Did A Rising Tide Lift All Boats? The NIH Budget And Pediatric Research Portfolio

Although funding for pediatric research increased from FY 1998 to FY 2003, its proportion of total NIH spending went down.

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ABSTRACT: This paper examines National Institutes of Health (NIH) pediatric research spending in absolute terms and relative to the doubling of the NIH overall budget between fiscal years 1998 and 2003. Pediatric spending increased by an average annual rate of 12.8 percent during the doubling period (almost on par with the NIH average annual growth rate of 14.7 percent). However, the proportion of the total NIH budget devoted to the pediatric portfolio declined from 12.3 to 11.3 percent. We offer recommendations for implementing existing commitments to strengthen the pediatric research portfolio and to protect the gains of the doubling period.

THE ALLOCATION OF FEDERAL DOLLARS for the support of dependent populations has become a major policy concern. Much of the previous attention focused on the economic well-being of children and the elderly—in particular, the declining impoverishment of the elderly and the growing poverty among children over the past half-century.[1] Trends in federal spending on both groups, reported in absolute terms and relative to each other, show evidence of growing intergenerational inequity, leading to increased concern about whether the projected growth in federal spending on health programs for the elderly will come at the expense of credible commitments to programs for children.[2]

With that broader debate in mind, we report on the status of the National Institutes of Health (NIH) pediatric research portfolio in absolute terms and relative to the overall NIH budget during the doubling period (fiscal years 1998–2003). We avoid framing NIH appropriations in terms of competition between children

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and adults for scarce biomedical research dollars. Instead, we ask whether a rising budgetary tide lifted all boats: How has the pediatric portfolio fared in the recent era of rapid overall NIH growth?

Congress has expressed particular interest in the status of pediatric spending and specifically requested that NIH develop performance indicators to measure its progress toward achieving a stronger pediatric portfolio. This paper is a systematic effort to examine the status of the pediatric portfolio during the doubling period, when the overall NIH budget increased by an actual cumulative growth rate of 98.3 percent (75.7 percent in inflation-adjusted terms).

We also highlight the status of the pediatric portfolio within four institutes: National Institute of Child Health and Human Development (NICHD); National Institute of Mental Health (NIMH); National Institute of Neurological Diseases and Stroke (NINDS); and National Human Genome Research Institute (NHGRI). We use these examples to illustrate the benefits of quantifying pediatric spending to assess progress as well as the dangers of drawing conclusions about limited pediatric spending without accounting for the benefits of biomedical research, which are often spread over subpopulations in undifferentiated ways.

Pessimistic assumptions about future annual growth in federal discretionary spending will prove important for understanding the status of the pediatric portfolio over the next decade. The dramatic increase in pediatric spending has permitted NIH to fund record levels of new research and therefore to accumulate a sizable commitment base. We conclude with a set of recommendations for implementing existing commitments to strengthen the NIH pediatric research portfolio and to protect the gains of the doubling period.

Background

■ **Federal research efforts.** Numerous federal research efforts focused on child health during the 1990s.[3] Concurrently, there was increasing congressional concern about the "inadequate attention and resources" that NIH was devoting to pediatric research.[4] In response, NIH issued its first pediatric research report in 1996, which contained a stated commitment "to use a variety of methods" to evaluate Institutes and Centers' (ICs') progress "in achieving a strengthened portfolio in research on children."[5] Congress also urged NIH to establish guidelines for including children in all clinical research trials. NICHD and the American Academy of Pediatrics concurred, and in 1998 NIH released formal guidelines to this end.[6]

■ **Mental health.** Increased attention also was focused on child and adolescent mental health in the 1990s. Pediatric research lagged behind that in other subspecialties, largely because of pharmaceutical companies' indifference to marketing psychotropic drugs to children and concerns about the ethics of including children in research. Childhood psychopathology emphasized psychodynamic analysis, and, thus, biomedical and psychopharmacologic research was considered unnecessary, potentially dangerous to children, and misguided.[7]

