Can Private Interests Buy Public Science?*

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ABSTRACT

Can private interest groups influence the decisions of independent experts to achieve their desired outcomes? This study analyzes a common non-market strategy — lobbying powerful politicians — through which interest groups seek to influence the allocation of public funds in the context of peer-reviewed funding for research on rare diseases by the National Institutes of Health (NIH). We find evidence suggesting that the lobbying of disease advocates increases political support, in the form of Congressional "soft earmarks" for the diseases, and NIH's peer reviewed funding responds to the earmarks associated with lobbying. We also find that lobbying by interest groups is more likely to succeed when it helps focus Congressional and expert attention on diseases with higher burden and greater scientific opportunity.

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1 Introduction

Rett Syndrome is a developmental disorder affecting about one in ten thousand children. The syndrome is primarily seen in females six- to eighteen- months old, and causes a loss of communication skills and the purposeful use of hands. In severe cases it causes seizures, leading to death. The syndrome has no known cure. In 1999, a discovery linking the disorder to mutations of a gene called MECP2 opened new avenues of research for a potential cure-. In 2002, The International Rett Syndrome Association (IRSA) mobilized parents, friends of patients, and scientists to lobby Congress to increase the National Institutes of Health's (NIH's) funding for research on the disease. In response, the House Appropriations Committee included language in the reports accompanying its appropriations for - NIH, "encouraging research" on Rett syndrome. Figure 1a displays the relevant excerpt from the Congressional report. As the accompanying chart (Figure 1b) shows, in the following year NIH grants for research on Rett Syndrome increased by 65 percent, from $4.6 million in 2002 to $7.6 million in 2003.

Figure 1 here

Private interest groups such as the IRSA lobby elected representatives for favorable treatment. But independent experts often determine allocations for projects and design regulations that affect interest groups, with limited formal oversight by elected representatives. For example, scientists at U.S. federal agencies like the Food and Drug Administration, the Environmental Protection Agency, and NIH make decisions that affect corporations and other research performers without Congressional guidance. Can interest groups obtain their desired outcomes when independent agencies have their own procedures for making allocations? If so, how?

We examine this issue in the context of the NIH, the world's largest single source of funding for biomedical research. The NIH allocates its funds ($31.2 billion in 2010) for research across hundreds of biomedical fields through the peer review process in which scientists evaluate the merit of research proposals submitted by scientists. Each year, the Congress appropriates public funds to the NIH, but does not include "hard" earmarks, or legislation that sets aside funds for specific projects, in its appropriations bills. Instead, it specifies "soft" earmarks: language that "urges" and "encourages" the NIH to support research on particular diseases in the text of the Congressional Committee reports that accompany appropriations bills (Hegde and Mowery 2008; Hegde 2009; Sampat 2009).[1] According to some experts, soft earmarks distort allocations away from the best science, towards projects favored by powerful interest groups (*e.g.*, IOM 1998). Motivated by this tension between private interests and public welfare, we investigate the following questions on the consequences of lobbying by disease advocates.

[1] Hard earmarks are common in Congressional appropriations for agencies such as the Department of Agriculture and the Department of Defense and typically specified in appropriations bills.

1. Does lobbying by disease advocates affect Congressional support for research on specific diseases?

2. Do NIH's peer reviewed allocations respond to Congressional support, particularly the support associated with lobbying?

3. Do disease advocates provide useful information to Congressmen about the diseases, or do they seek rents at the expense of the larger public?

Our study focuses on "rare diseases" for several reasons. First, our large-sample analysis requires linking information on diseases from disparate sources, and doing so reliably requires the diseases to be well-defined and unrelated to each other. Rare diseases tend to be discrete conditions and can be uniquely mapped to the funding, earmarking, disease burden and publication data used in our analyses. Second, although individual rare diseases have low prevalence, these diseases are collectively responsible for the deaths of nearly 300,000 Americans annually. Third, since private sector firms may find it unprofitable to invest in R&D for diseases with low prevalence, public funding is considered important to finding treatments for rare diseases (Ashbury 1985).[2]

Our findings contribute to an emerging literature on "non-market" strategies in three ways. First, there is little evidence that interest groups can obtain their desired allocations from independent experts, let alone through lobbying politicians with budgetary authority over the experts. The lack of evidence on this issue reflects several challenges: the pathways through which interest groups affect politicians and politicians influence bureaucrats do not leave clear footprints, and counterfactual allocations against which to assess the effects of interest groups typically do not exist (this problem is particularly common in studies that analyze the effect of interest group lobbying on regulatory outcomes). In addition to being important, the NIH allocation process permits us to tackle these challenges: we can link disease interest groups to their lobbying expenditures; we can control (albeit imperfectly) for demand-side characteristics (*i.e.,* disease burden and scientific opportunity) which influence counterfactual allocations for the diseases; and we can link Congressional support for particular diseases (in the form of soft earmarks) to agency allocations for the diseases. Hence, we are able to address, not only "if," but also "how," interest groups influence allocations through lobbying. Although the interest groups in our context are not-for-profit entities attempting to maximize research funding for their disease areas, our study has implications for the non-market strategies of other entities, including corporations, which attempt to maximize profits within the regulatory structures managed by politicians and bureaucrats.

[2] Various initiatives, such as The 1983 Orphan Drug Act, have attempted to create tax and market exclusivity incentives for stimulating private sector research on rare diseases.

