Letters to the Editor

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Could the Childhood Vaccine Act Be Bad?

To the Editor.—

The commentary[1] in the August 1992 issue by Caroline B. Hall and Neal Halsey on the control of hepatitis B answers many of the questions that have been raised regarding the recommendation that all infants receive this vaccine. It is extremely well-done and should reassure those physicians who have encountered doubts regarding the value and justification for such a program. However, there is one issue raised in their very last interrogatory that needs further consideration. The American Academy of Pediatrics (AAP) in the design of its "Childhood Vaccine Act" may inadvertently have called for an initiative which could have an unanticipated effect of reversing the recent progress and acceleration of vaccine availability and innovation.

In the 1970s in this country we were faced with a perilous supply system with sole manufacturers (actually only two) for all the recommended and mandated vaccines for infants and children. A production problem by one company resulted in a crisis period when diphtheria-tetanus toxoid-pertussis (DTP) was in such short supply that priorities had to be established for rationing the available vaccine. Fortunately the 1980s have seen a reversal of this situation; many new American as well as several foreign firms have entered the US vaccine market as new technology has accelerated the development of improved old as well as new vaccines. For the latter, there have been at least two or three different companies which produce these vaccines. The resultant competitive situation has been favorable to children and to the programs in general with an acceleration of the availability of improved antigens and a beginning decrease in their prices (eg, hepatitis B vaccine).

Why am I concerned that the "Childhood Vaccine Act" of the AAP might hamper this currently favorable situation? If all vaccines were bought on annual single federal contracts, as public supplies are now through the Centers for Disease Control, there would be only one successful bidder, effectively closing the market to any of the unsuccessful ones for at least the next 12 months. This would provide a very marked disincentive to those firms which are now investing millions of dollars in vaccine research and clinical trials. If they are unable to see the possibility of reclaiming their investment and providing some profit to their companies, corporate boards of directors will very quickly again move out of the vaccine business.

Yes, the cost of vaccines has increased over the past 20 years, and the numbers recommended during the first 15 months of life place a heavy burden on parents who pay out of their own pockets. The answer, however, would not seem to be a monolithic vaccine program such as that engendered by the AAP's "Childhood Vaccine Act" but an aggressive approach to the appropriate funding of preventive medicine programs (including vaccines) by health insurance, health maintenance organizations, employee benefits, etc.

Neither I nor any member of my family possesses stock in any of the pharmaceutical firms. But as one who has spent his professional lifetime being an advocate on behalf of children's vaccines, and as one who views with optimism the current scene with many research and development firms actively involved, I am deeply concerned that a single purchase contract for any of our childhood vaccines would result in the rapid disappearance from the field of those new players of recent years as well as a number of the foreign firms who are now also moving into the American market. We need desperately for every American infant to be immunized age-appropriately, but not by a mechanism of sole purchase. We need a health care system that ensures every child's receipt of the recommended immunizations while enjoying the benefits and availability of new, improved, and cost-appropriate vaccines.

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In Reply.—

The immediate problem of cost is certainly a barrier to the acceptability of the hepatitis B universal infant and adolescent immunization program. Whereas I agree that the mechanism of sole purchase may result in the detrimental and devastating effects you suggest, is it not possible to suggest that various groups of physicians or clinics combine to seek bulk purchase rates from all manufacturers? Could we encourage the various manufacturers to offer lowered bulk purchase rates, concurrently encouraging and sustaining commercial competitiveness? My assumption would be that the lowered bulk purchase price would not be detrimental to the manufacturer and their needed resources for production and research, as costs could be saved in distribution, sales, and greater use of the vaccines.

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Mythology of Lead Poisoning

To the Editor.—

I read with interest the recent paper by Drs Glotzer and Bauchner and enjoyed reading the excellent commentary by Drs Needleman and Jackson.[1,2] It is stated correctly that "the overall consensus is that elevated lead burdens in childhood . . . can result in adverse neurodevelopmental outcomes." Of even more concern is the detrimental effect of lead on developing and growing nervous systems: behavioral and learning disorders have been attributed to lead exposure in utero and in early infancy. Apart from these long-term sequelae, elevated blood lead level can actually increase the vulnerability to oxygen toxicity in neonates, because it has particular affinity for sulfhydryl groups, decreases serum ceruloplasmin, and may impair heme metabolism, disturbing the otherwise limited antioxidant protective mechanisms.[3]

On the basis of these findings, it seems reasonable to introduce chelation protocol for newborns with elevated lead levels to prevent both free radical damage and the late onset of neurological illness caused by subclinical toxicity of lead. In the neonatal period it is relatively easy to implement lead screening because blood from the umbilical cord is available at delivery.