■ **The Children's Health Act.** With the bipartisan Children's Health Act (CHA) of 2000, Congress authorized expanded research on and services for childhood and prenatal health problems. Congress directed NICHD to plan and conduct the National Children's Study (NCS), and the president's FY 2005 budget includes $12 million for the NCS, $7.5 million to come from NICHD's budget. Congress also established a Pediatric Research Initiative (PRI), to increase support for pediatric research, strengthen collaborative efforts among ICs, speed the development of pediatric clinical drug trials, and invest in training pediatric researchers. Congress authorized $50 million for the NIH Office of the Director (OD) to support the PRI in FY 2001. However, because the CHA became effective after the FY 2001 appropriations cycle, that fiscal year's appropriations did not include PRI funding. In FY 2002 the OD awarded $5 million, half of the Director's Discretionary Fund, for the ICs' pediatric proposals. Other federal developments during this period included an NIH Inter-Institute Committee on Pediatric Research to encourage the development of new initiatives and collaboration across ICs; an Interagency Autism Coordinating Committee; and Autism Research Centers of Excellence.

The CHA requires NIH to report annually to Congress on the total funds that ICs award for pediatric research. The FY 2002 and 2003 PRI report highlights initiatives and explains the research and clinical significance of collaboration and expanding the pediatric portfolio with supplemental discretionary dollars.[8]

Measuring The Pediatric Research Portfolio

High annual NIH growth rates have been accompanied by intensified interest in the internal allocation of funds. The selection of research program areas to be funded remains the responsibility of NIH, based on a system of investigator-initiated projects selected through merit-based peer review.[9] Many factors are considered, including public health needs and scientific opportunity.[10] Prior efforts to analyze spending focused on the flow of dollars to academic pediatric departments rather than on the pediatric portfolio.[11]

In this study, we did not attempt to determine whether the amount of funding that NIH awards for research on particular pediatric diseases was commensurate with measures of the burden of disease (prevalence, incidence, use of resources and costs, mortality, morbidity, and so forth). We also recognize that the degree of match between funding and disease burden is sensitive to the measure being used and that advocacy groups for specific diseases can emphasize data derived via a variety of different methods.[12] NIH has an obligation to respond to public health needs, but calculating these needs is very difficult, and there is not always a clear correlation between spending and outcomes.[13]

NIH defines pediatric research as "all categories of biomedical research (basic, clinical, epidemiological, behavioral, prevention, treatment, diagnosis, as well as outcomes and health services) that relate to diseases, conditions, or the health/development of [people] up to age 21."[14] In FY 1995 the NIH Budget Office directed

all ICs to report total funding (including grants, contracts, and intramural support) related to pediatric disease and cross-cutting research areas. The office reports annual spending by disease categories and populations.

The Budget Office provided specific data on congressional appropriations by IC for FY 1993–2004; pediatric spending by IC for FY 1993–2003; and overall estimates for FY 2005 and pediatric spending estimates for FY 2004 and FY 2005. The dollars reported for these years reflect each IC's estimates of how much pediatric research it is likely to fund based on overall budget increases and any new initiatives. The figures reported by some ICs for FY 1993 and FY 1994 are direct costs only. The NIH OD may provide seed money or may supplement IC funding, but the same funding is not counted in both the OD's and the IC's spending.

Because the "doubling period" is referred to in nominal dollars, we report growth rates in nominal terms unless otherwise noted. For future estimates, we calculated the estimated percentage change from FY 2004 to FY 2005 for the NIH budget and the pediatric portfolio, and report projections based on the assumption that the annual rates of change will remain constant through FY 2008.

The NIH Budget And Pediatric Portfolio, FY 1998–2003

■ **The budget.** Congress doubled the NIH budget between FY 1998 and FY 2003 (to $27.1 billion), an extraordinary commitment to accelerate appropriations, which over the previous four decades had doubled every ten years. NIH funding had increased at an average annual rate of 9 percent between FY 1971 and FY 1998.[15] In FY 1994, except for a double-digit increase for AIDS and breast cancer research, the NIH budget was static or contracting in real dollars.[16] It increased by an average annual rate of 5.8 percent between FY 1993 and FY 1997. The pediatric portfolio increased by an average annual rate of 4.7 percent.