Second, we document an understudied mechanism through which Congress influences agency allocations to private interests: "soft" earmarks. Much of the literature on earmarks, including work examining their effect on research funding focuses on "hard" earmarks (*e.g.,* de Figueiredo and Silverman 2006; Payne 2002). But soft earmarks have attracted recent scrutiny, even outside the NIH context: media reports suggest that politicians increasingly rely on soft earmarks while appropriating funds for agencies other than the NIH after the curbs on hard earmarks imposed by the 2007 Congress ethics rules (see Nixon 2010). However, there is little research on whether soft earmarks, which unlike hard earmarks do not have the formal authority of law, actually influence agency decisions. Here, we provide the first evidence that they do.

Third, our analysis complements previous work on the allocations for biomedical research, that has treated the allocations process itself as a "black box" (*e.g.,* Lichtenberg 2001, Bhattacharya and Packalen 2012; Cutler *et al* 2012). We provide a microanalysis of the allocations process and the first evidence that special interest groups and politicians influence the allocations. We show that the conventional "private interest versus public good" distinction and the conclusion that the non-market strategies of interest groups distort allocations may be simplistic.[3] In particular, lobbying may have an important role in communicating information about changes in disease burden and scientific opportunity to policy makers.

The rest of this paper proceeds as follows: Section 2 discusses the institutions involved in the allocation of federal funds for biomedical research. Section 3 specifies the empirical model we estimate, and discusses the data. Section 4 analyzes the relationship between lobbying by disease advocates and earmarking for the diseases. Section 5 investigates the relationship between Congressional earmarking and NIH allocations. Section 6 concludes.

2 Institutional Setting

2.1 The National Institutes of Health and peer review

The NIH is part of the U.S. Department of Health and Human Services and provides 85 percent of total federal support for R&D in the biological, medical, and psychological sciences (based on FY2008 federal obligations, NSF 2008). The agency is organized into 27 independent Institutes and Centers which specialize by disease (*e.g.*, National Cancer Institute), organ (National Eye Institute), field of science and medicine (*e.g.*, National Institute of General Medical Sciences), or by stages of human development (*e.g.,* National Institute on Aging) (McGeary and Smith, 2002). More than 80 percent of the agency's funding is

[3] For example, Becker (1996) has argued "the distribution of funds among diseases deviates from the socially most desirable allocation" since "well-organized advocacy groups for particular diseases … use their political clout to get disproportionate shares of the research budget."

awarded annually to researchers at over 3,000 universities, medical schools, and other research institutions.[4] NIH extramural funding for research on rare diseases increased from $1.95 billion (all $ figures throughout this paper are inflated to FY2010 $) in 1998 to $3.4 billion in 2008 for rare diseases, and from $14.5 billion to $22.1 billion for other research during the same period, reflecting the success of an unprecedented bipartisan effort to double the NIH's budget between 1998 and 2002 (Cook-Deegan and McGeary 2006).

The individual Institutes at the NIH utilize a "dual peer review" process to evaluate proposals from researchers. In the first stage of this process, grant applications are evaluated by panels of external scientists from the relevant fields. These peers score applications based on their significance, technical merit, innovativeness, and investigators' qualifications. Acceptable applications are assigned to the NIH Institute or Center best suited to fund the research where they are again reviewed by a "National Advisory Council" composed of scientists and public representatives. Each Institute's (or Center's) Advisory Council recommends applications for funding by considering priority scores and the proposed project's relevance to the Institute's mission. The Director of the Institute/Center makes the final funding decision based on the relevant Advisory Council's recommendation (NIH 2008).

The NIH is viewed by some experts as an exemplar research agency because of its commitment to funding the most meritorious projects identified through its peer review process (AAAS 2008). For example, Drazen and Ingelfinger (2003) note that "the selection of research for funding [for investigator-initiated grants] is based solely on merit; politics has no place in this system" (p 2259).[5] The former Director of the NIH, Harold Varmus, suggests Congressional reluctance to include hard earmarks in the NIH's spending bills "represent[s] votes of Congressional confidence in the NIH's system of peer review" (Varmus 2009, p 150).

2.2 The Congressional appropriations process and soft earmarks

Annual Congressional decisions concerning the NIH budget are made by the Labor, Health and Human Services, and Education and Related Agencies Subcommittee (LHHE) of the House and Senate Appropriations Committees. The bills reported out to the floor of the House and Senate by each chamber's appropriations committee indicate the total appropriations for each of the NIH Institutes and Centers every year.

[4] The rest of the funds support "intramural" research – work carried out by scientists at the NIH.

[5] Li (2012) studies NIH's peer review process and concludes that while peer reviewers are biased in favor of research proposals from their own sub field, this bias is trumped by the superior information the reviewers have about their fields which allows them to make better funding decisions.

Members of the LHHE subcommittee seek to influence the NIH's disease-specific allocations through soft earmarking, or language recorded in the annual appropriations committee's meeting reports that accompany the appropriations bills.[6] These soft earmarks have been the subject of considerable controversy. Some argue that earmarks are the only channel through which "public interest" can be incorporated into the NIH's allocation process, which (they contend) is otherwise narrowly oriented towards rewarding scientific opportunity. However, others worry that earmarks target diseases without concern for the scientific feasibility of research, and that this low quality research crowds–out funding for higher quality peer-reviewed research (Greenberg 1998).

