found that most parents did not want to be informed of all of the risks and benefits "and often seemed to resent the physician for presenting [the risks and benefits] to them. In this case, a desire to have a partial disclosure of the medical complications may be a result of the social, traditional, or religious considerations that motivate the request for [circumcision]."[5] On the basis of these observations, it is difficult to conclude that failure to disclose all known risks is negligent.

We suggest that clinicians provide parents with adequate information about the risks, benefits and alternatives that a reasonable person in the parents' position would need to know to make a decision. A nonjudgemental inquiry into the parents' reasons for circumcision may be useful. If the parents' decision is based on strong cultural beliefs and practices, a detailed, impersonal disclosure of all known risks and benefits would probably not be relevant or helpful. However, if the decision is based on personal experience (e.g., the father was circumcised), a detailed discussion of the risks and benefits may be useful in helping the parents come to a decision.

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References

1. American Academy of Pediatrics Committee on Bioethics. Informed consent, parental permission, and assent in pediatric practice. *Pediatrics* 1995;95(5 pt 1):314-7.
2. *Re Eve*, [1986] 2 SCR 388.
3. *Female circumcision, excision, and infibulation*. Toronto: College of Physicians and Surgeons of Ontario, 1992. College notices, no 25.
4. Fetus and Newborn Committee, Canadian Pediatrics Society. Neonatal circumcision revisited. *Can Med Assoc J* 1996;154:769-80.
5. Christensen-Szalanski JJ, Boyce WT, Harrell H, Gardner MM. Circumcision and informed consent. Is more information always better? *Med Care* 1987;25:856-67.