■ **Pediatric spending.** During the doubling period, NIH appropriations increased at an average annual rate of 14.7 percent. Pediatric spending increased by an average annual rate of 12.8 percent—very close to NIH's overall average annual rate. The most dramatic increase in pediatric spending occurred between FY 1998 and FY 2003: a growth rate of 82.4 percent in nominal terms (61.6 percent in inflation-adjusted terms) (Exhibit 1). A rising budgetary tide seems to have lifted all boats: The pediatric portfolio increased dramatically (almost on par with the NIH budget) during the doubling period.

In FY 2000 the pediatric portfolio's 18 percent growth rate exceeded the NIH rate of 14 percent. Only in FY 2003 did the pediatric growth rate (8.4 percent) fall well below NIH's 16.2 percent annual rate of growth. The FY 2003 shift to bioterrorism funding likely reduced awards to pediatric areas compared with earlier fiscal years. In FY 2004 the two growth rates converged (Exhibit 1).

Although the data show that pediatric research enjoyed a share of the benefits of the doubling period, the proportion of the NIH budget devoted to the pediatric portfolio declined slightly, from 12.3 to 11.3 percent, down from 13.1 percent in

EXHIBIT 1
National Institutes Of Health (NIH) Budget And Pediatric Research Portfolio, Fiscal Years 1993–2005

Fiscal year	Pediatric portfolio ($ billions)	NIH total budget ($ billions)	Pediatric portfolio as percent of NIH budget	Pediatric portfolio, annual percent change	NIH budget, annual percent change
1993	1.35	10.3	13.1	–	–
1994	1.55	10.9	14.1	14.7	5.9
1995	1.44	11.3	12.7	−7.0	3.3
1996	1.51	11.9	12.7	5.0	5.6
1997	1.60	12.7	12.6	6.1	6.8
1998	1.68	13.6	12.3	4.8	7.1
1999	1.90	15.6	12.2	13.2	14.5
2000	2.25	17.8	12.6	18.0	14.0
2001	2.51	20.5	12.3	11.8	14.8
2002	2.83	23.3	12.1	12.7	13.9
2003	3.07	27.1	11.3	8.4	16.2
2004	3.17	27.9	11.4	3.3	3.0
2005	3.25	28.7	11.3	2.6	2.8
Average/percent change (FY 1998–2003)	2.4	19.7	12.1	82.4 (61.6)[a]	98.3 (75.7)[a]

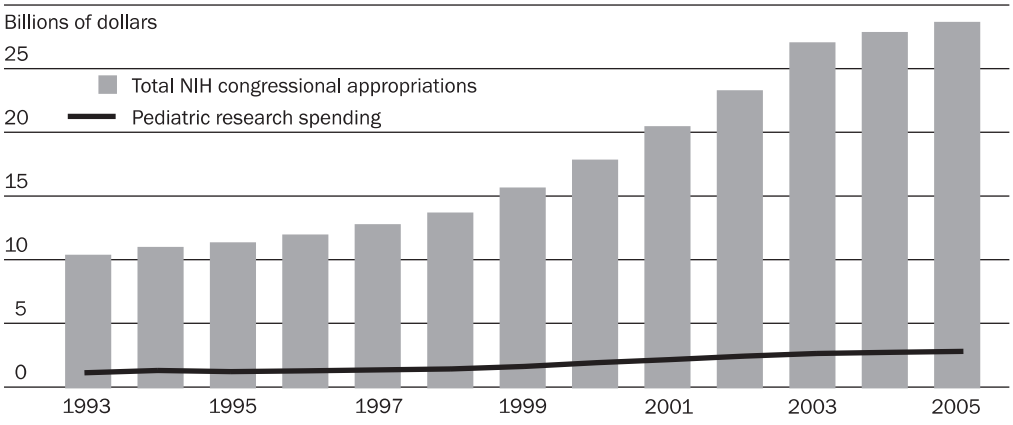
SOURCES: NIH Budget Office: congressional appropriations (FY 1993–2004; 2005 estimate); pediatric research spending (FY 1993–2003; 2004–2005 estimates).