2.3 Disease interest groups

Disease interest groups seek to maximize research funding for specific fields though a number of channels: by lobbying Congress (either directly or through registered lobbyists), organizing testimony to persuade the Congressional appropriations committee of the need for enhanced research funding, as well as mobilizing grassroots advocacy campaigns that, for example, encourage patient groups to inform their representatives of the importance of supporting research in particular diseases. Although we do not analyze the determinants of interest group influence here, the groups' ability to organize their lobbying efforts and influence allocations depends on various factors (Bertrand *et al* 2011 and de Figueiredo and Cameron 2010 study these factors). Some groups may be better able to organize and generate media attention, while others, such as those with few survivors (*e.g.,* lung cancer or pancreatic cancer) or associated with a social stigma (*e.g.,* depression or urinary incontinence) may have few advocates leading to less attention by policymakers (see Armstrong *et al* 2006 and Best 2012 for accounts of factors that shape the intensity and success of disease advocacy).

Concerns that earmarks respond to lobbying fueled considerable controversy during the 1990s, including Congressional hearings with testimony by the NIH Director (Varmus 1997) and an Institute of Medicine inquiry into NIH's priority setting process (IOM 1998). These investigations followed an era when powerful and well organized advocates for specific diseases—notably AIDS and breast cancer—became active in lobbying for increased research on these diseases, including obtaining Congressional

[6] For example, House Report 109–515 accompanying the appropriations bill for FY2007 includes soft earmarks for Interstitial Cystitis ("research on IC is still in its infancy ... the Committee encourages NIDDK to place emphasis on Interstitial Cystitis-specific funding in order to focus on the basic science of IC and to attract and sustain research in the field"). The analogous Senate report includes soft earmarks for Batten Disease ("the Committee strongly urges the Institute to increase funding for Batten disease research by actively soliciting grant applications and taking aggressive steps to assure that a vigorous research program is established").

report language to bypass the peer review process. The disease advocates argue that lobbying is necessary because mechanisms for the NIH to seek input from interest groups and incorporate this input in their allocation decisions are absent. For example, according to one disease advocate "…patient groups believe the decision-making process at the NIH is basically a closed process where patient organizations are only consulted at later stages, when decisions in fact have already been made" (quoted in Dresser 2001, p 80).

3 Empirical specification and data

3.1 Empirical model

We begin with a stylized model of optimal NIH funding, adapted from Lichtenberg (2001). The model is simplistic and ignores the complexity of the allocation process, but provides structure to our empirical analyses. Following Lichtenberg, we start by assuming the presence of two diseases. Let M_i be the number of people killed by the disease i (i=1, 2). We use the number of deaths associated with a disease to indicate disease burden, but other measures (*e.g.,* costs of a disease, incidence, disability-adjusted life years) could be used. Let π_i be the probability of finding a treatment for the disease i. π_i is a concave function of research funding for the disease, Y_i, and a disease-specific scientific opportunity parameter, P_i such that $\pi_i = P_i\ Y_i^{\alpha}$ where $0 < \alpha < 1$. We assume that the total research budget, Y, is exogenously given and fixed, such that $Y = Y_1 + Y_2$. In this model, policymakers attempting to maximize the expected total number of people cured of both diseases would choose Y_1 to maximize:

$$W^* = M_1\pi_1 + M_2\pi_2 = M_1\ P_1 Y_1^{\alpha} + M_2 P_2 Y_2^{\alpha}$$

$$= M_1 P_1 Y_1^{\alpha} + M_2 P_2 (Y - Y_1)^{\alpha} \quad (1)$$

The first-order condition implies that relative funding of research on the two diseases should satisfy:

$$\ln\left(\frac{Y_1}{Y_2}\right) = \left(\frac{1}{1-\alpha}\right)\ln\left(\frac{M_1}{M_2}\right) + \left(\frac{1}{1-\alpha}\right)\ln\left(\frac{P_1}{P_2}\right) \quad (2)$$

Re-writing $\beta = \left(\frac{1}{1-\alpha}\right)$ and generalizing the model to the case of i>2 diseases, we obtain i-1 equilibrium conditions of the form:

$$\ln Y_i = \text{constant} + \beta \ln M_i + \beta \ln P_i \quad (3)$$

Equation 3 implies that, in this model, public funding (Y) for a given disease (i) should be an increasing function of disease burden and scientific opportunity.[7]

[7] This implication is consistent with the views of various experts and scholars on the desired determinants of applications. For example, the 1998 IOM Report on NIH allocations is titled: *Scientific Opportunities and Public Needs*. The IOM Report also emphasizes other dimensions that this model does not, including equity considerations and extent of market failure (Garber and Romer 1996).

