sponsibilities of the FDA, drug manufacturers, and clinicians to provide the drug information.

One issue raised concerns the possible impact of information on consumers' peace of mind. Committee member Jacobi stated that, if effects are only short term, there is no need to put anything "scary" into the package insert. Committee member Sugioka disagreed, noting that informed parents are less alarmed than uninformed parents when adverse effects do appear.

I then noted that, when an approved drug is used for a nonapproved purpose, its status reverts to "investigational," that is, the drug is being used experimentally. For example, mepivacaine (Carbocaine) is a relatively new local anesthetic agent frequently used in obstetrics, but it is unapproved for that purpose. When it is used for anesthesia during childbirth, that birth literally becomes an experiment, and the mother and infant become experimental subjects. Under current Department of Health, Education, and Welfare guidelines for protection of the rights of human subjects, the physician-experimenter is required to disclose all information that bears upon the mother's giving informed consent for her own participation and proxy consent for her unborn child's participation (*23*). Thus, the mother is entitled to drug information both on moral and on legal grounds.

Committee member Matanoski raised the issue of fiduciary trust and consumer information. She pointed out that, in the absence of information, patients assume the drugs they receive are nonexperimental and risk-free. She drew the committee's attention to the fact that its motion disclaiming long-term effects does not mean they don't exist, but rather that current data on long-term effects are insufficient. She stressed the importance of adding such a statement to drug labels so that consumers will not assume that the absence of information means the drug is safe (*24*).

It was also pointed out that increasing demands by patient-consumers for drug information (*25*) and participation in decision-making (*26*) is reflected in recently passed and pending legislation and in recent judicial decisions. For example, the state of New York passed a law, effective 1 September 1978, requiring physicians and nurse-midwives to inform pregnant women of all drugs to be used during pregnancy and delivery and of their effects on mother and child. Currently pending New York State legislation specifies 13 separate points of information to be given pregnant women. Legislation is also pending before the U.S. Senate (S. 865) and House of Representatives (H.R. 3444) that ensures the right of individuals to obtain copies of their medical care facility records. The state of California is considering adoption of a regulation requiring that certain categories of over-the-counter drugs carry labels encouraging caution in use of the drug by pregnant and nursing women. In the state of New York, two recent Court of Appeals decisions (*27*) found physicians negligent in failing to advise, or advise accurately, the pregnant women who consulted them to obtain such information.

In connection with lawsuits, I reminded the committee that providing patients with information is the clinician's best defense against litigation, since the extent to which the patient herself accepts responsibility in deciding to consume drugs is the extent to which the physician is relieved of that responsibility and is therefore less vulnerable to suits for malpractice, negligence in providing information, and failure to obtain informed consent for experimentation.

Despite its agreement that short-term drug effects have been demonstrated in infants, the committee was not persuaded by the arguments in favor of providing consumers with this information. Chairperson Burnell R. Brown, Jr., created a subcommittee to study the matter.

YVONNE BRACKBILL
Department of Psychology, University of Florida, Gainesville 32611