NOTE: FY 1998 is the base level for the doubling period.

[a] Figures in parentheses represent Consumer Price Index (CPI) inflation-adjusted growth rates in 2003 constant dollars.

1993. Thus, while overall and pediatric spending both increased in nominal and real terms, the proportion devoted to pediatrics remained flat, as it has done since FY 1993 (Exhibit 2).

EXHIBIT 2
National Institutes Of Health (NIH) Appropriations And Pediatric Research Portfolio, Billions Of Dollars, Fiscal Years 1993–2005



SOURCE: NIH Budget Office: congressional appropriations (FY 1993–2004; 2005 estimate); pediatric research spending (FY 1993–2003; 2004–2005 estimates).
NOTES: Nominal dollars not adjusted for inflation. FY 1998 is the base level for the doubling period.

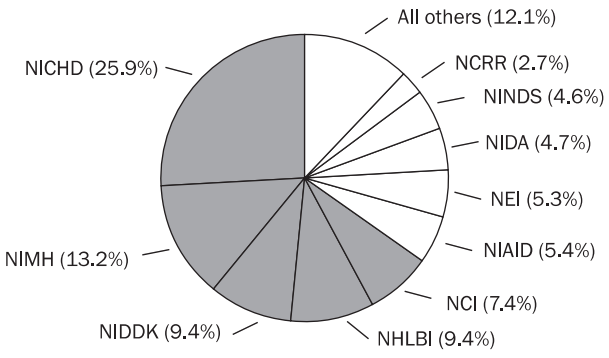
■ **Distribution of the pediatric portfolio.** In FY 2004 twenty-two ICs invested in an NIH pediatric portfolio of $3.2 billion, a major increase from the $1.7 billion distributed across eighteen ICs in FY 1993. The portfolio was not evenly distributed across the twenty-two ICs: Almost two-thirds was concentrated in five institutes (Exhibit 3). With few exceptions, the leading pediatric spenders have been the same since FY 1993. They will account for the majority ($1.8 billion) of the $3.2 billion portfolio in FY 2004. Their pediatric spending grew at an average 82.5 percent rate (on par with the pediatric portfolio 82.4 percent rate).

Pediatric 'High' And 'Low' Spenders

Here we report on the status of pediatric research within two "leading" ICs (as a percentage of total NIH pediatric spending) to explore how the portfolio has fared within individual ICs and in comparison with others (Exhibit 4). NICHD sponsors the most pediatric research; it awarded $821.1 million in FY 2004. During the doubling period, its budget grew by 78.7 percent, while pediatric spending within NICHD grew by 74.1 percent. While the NIH budget more than doubled, NICHD, the lead pediatric IC, experienced a smaller rate of growth (Exhibit 5).

■ **High spenders.** *NICHD.* In FY 2004, 66.1 percent of NICHD's budget was awarded to pediatric research, by far the highest proportion of all ICs. NICHD's portfolio excludes all reproductive, behavioral, demographic, and rehabilitation research not specifically aimed at pediatric populations. While it is often viewed as the institute for the "profession of pediatric research," NICHD accounted for only a quarter of the NIH pediatric portfolio in FY 2004 (Exhibit 3). Thus, the majority of pediatric dollars are awarded by other ICs. In addition, while pediatric spending has

EXHIBIT 3
National Institutes Of Health (NIH) Pediatric Portfolio, By Top Ten Institute Pediatric Spenders (As Percentage Of Total), Fiscal Year 2004



SOURCE: NIH Budget Office.
NOTES: Shaded segments are the five top-spending institutes. NCRR is National Center for Research Resources. NINDS is National Institute of Neurological Diseases and Stroke; NIDA is National Institute on Drug Abuse; NEI is National Eye Institute; NIAID is National Institute of Allergy and Infectious Diseases; NCI is National Cancer Institute; NHLBI is National Heart, Lung, and Blood Instutute; NIDDK is National Institute of Diabetes and Digestive and Kidney Diseases; NIMH is National Institute of Mental Health; and NICHD is National Institute of Child Health and Human Development.