With cross-sectional data on measures of disease burden and scientific opportunity, we could estimate β. In the above model, scientific opportunity enters into the objective function the same way as disease burden, hence the same parameter β for both. However, so that we do not restrict actual allocations to being identically responsive to both disease burden and scientific opportunity, we separately estimate β_1, which captures the effect of M, and β_2 which captures the effect of P, on allocations (as in equation 4). Since M and P enter the expenditure function as log terms, the estimated coefficients have elasticity interpretations. Thus, we can write the equation to be estimated as:

$$\ln Y_i = \beta_0 + \beta_1 \ln M_i + \beta_2 \ln P_i + e_i \quad (4)$$

A key empirical challenge for isolating the influences of the two disease characteristics (M and P) on allocations is controlling for other attributes of the diseases, *e.g.*, prevalence, the income levels of the populations affected by the diseases, or private funding for research. These other attributes of the diseases may be correlated with M, P and Y, and if omitted from the OLS regressions, lead to biased estimates. Since it not feasible to observe and measure all these "other" attributes of the diseases, we use disease-specific fixed effects to control for such confounders. These disease-fixed effects ($\sum I_i$) account for unobserved disease-specific influences on funding that remain constant across the years of the study. Hence, with panel data, we can hold constant disease-level characteristics ($\sum I_i$ representing a vector of disease-specific indicator variables) and estimate how disease-specific funding support (Y) responds to changes in M and P. The corresponding equation can be written as:

$$\ln Y_{i,t} = \beta_0 + \beta_1 \ln M_{i,t} + \beta_2 \ln P_{i,t} + \sum I_i + e_{i,t} \quad (5)$$

Our analysis spans 11 years, a relatively short period of time. With disease-fixed effects, there may not be sufficient within-disease variation to estimate the effects of disease burden or scientific opportunity. However, the primary goals of our analysis are to understand: (i) the relationship between the lobbying efforts of interest groups and Congressional earmarking for diseases and (ii) the relationship between Congressional earmarking and NIH allocations, controlling for factors that influence allocations and political support. Accordingly, we extend Equation 5 to examine how disease-level support responds to additional factors such as the lobbying efforts of interest groups (L):

$$\ln Y_{i,t} = \beta_0 + \beta_1 \ln M_{i,t} + \beta_2 \ln P_{i,t} + \beta_3 \ln L_{i,t} + \sum I_i + e_{i,t} \quad (6)$$

In estimating the model, we first focus on the effects of lobbying expenditures (L) of interest groups on Congressional support for diseases (Y^C) controlling for M and P. Funding levels during the past year may influence both lobbying intensity and Congressional earmarking. Accordingly, we include NIH funding in the previous year (K) as an explanatory variable. Year-specific indicator variables ($\sum T_t$) control for time-trends in funding. Y^C, P, M and L each vary across the diseases (*i*) and over time (*t*); the

unit of analysis in our study is disease-year. Thus, the equation that estimates lobbying influence on Congressional earmarking is:

$$\ln Y^{C}_{i,t} = \beta_0 + \beta_1 \ln M_{i,t-1} + \beta_2 \ln P_{i,t-1} + \beta_3 \ln L_{i,t-1} + \beta_3 \ln K_{i,t-1} + \sum I_i + + \sum T_t + e_{i,t} \quad (7)$$

Next, we examine NIH's grants for specific diseases (Y^{NIH}) as a function of *M* and *P* for each disease-year. Since we expect lobbying to influence NIH's funding not directly, but through their effect on Congressional support (Y^{C}), we use a two-stage least squares framework to estimate this indirect effect. Specifically, we use the effect of lobbying on earmarks obtained by estimating (6) in the first stage to investigate the effect of (lobbying-driven) Congressional earmarking on NIH's funding in a second stage. Thus, we examine the effect of earmarks and other disease-specific characteristics on NIH's allocations by estimating the following model, with L used in the spirit of an instrument for Y^{C} :

$$\ln Y^{NIH}_{i,t} = \gamma_0 + \gamma_1 \ln M_{i,t-1} + \gamma_2 \ln P_{i,t-1} + \gamma_3 \ln Y^{C}_{i,t-1} + \gamma_3 \ln K_{i,t-1} + \sum I_i + + \sum T_t + u_{i,t} \quad (8)$$

3.2 Data and descriptive statistics

Rare diseases have no official definition, but are typically characterized as those with prevalence of less than 200,000 individuals. The National Organization for Rare Diseases (NORD) identifies 1,200 such diseases in its Rare Disease Database. Since some of these are not "true" rare diseases (*e.g.,* HIV-AIDS) we focus on the subset of 955 that are also identified as rare-diseases in NIH's database. Even this list includes some diseases that have high prevalence. Thus the NIH cautions that the list "should not be used as a reference or guarantee that a condition is rare" and that "[some] diseases with 200,000 or more affected individuals may be included in this list if certain subpopulations of people who have the disease are equal to the prevalence standard for rare diseases." Accordingly, we use the term "rare disease" in this paper to specifically mean a disease identified as 'rare' in both the NORD and NIH rare disease databases.

The NORD database also provides all known synonyms for each disease, and we use each of the synonyms to collect and assemble data on the characteristics of each disease from five different sources as described below. The NORD data also include information on all organizations associated with each disease, allowing us to link them to data on lobbying expenditures.

3.2.1 Dependent variables

(i) Congressional support for diseases (Y^{C}), measured by the number of "soft" earmarks

We collected data on all report language that mentioned support for the 955 rare diseases (and/or their synonyms) from the House and Senate LHHE subcommittee appropriations reports accompanying appropriations bills for FY1998 through FY2008. We carefully read the reports for each year and chamber, and coded as an earmark any mention of a rare disease in conjunction with words indicating support (mainly "urge," "encourage," and "direct"). Occasionally, diseases are mentioned in the report language for not one but multiple NIH Institutes; in such cases we count each earmark as a separate

instance of Congressional support for the disease. During our study period, House reports specified an average of 56 earmarks for rare diseases each year. Senate reports specified a higher number of earmarks for rare diseases (on average, 85 per report) during the period. Overall, the Congressional reports specified 142 earmarks, supporting 32 rare diseases on average, each year.

