

that every baby born in Massachusetts (not just those born to families who could afford supplemental testing) would have the opportunity to access screening services beyond the 10 disorders for which all babies were already screened on a mandatory basis, and, second, to evaluate the efficacy of newborn screening and early intervention for a particular set of 20 disorders (1).

The statement that parents "aren't asked for consent" for entering these pilot studies is not correct. The Human Subjects Committees that reviewed the protocols determined that the pilot screening constituted a "human research study" requiring informed consent. These committees accepted an alternative mechanism (verbal consent) conditional to a protocol in which the nurses ask all parents for their decisions about participation in the pilots after parents have been informed about the pilots through a brochure (see also <http://www.umassmed.edu/nbs/>).

Marshall also says that Massachusetts "gathers more data than it reports, informing parents only of disorders that are considered treatable," implying that the New England Newborn Screening Program (NENSP) withholds testing results on babies with untreatable disorders. This is not true. In Mas-

sachusetts, every out-of-range result is reported to the specific healthcare provider for the baby. This is true for results of both mandated and pilot tests, and indeed, for the pilot tests, this reporting is a requirement of the Human Subjects Committees.

The article focuses on metabolic disorders detectable by tandem mass spectrometry, but Marshall briefly mentions screening for cystic fibrosis [which was first implemented in the United States by Colorado and Wisconsin (2)]. Therefore, we also note that the second pilot study in Massachusetts provides for cystic fibrosis screening on the same blood sample. To our knowledge, ours was the first program to include DNA analysis for 27 mutations on all babies with elevated immunoreactive trypsinogen screens. Genetic counseling is incorporated into the protocol.

Finally, as Marshall mentions, the NENSP provides testing services for states other than Massachusetts. Maine now offers the same expanded list of metabolic tests as Massachusetts (bringing their total number to 28 disorders, not 9). Indications are that other New England states will avail themselves of our expanded testing capabilities shortly.

ANNE MARIE COMEAU, ROGER B. EATON
New England Newborn Screening Program, Univer-

sity of Massachusetts Medical School, Jamaica Plain, MA 02130, USA. E-mail: AnneComeau@state.ma.us, RogerEaton@state.ma.us

References and Notes

1. K. Atkinson *et al.*, *Public Health Rep.*, in press.
2. K. B. Hammond, S. H. Abman, R. J. Sokol, F. J. Accurso, *N. Engl. J. Med.* **325**, 769 (1991); P. M. Farrell, R. A. Aronson, G. Hoffman, R. H. Laessig, *Wis. Med. J.* **93**, 415 (1994).

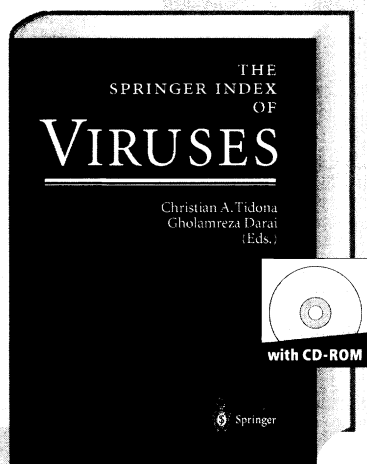
Response

THE FIGURE MENTIONED BY COMEAU AND Eaton on page 2274 of my article is a summary of mandated state programs, not pilot research efforts like those offered in Massachusetts and Maine. Although Massachusetts has an excellent process for informing parents about newborn screening, it does not obtain signed consent as Maryland does. I regret any suggestion that Massachusetts withholds important data from parents.

ELIOT MARSHALL

CORRECTIONS AND CLARIFICATIONS

BREVIA: "Miniature genome in the marine chordate *Oikopleura dioica*" by H.-C. Seo *et al.* (21 Dec., p. 2506). In the affiliations list, the name "Sars" of the Sars Centre for Marine Molecular Biology in Bergen, Norway, was misspelled.



Christian A. Tidona; Gholamreza Darai (Eds.)

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