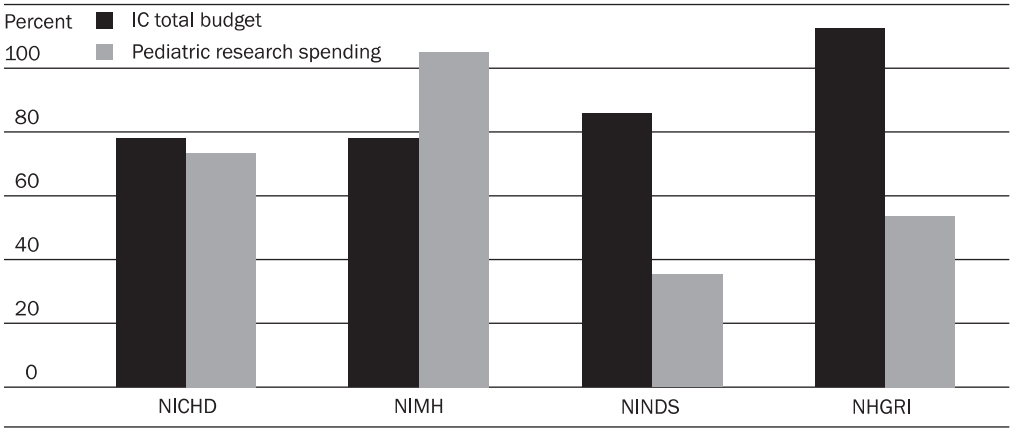
EXHIBIT 4
Selected National Institutes Of Health (NIH) Institute Budgets And Pediatric Portfolios, Millions Of Dollars, Fiscal Years 1993–2005

Fiscal year	NIH ($)		NICHD ($)		NIMH ($)		NINDS ($)		NHGRI ($)	
	Ped.	Total	Ped.	Total	Ped.	Total	Ped.	Total	Ped.	Total
1993	1,349	10,327	528	528	53	584	68	600	0	106
1994	1,547	10,938	552	555	150	613	89	631	10	127
1995	1,439	11,300	391	512	169	542	86	627	15	152
1996	1,512	11,928	408	593	188	660	86	684	15	169
1997	1,604	12,741	425	632	192	701	98	729	14	189
1998	1,681	13,648	453	672	197	750	105	781	16	218
1999	1,903	15,629	506	750	237	861	109	903	14	265
2000	2,245	17,821	587	858	286	973	65	1,029	15	336
2001	2,510	20,458	664	976	336	1,106	81	1,176	16	382
2002	2,829	23,296	734	1,112	388	1,247	119	1,327	20	429
2003	3,066	27,067	790	1,206	405	1,341	142	1,456	25	465
2004	3,168	27,888	821	479	417	613	145	631	25	479
2005	3,251	28,677	846	1,281	429	1,421	147	1,546	26	493
Percent change (FY 1998–2003)	82.4%	98.3%	74.1%	78.7%	105.8%	78.7%	35.6%	86.6%	54.1%	113.6%

SOURCES: NIH Budget Office: congressional appropriations (FY 1993–2004; 2005 estimate); pediatric research spending (FY 1993–2003; 2004–2005 estimates).

NOTES: All figures and growth rates are reported in nominal dollars. FY 1998 is the base level for the doubling period. Prior to FY 1995, the National Institute for Child Health and Human Development (NICHD) reported its total appropriation as "funding for children." After FY 1995, NICHD narrowed its criteria to exclude research not aimed at improving the health of pediatric populations. The National Institute of Mental Health (NIMH) reported that prior to FY 1995 it had not included intramural research and contracts in the budget data. NINDS is National Institute of Neurological Diseases and Stroke. NHGRI is the National Human Genome Research Institute.