Rare diseases appear to receive a disproportionate number of earmarks, relative to their prevalence. For example in year 2006, House and Senate reports together specified a total of 310 earmarks of which 140 (or 45% of earmarks) focused on rare diseases. By comparison, the 955 diseases in our data received around 15 percent of NIH's overall funds, and account for roughly the same percentage of deaths in the U.S., and of NIH-funded publications indexed by MEDLINE.

(ii) Agency allocations for diseases (Y^{NIH}), measured by NIH's peer-reviewed funds

We searched the NIH's (CRISP) database for the names of each of the 955 diseases and their synonyms in the abstracts of each of the 600,000 grants awarded between 1998 and 2008, associating a grant with a disease if any of the words in the abstract matched the primary name of the rare disease or any of its synonyms.[8] Overall, the 955 diseases mapped to 77,005 distinct grants during the period. We used a separate NIH database, Research Portfolio Online Reporting Tools (RePORT), to collect information on the amount of funds associated with each grant, and aggregated the funds received by each disease for each year. In an average year during 1998-2008, the 955 rare diseases in our sample together received 7,000 grants, or $2.8 billion in NIH funding.[9]

3.2.2 Independent variables

(i) Disease burden (M), measured by deaths caused by diseases

We measure disease burden as the number of deaths associated with each disease, as reported in the Multiple Cause of Death Mortality files, developed through the National Vital Statistics System of the

[8] Previous research (*e.g.,* Toole 2007; Lichtenberg 2001) has used "thesaurus" keywords provided in the CRISP data to identify and measure funding for diseases. However, we found the thesaurus terms unreliable for rare diseases. For example, many grants referenced a rare disease in the title and abstract but not in the thesaurus keywords and many rare diseases did not have entries in the CRISP thesaurus.

[9] Historically, the NIH has not reported data on funding by disease, but the agency's recent Research and Conditions Disease Categorization (RCDC) initiative tabulates disease-specific funding data for a subset of diseases and for the years after 2007 (Sampat 2011). For the 33 diseases in our sample also listed on the RCDC, we compared our funding numbers for the year 2008 to those available from the RCDC (see Figure A1 of the Supplementary Appendix). The correlation between the funding numbers obtained through our search and the numbers reported by the RCDC is 0.92, suggesting that our strategy generates numbers comparable to the official RCDC benchmark.

National Center for Health Statistics. We also examine another measure of disease burden, the number of hospital discharges associated with diseases, in robustness checks.

The Mortality Files provide data on deaths by disease, using disease categories from the Tenth Edition of the International Classification of Diseases (ICD10). Accordingly, we determined the ICD10 code for each disease in our dataset (using their synonyms, where necessary) and constructed numbers of deaths from each disease. The 955 rare diseases in our sample account for between 13 and 15 percent of all (disease-related) deaths between 1998 and 2008. The 955 diseases collectively are responsible for 307,182 U.S. deaths during an average year of our study. Column 1 of Table 1 shows trends in the deaths associated with these diseases.

Table 1 here

(ii) Scientific opportunity (P), measured by number of scientific publications in disease-field

Scientific opportunity is difficult to measure across diseases; indeed, NIH peer reviewers spend hours discussing it for individual applications. We use information from MEDLINE on publications associated with the diseases to construct a measure of scientific opportunity associated with the diseases. We mapped each disease (and its synonyms) to a MeSH (Medical Subject Heading) entry in MEDLINE, and constructed disease-specific publication counts by year. The idea behind this measure is that disease areas where there is an increase (decrease) in scientific opportunity should see a corresponding increase (decrease) in publications. While admittedly imperfect — for example, publications could reflect scientific fads rather than actual opportunity – we believe the measure captures what NIH reviewers consider when evaluating applications: the probability that research in an area will yield results. On average, there were 19,836 rare-disease related publications per year, roughly 15 percent of all MEDLINE publications related to diseases. Since simple counts of publications can be a noisy indicator of scientific output, we also examine quality-weighted publications as a more refined measure of output in robustness checks.

Our regressions also include lagged NIH funding for a disease as a control variable: this variable arguably captures the NIH's own assessment of scientific opportunity and the effect of other disease specific attributes (*e.g.*, public burden) that the agency considers in its disease-specific allocations.

(iii) Lobbying intensity (L) measured by lobbying expenditures of disease interest groups

The Lobbying Disclosure Act of 1995 requires organizations that lobby Congress to disclose good-faith estimates of their lobbying-related expenditures, rounded to the nearest $20,000, to the Secretary of the Senate's Office of Public Records (SOPR). Under the Act, lobbying expenditures include money spent by the organization on lobbying by internal personnel and by hired external lobbyists. The Center for Responsive Politics (CRP) has collected these data for each organization that lobbied Congress and

federal agencies in each year since 1998.[10] We identified in the CRP data any organization associated with the 955 diseases in our data as indicated by the NORD disease-organization correspondence. During this period, 98 unique organizations reported positive lobbying expenditures. A large majority of these organizations are non-profit professional and disease advocacy groups, such as *American Speech-Language-Hearing Association*, *March of Dimes Foundation*, and *Autism Speaks*. Some of these organizations are associated with lobbying for multiple diseases. In these cases, we divided the total lobbying expenditures reported by the organization by the number of diseases associated with the organization. We thus constructed the lobbying expenditures for each disease by totaling the lobbying expenditures of all the organizations associated with the disease for each year during 1998-2008.

