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Editor's note: Drs. Davis and Shinefield and Mr. Fireman report having received research grants from Wyeth–Ayerst, maker of the referenced pneumococcal conjugate vaccine.

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THE AUTHORS REPLY: We are gratified to learn that there was only a small, statistically nonsignificant excess of asthma episodes among recipients of the 7-valent conjugate pneumococcal vaccine in the northern California study.¹ Differences in study design, follow-up, and detection of cases make direct comparisons of rates difficult to interpret. The administration of meningococcal conjugate in controls and the continued inclusion in the control group of the 23 percent of controls who received pneumococcal vaccine after the completion of the trial may have reduced the strength of the association between vaccination and asthma in that study. On the assumption of a follow-up time per group of 107,000 person-years in the California study,¹ the intention-

to-treat rates of asthma episodes in that study were 760 per 100,000 person-years among vaccinees and 707 per 100,000 person-years among controls (an excess of 53 episodes per 100,000 person-years). In Soweto, South Africa, there were 128 episodes per 100,000 person-years in vaccinees and 71 per 100,000 in controls (an excess of 57 episodes per 100,000 person-years). The higher rates in California may be due to increased identification of outpatient diagnoses of asthma (the Soweto data include only patients in whom asthma was diagnosed at the hospital) and higher rates of asthma among older children included in the California follow-up study. Attack rates of asthma continue to be monitored in our trial, and these data suggest that they should continue to be monitored in post-marketing surveillance and in ongoing trials of pneumococcal conjugate vaccine in the Czech and Slovak Republics, the Gambia, and the Philippines.

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The Charitable Trust as a Model for Genomic Biobanks

TO THE EDITOR: Biobanks are a crucial resource for the advancement of genomic discoveries into clinical care. A charitable-trust model for biobanks, proposed by Winickoff and Winickoff (Sept. 18 issue),¹ has merit. However, the premise that this model is the most effective way to protect patients' interests is untested. For-profit organizations can be structured with identical safeguards; Ardais and other corporations have these as well as additional safeguards. Although a charitable-trust model may be interesting conceptually, we believe it would face substantial challenges in overcoming the financial and organizational difficulties involved in effectively managing a biobank to protect patients' interests and promote society's interests in research, as well

as substantial challenges in managing potential conflict-of-interest and privacy issues.^{2,3} For-profit models can be altruistic while receiving due compensation for the considerable investment and effort required to run an ethical, efficient biobank.

The structures and procedures of Ardais⁴ start from the National Bioethics Advisory Commission's recommendations⁵; result from numerous consultations with scientific, community, medical, government, and academic leaders, as well as patient groups, clergy, and bioethicists; and put the patient or donor first. Institutional review boards approve all Ardais-sponsored collection activities, proposed research, sponsors, and principal investigators, and a bioethics advisory board reports to the board of

directors to ensure independence. Most important, the medical center–Ardais collaboration protects patients through detailed, auditable data-access protocols; an informed-consent process carried out by dedicated nurses using full-disclosure forms; procedures whereby all identified materials and information are handled solely by members of the medical-center staff; and de-identification of data. In summary, our “chain of trust” model ensures privacy, confidentiality, and information at each step, from patient to doctor, to medical center, to Ardais, and to researcher. The recent literature and the experience of Ardais confirm that this model protects patients’ interests and wishes as we seek better health care for all.⁶

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THE AUTHORS REPLY: Though we applaud the desire of Ardais to implement strong privacy protections in its biobanking model, the problems of autonomy, entitlement, and governance outlined in our article remain troublesome. For example, the structure

described by Otten and colleagues contains no mechanism for informing donors or the hospital’s institutional review board about the specific uses of samples and contains no mechanism for group consent when, for example, ethnic groups are studied, even though both of these mechanisms have been recommended by the National Bioethics Advisory Commission.¹ The structure they describe also denies the donors rights to any new treatment developed from their donations, even when they cannot afford such treatment, and it does not always adequately represent the medical and financial value of donated tissue and records on the consent form.² Can this sort of process really be said to “put the patient or donor first”?

Academic medical centers face difficult choices in deciding how to handle the new market value of donated tissue and medical information. We argue that a collaborative model, embodied in a charitable-trust structure, is economically feasible, socially preferable, and scientifically advantageous. As the Framingham Study amply demonstrates, people and their good will — not just their samples or health records — are the real resource.³ We are cognizant that our proposal goes against the grain of privatization in the medical-research arena, but our proposal does not work against market logic — it only allows the donor community to maximize the altruistic value of its gift.

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Staging of Lung Cancer with Integrated PET–CT

TO THE EDITOR: Lardinois et al. (June 19 issue)¹ state that tumor and nodal staging is more accurate with integrated positron-emission tomography and computed tomography (PET–CT) than with CT or PET alone. In their study, PET alone was visually corre-

lated with CT, which is the standard of practice for reading PET scans. However, Lardinois et al. used non–diagnostic-quality, non–contrast-enhanced CT, which is not the type generally used for correlation at most PET centers. It is not surprising that PET–