EXHIBIT 5
National Institutes Of Health (NIH) And Pediatric Growth Rates By Selected Institutes, Fiscal Years 1993–2005



SOURCE: NIH Budget Office: congressional appropriations (FY 1993–2004; 2005 estimate); pediatric research spending (FY 1993–2003; 2004–2005 estimates).

NOTES: All figures are in nominal dollars. FY 1998 is the base level for the doubling period. IC is Institutes and Centers. NICHD National Institue of Child Health and Human Development. NIMH is National Instute of Mental Health. NINDS is National Institute of Neurological Diseases and Stroke. NHGRI is National Human Genome Research Institute.

increased, NICHD's proportion of the pediatric portfolio has remained relatively flat at 26 percent.

Historically, a small percentage of NIH funding has flowed to pediatric departments. NICHD, as directed by the CHA in 2000, has increased the number and size of research training grants to institutions supporting pediatric training and career development awards to individuals in pediatric clinical and basic research. In FY 2003 NICHD supported $17.6 million ($2.1 million more than in FY 2002) in funding through fellowships, career awards, training grants, and the Child Health Research Centers (CHRCs).

NIMH. NIMH, the second leading pediatric spender, accounted for 13.2 percent of the portfolio in FY 2004. During the doubling period, the NIMH budget increased by a rate of 78.7 percent. Its pediatric spending grew 105.8 percent (compared with the NIH pediatric portfolio rate of 82.4 percent). NIMH is one of a few ICs whose pediatric spending growth rate well exceeded the institute's overall rate during the doubling period (Exhibit 5). Much of the newly committed funding went to studies of depression and anxiety in children and adolescents. It is difficult to determine whether this sizable increase is the result of a growing incidence of children's mental disorders or a contributor to their identification and diagnosis.

■ **Low spenders.** NINDS and NHGRI offer examples of ICs with pediatric spending that is below the NIH average (defined as a percentage of the NIH pediatric portfolio). However, data from each illustrate the complexities of quantifying pediatric spending as well as the danger of drawing inappropriate inferences about the implications of such spending for the status of their portfolios.

NINDS. NINDS had one of the largest overall budget increases during the doubling period, 86.6 percent. In part, this reflects advances in the understanding of neurological diseases and recognition of their strong impact on families. However, NINDS' pediatric spending experienced more modest growth of 35.6 percent—less than half the ICs' rate (Exhibit 5). The proportion of the NINDS budget awarded to pediatrics decreased from 11.3 percent to 9.7 percent between FY 1993 and FY 2003. NINDS has fallen in the rankings from sixth (in 2000) to ninth (in 2003) in terms of the percentage of its budget awarded to pediatric research.

Why has NINDS' pediatric spending fallen if, like other ICs, it makes no allocation of funds by subpopulation? Some of the decrease could represent a problem with labeling what research is relevant to pediatric neurological diseases. Other changes have also played a role. The number of child neurologists has been stagnant during the past decade, while the demand for clinical services has ballooned. NINDS is attempting to encourage more child neurologists to choose research careers by funding the K–12 Neurological Sciences Academic Development Award. The effectiveness of this program remains unknown.

In addition, clinical studies of children usually require multicenter collaboration. NINDS and professional child neurology organizations have not been able to organize many collaborative efforts. NINDS has sponsored workshops to help in-

vestigators develop directions for collaborative research, but the resulting recommendations have led to projects only infrequently. For example, the NINDS Workshop/Report on Perinatal and Childhood Stroke recommended a multidisciplinary collaborative effort. Although professionals have met to plan research, no funded collaborative studies are forthcoming. Many studies of children's neurological diseases have been organized under the sponsorship of the pharmaceutical industry, especially when this was required by the Food and Drug Administration (FDA). These trends have resulted in fewer investigators and studies that bring advances in basic science to children with neurological diseases.