We emphasize that we do not know the extent to which the lobbying expenditures of organizations are directed at obtaining earmarks for research funding versus other activities (*e.g.*, changing reimbursement rules associated with Medicare). Our informal discussions with disease advocates and a review of their websites suggest that augmenting research funding for diseases is a key objective of their lobbying activities. Still, in the empirical analyses below, we conservatively interpret lobbying expenditures as a proxy for the intensity of advocacy for a rare disease and do not attempt to estimate the financial returns to lobbying. The lobbying expenditures of interest groups associated with the rare diseases in our sample increase from $7.3 million in 1998 to $12 million in 2008.

Table 2 here

Table 2 statistically describes the five variables discussed above, using the 10,505 disease-year observations (955 diseases, 11 years) in our empirical analyses. Notice that the average number of annual earmarks is small; this is because only a small fraction of the 955 diseases—on average 36 rare diseases—receive earmarks in a given year.

4 Congressional earmarking for rare diseases

4.1 Relationship between lobbying and soft earmarks

We begin our econometric analysis by estimating the effect of our measures of disease burden (number of deaths) and scientific opportunity (number of publications) on our measure of Congressional support for the diseases (the number of soft earmarks). The first three columns of Table 3 report ordinary least squares (OLS) estimates of equations (4), (5), and (7).[11] Column 1 shows that a 1 percent increase in

[10] An organization that spends less than $10,000 in any six-month period does not have to report its expenditures. In those cases, the Center treats the figure as zero.

[11] Equations 4 and 5 are estimated with the explanatory variables lagged by a year to account for the lagged relationship between disease characteristics and Congressional support. We experimented with

past-year deaths and past-year publications are each associated with a 0.02 percent increase (statistically significant at $p<0.01$) in Congressional earmarks for the disease. This baseline model with measures of burden and opportunity explains about seven-percent of the variation in congressional support across rare-disease years.

Table 3 here

Column 2 shows that the estimated effects of deaths and publications are weaker when disease-specific fixed effects are included, although the estimated elasticity of publications remains statistically significant (estimated $\beta_2 = 0.01$; significant at $p<0.05$). The inclusion of disease-fixed effects also increases the amount of explained variation to 66 percent. Column 3 introduces lagged lobbying expenditures (L), our main variable of interest. A 1 percent increase in lobbying is associated with a 0.04 percent increase in earmarks (significant at $p<0.01$). This estimated effect, which controls for unobserved heterogeneity among diseases with disease-fixed effects, is nearly four times the estimated effect of changes in publications on earmarks. The estimate is obtained by holding constant lagged funding by the NIH for the disease. To the extent that the agency's funding for diseases reflect its assessment of the scientific opportunity (and other factors) associated with the diseases, the variable directly controls for disease-specific, time-varying, characteristics that may influence both Congressional support and lobbying not captured by the inclusion of disease-specific intercepts and our measures of burden and opportunity. The variable, lagged funding by the NIH, however, is not significantly related to earmarking in any of the specifications.

In the models discussed above, the dependent variable is the natural log of earmarks. In alternative specifications, we examined the effects of lobbying on the number of earmarks (in Column 4), and on the probability that a disease receives an earmark at all (in Column 5). A one-percent increase in lobbying in the previous year is associated with 0.20 more earmarks (recall that the mean disease-year in the data receives 0.09 earmarks) and a 0.02 percent increase in the probability that the disease receives one.

According to Congressional scholars (Fenno 1966), subcommittees of the Senate Appropriations Committee are more successful in influencing allocations through earmarks than their counterparts in the House. This is because the Senate subcommittees deliberate on agency appropriations after the House, and advocates approach Senators if their interests have been ignored by House Representatives. Also, Senators serve larger constituencies (states), enjoy longer tenures, and are more accommodative of each other's interests, making it easier for them to accommodate requests for earmarks. Table A1 in the Supplementary Appendix supports this view in the context of earmarks for rare diseases: the average

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different lag structures including two-year lags and contemporaneous variables, but found one-year lags to yield to most robust relationship between earmarks and the explanatory variables of interest.

estimated elasticity of House earmarks with respect to lobbying is 33% lower than the corresponding elasticity of Senate earmarks (however, this difference is not statistically significant at $p<0.05$).

4.2 Omitted variable bias?

Overall, our estimates suggest that Congressional earmarking is responsive to the lobbying expenditures of disease advocates. The model with disease-fixed effects controls for unobserved disease-specific attributes and reveals that within-disease increases in lobbying expenditures are significantly related to increases in Congressional earmarks for the disease. However, one may be concerned that these estimated effects reflect the influence of unobserved disease-specific factors that vary with time. For instance, it is possible that changes in disease burden or scientific opportunity are not captured by our measures for the two. Unmeasured changes in the severity of the diseases, or the demographic characteristics of afflicted groups, could be driving both lobbying and earmarks, and our estimates of the relationship between the two.

We examine the possibility that our estimates are biased by the omission of time-varying disease-specific characteristics by analyzing changes in the chairmanship of the LHHE subcommittee that makes appropriations to the NIH and specifies earmarks. We focus on changes in chairmanship, since, as Savage explains, "the chair's power stems from the drafting of the mark-ups [associated with appropriations to individual agencies], the timing of the release of the mark-ups to the subcommittee, and the management and control of the staff (Savage 1991, p 338). LHHE chairmanship is determined by seniority and changes in chairmanship result from either the incumbent's resignation (or defeat), or a change in the party controlling that branch of congress (Cohen *et al* 2012). Hence, the changes are unlikely to be related to changes in unobserved disease-specific characteristics.