D-Penicillamine (DPA) "would be an appropriate or the preferred chelating agent" for the treatment of lead poisoning in neonates too, presuming that this protocol "begins and ends with removing lead from the child's environment."

Our DPA research embraces a period of more than 20 years. In our pediatric departments we have had experiences in the DPA therapy of neonatal jaundice since 1973. In several papers we have reported that the use of this drug in premature infants is associated with a marked decrease in the incidence of severe retrolental fibroplasia. Infants were given three daily doses of 100 mg of DPA/kg body weight intravenously for 3 days in treating neonatal hyperbilirubinemia. Subsequently, the very low birth weight infants continued to receive a dose of 50 mg/kg of DPA once daily intravenously until the end of the second week of life to prevent retinopathy.[4] In the last 19 years, we have treated approximately 20 000 term and preterm infants with DPA in Hungary, observing neither acute nor long-term adverse effects nor any late complications during several years follow-up. The drug has no bilirubin-displacing effect on the albumin-bilirubin complex, and none of the side effects described in adults have ever been encountered in our patients.[5–7]

I believe that these clinical observations provide sufficient evidence for a controlled trial, which we intend to perform in the immediate future, to determine the effectiveness of DPA in reducing elevated blood lead level in newborns and to analyze results relating to the long-term outcome of these babies.

I look forward to reading about the comments of pediatricians familiar with lead-related issues.

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To the Editor.—

The commentary offered by Needleman and Jackson[1] has raised some interesting points for discussion regarding the mythology surrounding the issue of lead poisoning and its treatment. Whereas the opening statement of the authors suggests that standards of practice are falling behind the scientific understanding of lead, the article under discussion by Glotzer and Bauchner makes it clear that both the science and standards of practice are very much lacking in the area of treatment for low level lead exposure. For a number of years it appears that our research efforts have focused on the impact of lead on children, and studies regarding therapeutic intervention have lagged well behind. It is time to place an emphasis not only on preventive aspects, but also to gain prospectively information regarding the relative risks and benefits of treatment for low level lead exposure, particularly with newer chelating agents such as succimer.

A second and perhaps more troublesome aspect of this article is the call-to-arms for funding to begin the deleading process for housing in the United States. Certainly tremendous strides have been made by the reduction of lead in gasoline and improvements in a number of factors such as nutrition. The interaction of lead with environmental factors such as nutrition and child rearing practices has been a subject of over-debate, perhaps. One consistent thread in all the studies relating intelligence to lead has been the finding that maternal and socioeconomic factors are strong predictors of intellectual outcome. A recent study published in abstract[3] suggests that Head Start Programs can obviate the impact of lead on intellectual development. This study will require scrutiny after peer review publication but it does support an idea that seems generally believed in the medical community: preventive health programs such as Head Start and The Special Supplemental Food Program for Women, Infants, and Children (WIC) remain our best lines of defense against the multifactorial effects of poverty on intellectual development. Historically, our government has taken the approach of reacting to public pressure to fund interventional programs by shifting dollars from existing programs. This may be by subtly changing eligibility requirements or allowing the effects of inflation to gradually erode the numbers of individuals eligible for these programs. As we consider the needs of this nation to undertake lead abatement, it is absolutely critical that we guard against the "band wagon" approach that may undermine programs likely to have a greater impact on improving children's health than lead abatement.

A further issue not addressed by this commentary is that of regional priorities. Although we must all accept responsibility for being citizens of the world and nation, it is also important to retain some advocacy for the children of our region. In response to the Centers for Disease Control (CDC) guidelines,[4] we were concerned that a large amount of current resources might be diverted toward lead screening in a state where virtually no lead screening currently is undertaken. To assess our needs we undertook a survey of children in high risk areas of our inner city. Children from lower socioeconomic status living in parts of the city with older construction were screened after informed consent was obtained. In 261 children screened to date, we have failed to identify any children with a blood lead in excess of 15 μg/dL and only 4.2% in excess of 10 μg/dL. Coincidentally, during the time of the screening study, public health officials were restricting school recess activities to indoors because of concerns regarding the air quality in our region. The recent CDC guidelines state that all US children should be screened for lead "...unless it can be shown that the community in which these children live does not have a childhood lead poisoning problem."[4] It is unclear to us, according to this statement, whether we can abandon routine screening in our area based on our findings. The decision is not trivial as budgetary constraints will likely require shifting of the costs of screening from existing programs.

In summary, the challenge for the individual child is to develop effective and safe strategies for dealing with heavy body burdens of lead. Our public health challenge is to develop an overall program to improve the health of children in poverty rather than allowing a single issue to take precedence over others. A third challenge is to allow public policy to reflect regional priorities to avoid divisive arguments within the community of pediatricians.

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