NHGRI. NHGRI represents a case where quantification of pediatric spending can underestimate the impact of biomedical research that is not specifically reported as part of the official pediatric portfolio. For example, NHGRI spent $25.3 million on pediatric research in FY 2004, just 5.3 percent of its budget. NHGRI's budget more than doubled (113.6 percent) and its pediatric spending increased by 54 percent during the doubling period (Exhibit 5). However, NHGRI's research has implications for pediatric populations, although it is not counted as pediatric spending per se. As opposed to other ICs, NHGRI provides resources for biomedical research with a broad array of applications, such as the effort to map the human genome sequence. This is typical of much of what NHGRI does, including such initiatives as the Encyclopedia of DNA Elements (ENCODE) and the Haplotype map (HapMap). This "nonpediatric" research will have important implications for advancing knowledge of childhood disorders.[17]

Caveats On Interpreting Spending Trends

■ **Diffuse research categories.** In drawing inferences from aggregate research spending patterns, we note that there is always a challenge in determining the "appropriate" amount of spending on a particular subpopulation or disease. In addition, more and more biomedical research has implications that can be generalized across diseases, organs, and age groups, and this can frustrate any true effort to "count" them under any single disease or subpopulation biomedical research category.

■ **Clinical research.** The data reported include NIH support for research in developmental biology and clinical pediatrics. Thus, developmental biology alone could account for the steady growth rate of the pediatric portfolio. Although this work may lead to new insights into the pathophysiology of diseases that affect children, and hence to new ways to diagnose and treat them, many clinical researchers remain concerned that we are not applying what we already know. Also, the lack of integration of research efforts into centers where basic and clinical scientists research and care for children with complex medical needs compounds the difficulty of performing high-quality, outcomes-based clinical and basic science research.

■ **Bioterrorism spending.** Bioterrorism took a big share of NIH appropriation growth in the final years of the doubling period, and the shares of the overall increase going to pediatric-related research areas have likely dropped off. For example,

NIH reported a 536 percent increase in bioterrorism spending between FY 2002 and the FY 2005 request. There is concern that the continuing increases in biological defense funding may "crowd out" spending for pediatric areas.

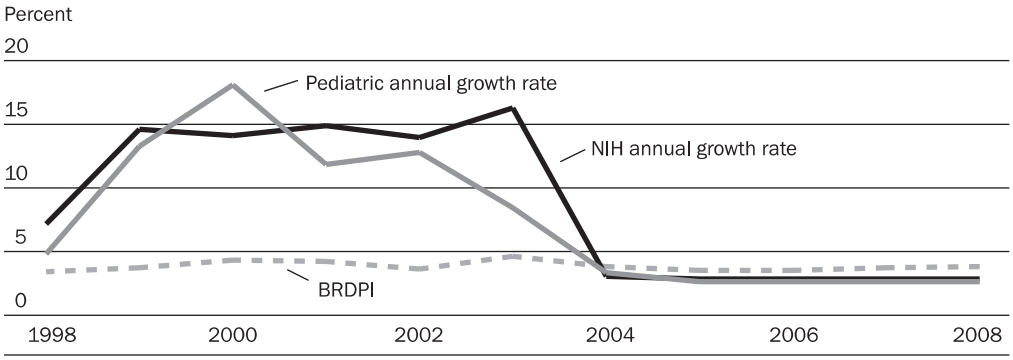
■ **Erosion of doubling-era gains.** Finally, many biomedical researchers fear that future annual levels of growth below 6–8 percent may erode the gains NIH achieved during the doubling period. Between FY 2004 and FY 2005, NIH appropriations are projected to increase by 2.8 percent, while pediatric spending is projected to grow by 2.6 percent. According to the FY 2004–2008 Biomedical Research and Development Price Index (BRDPI) estimates, the NIH budget would need to grow by at least 3.5–3.8 percent just to keep pace with inflation (Exhibit 6). These are far from double-digit increases and might not be enough to maintain the commitments of the doubling era.

The Future Of The Pediatric Portfolio, FY 2005–2010

The recent growth of the NIH budget and its pediatric portfolio has permitted ICs to fund record levels of research and therefore to accumulate a substantial commitment base. The challenge for NIH will be to balance current commitments, new projects, and funding of new investigators. Management of that base will make NIH vulnerable if funding levels remain static. To protect the gains achieved and to capitalize on recent commitments to strengthen the pediatric portfolio, we recommend the following.