If our results on the effects of lobbying on earmarks were due to changes in omitted disease-characteristics, the estimates should not be systematically related to changes in LHHE chairmanship. On the other hand, if the estimates capture the true influence of lobbying on earmarking, we expect the relationship between earmarks and lobbying to be weaker in years immediately following changes in the LHHE's Chairmanship. This is because lobbyists and disease advocates cultivate connections with politicians over time, and these connections lose their value when political power changes hands (Vidal *et al* 2010; Eggers 2010). Hence, if earmarks respond to lobbying, we expect to see a decrease in the responsiveness when connections between lobbyists and Congressmen with the authority to earmark are disrupted.

We focus on 2001 when Ralph Regula replaced John Edward Porter as the Chair of the House LHHE subcommittee, and Tom Harkin replaced Arlen Specter as the Chair of the Senate LHHE. We can examine the effectiveness of lobbying both for a reasonable span before and after the change in 2001. Figure 2 plots estimates of the effect of lobbying on earmarks for each of the years during 1999-2008

obtained by interacting lobbying expenditures with indicators for each year (the regression estimates are also reported in Table A2 of the Supplementary Appendix). The figure shows that while the estimated elasticity of earmarks with respect to lobbying is in the range of 0.046-0.06 percent for years other than 2002-03, the elasticity drops to 0.037 percent and 0.034 percent for the two years following the 2001 change but returns to 0.054 in 2004. The estimated elasticities for 2002-03 are significantly different from the elasticities for 2001 and 2004 respectively (at $p<0.05$). Figure 2 also suggests a drop in the effects of lobbying in 2007 and 2008. Though this change is not as sharp as the one immediately after 2002, it coincides with another change in LHHE leadership: David Obey replaced Ralph Regula as the Chair of the House LHHE subcommittee, and Tom Harkin once again replaced Arlen Specter as the Chair of the Senate LHHE in the year 2007.[12]

Figure 2 here

Hence, although we cannot rule out the possibility of unobserved disease-specific factors influencing our estimates of influence, the drop in the effectiveness of lobbying in the years after chairmanship turnover support the view that lobbying influences Congressional support for diseases.

We also estimated the effects of lobbying separately on earmarking by the House LHHE and earmarking by the Senate LHHE (the figure includes information on the party affiliations of the LHHE Chairs) and found that the Senate is more responsive to lobbying than the House (the corresponding estimates are reported in Table A1 of the Supplementary Appendix). This result is consistent with the views of Congressional scholars (*e.g.,* Fenno 1966) who note that the House Appropriations Committee is typically more frugal than its Senate counterpart in generating earmarks. The finding provides further evidence that the estimated elasticity of earmarks with respect to lobbying is tied to political channels of influence, and unlikely to be entirely driven by omitted disease-specific characteristics.

4.3 Favoring powerful groups or responding to information?

Critics of disease advocacy and earmarks implicitly view interest groups as seeking to draw funding away from diseases that impose greater burden or are associated with greater scientific potential (*e.g.,* Stigler 1971; Tullock 1980; Peltzman 1989; Becker 1996). But a large literature also suggests that interest groups may provide information to Congressional decision-makers about issues and allocations where policy interventions are most beneficial (*e.g.*, Krehbiel 1991; Banks and Weingast 1992; Grossman and Helpman 2001).

We investigate these two contrasting views about the role of interest groups by estimating the effect of changes in lobbying expenditures when accompanied by changes in disease burden or scientific

[12] While changes in the returns to lobbying appear to lag the 2001 shock by a year, changes in the effects of lobbying are concurrent with the 2007 change in control.

opportunity. Specifically, we test whether the within-disease interaction effects of lobbying expenditures and deaths, and the interaction of lobbying expenditures and publications, are related to earmarking. Table 4 shows that the effect of lobbying on earmarks depends on the magnitude of deaths and publications: each of the interaction terms is positive and significant. However, the effect of lobbying alone is not statistically different from zero.

Table 4 here

Thus Congress appears to respond to within-disease increases in lobbying when accompanied by increases in disease burden and/or scientific opportunity, consistent with the view that lobbying influences Congressional priority-setting by providing information. This is consistent with the events described in our Rett Syndrome anecdote, in which the IRSA mobilized support for research in the disease following a scientific breakthrough. Hence, lobbying may not be a barrier to Congressional priority setting based on science and health considerations, but instead facilitate more informed allocations.

5 NIH funding for rare diseases

5.1 Relationship between earmarks and NIH allocations

In this section, we assess the effects of earmarks, and lobbying-related earmarks, on NIH funding for the 955 rare diseases. It is possible that soft earmarks are an inexpensive Congressional response to lobbying, and do not affect actual agency choices. As we noted above, "soft" earmarks are specified in committee reports that, unlike appropriations bills, are not voted on by the full Congress, and do not have the force of the law. Further, since many of them "urge" and "encourage" funding, rather than use more direct language, it is plausible that the NIH does not respond to these earmarks.