References and Notes

1. Great Britain and Japan already have legislation requiring behavioral teratological testing of new drugs before marketing.
2. B. R. Fink, Ed., *Toxicity of Anesthetics* (Williams and Wilkins, Baltimore, 1968). For a review of antimitotic effects on plants of anesthetics, sedatives, narcotics, and tranquilizers, see N. B. Andersen, *Acta Anaesthesiol. Scand. Suppl.* **10** (No. 22) (1966).
3. Notwithstanding the implication of R. E. Myers and S. E. Myers [*Am. J. Obstet. Gynecol.* **133**, 83 (1979)], based on histological and post-strangulation survival time in wild rhesus monkeys, that barbiturates are good for human mothers and babies (see also R. E. Kron and Y. Brackbill, unpublished manuscript), and the assertion of D. H. Ralston and S. M. Shnider [*Anesthesiology* **48**, 53 (1978)], based on Canadian data as yet unanalyzed epidemiologically or statistically [Ontario Perinatal Mortality Study Committee, *Second Report of the Perinatal Mortality Study in Ten University Teaching Hospitals* (Department of Health, Toronto, 1967)] that obstetrical anesthesia reduces maternal mortality.
4. E. Conway and Y. Brackbill, *Monogr. Soc. Res. Child Dev.* **35** (No. 137), 24 (1970).
5. Y. Brackbill, J. Kane, R. L. Manniello, D. Abramson, *Anesthesiology* **40**, 116 (1974); *Am. J. Obstet. Gynecol.* **118**, 377 (1974); A. L. VanderMaelen, M. E. Strauss, R. H. Starr, Jr., *Dev. Psychol.* **11**, 711 (1975).
6. T. Moreau and H. G. Birch, *Dev. Med. Child Neurol.* **16**, 612 (1974); Y. Brackbill, *Dev. Psychobiol.* **9**, 353 (1976).
7. P. C. Wiener, M. I. J. Hogg, M. Rosen, *Br. Med. J.* **2**, 228 (1977).
8. S. L. Friedman, Y. Brackbill, A. J. Caron, R. F. Caron, *Merrill-Palmer Q.* **24**, 111 (1978).
9. S. Turner and A. MacFarlane, *Dev. Med. Child Neurol.* **20**, 727 (1978).
10. S. Broman and Y. Brackbill, in preparation.
11. J. G. Hughes, B. Ehemann, V. A. Brown, *Am. J. Dis. Child.* **76**, 626 (1948); J. G. Hughes, F. S. Hill, C. R. Green, B. C. Davis, *ibid.* **79**, 996 (1950); A. D. Borgstedt and M. G. Rosen, *ibid.* **115**, 21 (1968); K. R. Brower, D. H. Crowell, P. Leung, T. Cashman, *Anesth. Analg.* **57**, 303 (1978).
12. T. B. Brazelton, *J. Pediatr.* **58**, 513 (1961); R. E. Kron, M. Stein, K. E. Goddard, *Pediatrics* **37**, 1012 (1966); J. Dubignon, D. Campbell, M. Curtis, M. Partingnon, *Child Dev.* **40**, 1107 (1969); H. Kraemer, A. Korner, E. Thoman, *Dev. Psychol.* **6**, 128 (1972); R. Hodgkinson, C. N. Wang, G. F. Marx, *Anaesthesia* **31**, 143 (1976).
13. M. P. M. Richards and J. F. Bernal, in *Ethological Studies of Child Behaviour*, N. B. Jones, Ed. (Cambridge Univ. Press, Cambridge, England, 1971), pp. 175–197.
14. R. Hodgkinson, G. F. Marx, S. S. Kim, N. I. Miclat, paper presented at the 50th Congress, International Anesthesia Research Society, Phoenix, Ariz., March 1976.
15. K. Standley, A. B. Soule III, S. A. Copans, M. S. Duchowny, *Science* **186**, 634 (1974); G. Stechler, *ibid.* **144**, 315 (1964).
16. M. K. Aleksandrowicz and D. R. Aleksandrowicz, *Child Dev.* **45**, 935 (1974); J. W. Scanlon, W. U. Brown, Jr., J. B. Weiss, M. H. Alper, *Anesthesiology* **40**, 121 (1974).
17. R. N. Emde, J. Swedberg, B. Suzuki, *Arch. Gen. Psychiatr.* **32**, 780 (1975).
18. E. Tronick, S. Wise, H. Als, L. Adamson, J. Scanlon, T. B. Brazelton, *Pediatrics* **58**, 94 (1976).
19. R. K. Yang, A. R. Zweig, T. C. Douthitt, E. J. Federman, *Dev. Psychol.* **12**, 6 (1976).
20. R. J. Palahniuk, J. Scatliff, D. Biehl, W. Wiebe, K. Sankaran, *Can. Anaesth. Soc. J.* **24**, 586 (1977); R. Hodgkinson, M. Bhatt, G. Grewal, G. F. Marx, *Pediatrics* **62**, 294 (1978); R. Hodgkinson, M. Bhatt, C. N. Wang, *Can. Anaesth. Soc. J.* **25**, 405 (1978); T. B. Brazelton, Y. Tryphonopoulou, B. M. Lester, *Pediatrics* **63**, 279 (1979); B. M. Lester, H. Als, T. B. Brazelton, unpublished manuscript.
21. F. D. Horowitz, J. Ashton, R. Culp, E. Gaddis, S. Levin, B. Reichmann, *Child Dev.* **48**, 1607 (1977).
22. M. F. Johnson, G. W. Pledger, S. D. Dubey, unpublished manuscript; R. B. D'Agostino, in *Minutes of the Meeting of the Anesthetic and Life Support Drug Advisory Committee* (Food and Drug Administration, Rockville, Md., 20 March 1979), p. 111.
23. C. Fried, *Medical Experimentation: Personal Integrity and Social Policy* (American Elsevier, New York, 1974); *Fed. Reg.* (3 November 1978), part 4, p. 51559.
24. Current examples of approved drugs used for unapproved purposes during labor are adrenergic beta receptor agonists [for example, isoxsuprine HCl (Vasodilan)] when administered to inhibit labor and adrenal cortex steroids [for example, dexamethasone (Decadron)] when administered to accelerate surfacant-producing systems in the lungs of preterm fetuses. [For a more detailed discussion, see Y. Brackbill, in *Pre-term and Post-term Births: Relevance to Optimal Psychological Development*, S. L. Friedman and M. Sigman, Eds. (Academic Press, New York, in press).]
25. S. C. Rosenberg, *Hosp. Formul. Manage.* **6**, 14 (1971); L. Fleckenstein, P. Joubert, R. Lawrence, B. Patsner, J. M. Mazzullo, L. Lasagna, *J. Am. Med. Assoc.* **235**, 1331 (1976); L. A. Morris, M. Mazis, E. Gordon, *ibid.* **238**, 2504 (1977); L. A. Morris and J. A. Halperin, *Am. J. Public Health* **69**, 47 (1979).
26. Between 1975 and 1978, the number of "free-standing" birth centers in the United States increased from 5 to 50. Between 1975 and 1979, home deliveries increased from 0.7 percent to 2 percent of all deliveries (D. Stewart, personal communication). Between 1968 and 1975, the number of couples enrolled in Lamaze prepared childbirth classes increased from 8500 to 2.8 million (M. Gandy, personal communication).
27. Becker *vs.* Schwartz, **46** *N.Y. 2nd Ser.*, 401 (1979); Park *vs.* Chessin, *ibid.*

Erratum: In the article "Nuclear risks: Still uncertain" (News and Comment, 18 May, p. 714), in the fourth paragraph, the sentence, "If one assumes that 40 gigawatts are produced a year, as was the case in 1975 . . ., then the nuclear industry is causing *two* cancer deaths a year," should have read, "*20* cancer deaths a year."