■ **Fund NIH to exceed biomedical inflation.** Congress appropriated a 3.7 percent increase to NIH in FY 2004. The president's FY 2005 budget proposed a 2.6 percent increase.[18] Most of the twenty-seven ICs would receive increases in the 2.8–3.0 percent range, and NICHD would receive a 3.1 percent increase. Biomedical

EXHIBIT 6
Annual Growth Rates Of National Institutes Of Health (NIH) And Pediatric Portfolio, Relative To Biomedical Inflation (The BRDPI), Fiscal Years 1993–2008



SOURCE: NIH Budget Office: congressional appropriations (FY 1993–2004; 2005 estimate); pediatric research spending (FY 1993–2003; 2004–2005 estimates); Biomedical Research and Development Price Index (BRDPI) (FY 1998–2003; projections FY 2004–2008).
NOTES: FY 1998 is the base level for the doubling period. The BRDPI measures changes in the weighted average of the prices of all inputs (such as personnel services, various supplies, and equipment) purchased with the NIH budget to support research.

research inflation tends to exceed the Consumer Price Index (CPI) by approximately 1.5 percent per year. Unless Congress provides annual increases that well exceed the BRDPI rates, NIH and the pediatric-specific commitments it made during the doubling period will become increasingly vulnerable.

■ **Fund the PRI with specific appropriations.** The main purpose of the PRI was to increase existing support for pediatric research. While Congress authorized $50 million to support the PRI in FY 2001 and "such sums as may be necessary" for FY 2002–2005, to date there have been no specific PRI appropriations. According to a key staffer, Congress never intended to make earmarked appropriations, consistent with its usual practice of funding ICs but not disease areas or subpopulations. Accordingly, it was expected that NIH would allocate dollars from within its overall budget to fund research consistent with the PRI. If the PRI is to be supported with dedicated dollars that represent new funding, supplemental appropriations are the only mechanism by which the pediatric portfolio can expand beyond its "fixed" slice of the budgetary pie.

■ **Support the NIH child inclusion policy and report on its performance.** With a static proportion of funding awarded to pediatric research, including children in all relevant clinical research will become increasingly important. There has never been any effort to evaluate the impact of or develop performance indicators for NIH's child inclusion policy. Because children are counted in numbers of research subjects along with adults, retrospective evaluation may be difficult. It is important, if only prospectively, to know whether the NIH guidelines can be effective and to recommend ways to strengthen the inclusion of children in future research.

■ **Examine and evaluate the NCS's budgetary trade-offs.** NICHD's FY 2005 budget request includes planning dollars for the National Children's Study (NCS) but not funding to launch it. Congress has yet to allocate any specific additional appropriations for study implementation. Excluding expenditures for analysis and reporting, estimated total implementation costs are approximately $2.3 billion (not adjusted for inflation). For recruitment and follow-up during pregnancy and infancy, costs increase to a maximum of $151 million in 2007, then decrease to approximately $93 million per year from 2010 to completion in 2028.[19] In the current era of tight budgets, it is inevitable that internal funding designated for the study would take money away from other program research areas. Without additional appropriations or nongovernmental support, it is highly unlikely that NICHD, as the lead agency, can move beyond the planning stage.

■ **Broaden the life-cycle focus of pediatric research.** The tendency to define all economic and health well-being issues as distributional problems among age groups at a slice in time must be avoided. The pediatric community needs to emphasize the potential for investments in pediatric research to influence health and human development across the life cycle. For example, a more complete understanding of the plasticity of the brain might contribute to methods for educating children and preserving cognitive function throughout life. Also, an understanding of the rela-

tionship between genetic variation and disease risk promises to change greatly the prevention and treatment of childhood and adult illnesses. Pediatricians and advocacy groups will need to form partnerships with their adult-focused research and policy colleagues and offer new conceptual arguments (and evidence) about the longer-term benefits of today's investment in the health and well-being of our children.

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