In examining the effects of earmarking on funding, we focus on new NIH grants, rather than continuations. Although allocations for continuations compose the bulk of NIH's expenditures each year (83 percent of all funding over the 1998-2008 period), these continuations are annual disbursements for multi-year projects funded in previous years, and create inertia in NIH funding patterns. We focus on funding via new grants (accounting for about 17 percent of funding) since these are most plausibly responsive to changes in disease-specific attributes.

Column 1 of Table 5 displays OLS regression estimates obtained by fitting our data to equation 4, the baseline model. The dependent variable in the regressions is NIH funding for a disease in year t. We find that a 1 percent increase in lagged deaths is associated with a 0.24 percent increase in funding, and that a 1 percent increase in publications is associated with a 0.48 percent increase in funding. (Each of these estimates is significant at the 1 percent level.) These two variables (together with year dummies) explain 21 percent of the variation in NIH funding for diseases in our sample.

Table 5 here

Column 2 shows that the effects of deaths and publications are not statistically different than zero when disease-specific fixed effects are included. Inclusion of fixed effects increases the amount of explained variation to 66 percent. Columns 3 and 4 respectively test whether the lobbying expenditures of interest groups, and earmarking by the Congress, have a direct effect on NIH allocations for research in diseases. These estimations include disease-fixed effects (as in equation 8) and hold constant past-year lagged funding by the NIH for each disease. Neither lobbying nor earmarking appears to be significantly related to NIH funding for new projects in the disease areas. The result that lobbying does not directly influence NIH allocations is noteworthy for two reasons. First, it confirms the anecdotal suggestions of interest groups (quoted under Section 2.3) that the peer review system at the NIH does not directly incorporate the preferences of interest groups. Second, it validates the use of lobbying in a two-stage regression set up where we use it as an instrument for earmarks: the finding that lobbying is not significantly related to NIH allocations directly provides support for the exclusion restriction that the instrument (lobbying) influences the outcome (NIH funding) only indirectly through the treatment (earmarks), and not directly.

Accordingly, we also estimate the effect of lobbying and earmarks on NIH funding with a two stage-least squares model. The first stage of the model estimates the effect of lobbying on earmarks (as in the previous section). The second stage uses estimates of the earmarks associated with lobbying (obtained from the first-stage) to estimate the effect of lobbying-driven earmarks on NIH funding. Column 4 of Table 5 reports estimates from this model. We find that a 1 percent increase in earmarks associated with lobbying increases NIH funding for new projects for the corresponding rare disease by 2.2 percent (significant at $p<0.05$). This suggests that, unlike soft earmarks in general, the variation in soft earmarking that is associated with lobbying activity has a strong influence on NIH funding patterns.

5.2 Earmarks and grant mechanisms

In this section, we examine how different grant mechanisms respond to earmarking. This is important since a number of participants in, and observers of, the NIH allocation process suggest that in a context where most of NIH funding is allocated to investigator-initiated research project grants (reviewed by external peer reviewers for their scientific merit) the channels through which NIH funding could be responsive to extra-scientific considerations, including earmarking, are limited (Varmus 1997, Drazen and Ingelfinger 2003).

However, as the IOM (1998) and others suggest, some grant mechanisms—including Requests for Applications (RFAs) and Program Announcements (PAs)—are more focused, and may allow the NIH to steer the direction of research in response to Congressional earmarking. RFAs and PAs are solicitations by the NIH for grant applications that address a defined research topic. PAs are used by the NIH to

announce its interest in building or enhancing research in specific areas considered to be of high priority. RFAs, like PAs, also specify an area of research, with suggested approaches to the research topic described in the announcement. The IOM notes (about RFAs) "Because of their directedness, such mechanisms tend to be specified by Congress in legislation or report language when Congress concludes that NIH should move more quickly to attack a particular disease or other problem" (IOM 1998). Our own review of Congressional report language confirms that RFAs and PAs are commonly requested in the earmarks. For example, the FY2006 Committee report contained the following soft earmark: "The Committee encourages NIH to identify new research opportunities on Charcot-Marie-Tooth that could lead to a relevant program announcement or request for applications." A recent report by the Government Accountability Office, responding to Senator Harry Reid's (D-NV) queries about how the NIH had been responsive to Congressional report language on Chronic Fatigue Syndrome, notes, "NIH develops extramural research on diseases, including CFS, primarily by creating program announcements for grant applications" (GAO, 2000; p 21).

About 30 percent of NIH funding associated with new grants for rare diseases is funded via RFAs and PAs Given their apparent connection with earmarking in these qualitative accounts, we examined whether RFAs and PAs are differentially responsive to earmarks and lobbying. We find that both earmarks in general, and those associated with lobbying expenditures (predicted from two-stage models) have a positive association with funding through RFAs and PAs (significant at $p<0.05$). Moreover, the estimated effects of both earmarks and instrumented earmarks are larger in magnitude for RFAs/PAs than for other funds (Table A3 of the Supplementary Appendix displays the estimated effects of earmarks, both "uninstrumented" and instrumented, with lobbying expenditures on grants for new projects associated with RFAs and PAs). This suggests that RFAs and PAs are particularly responsive to Congressional influence. As with all NIH allocations, earmarks related to lobbying activity have a stronger influence on RFA/PA grants than earmarks in general.

Why does the NIH respond to Congressional soft earmarks that are non-binding and loosely specified? We speculate that federal agencies, such as the NIH, are attentive to soft earmarks because they express the preferences of powerful Subcommittee members who enjoy long tenures and have the power to punish noncompliant agencies in subsequent appropriations. The threat of punishment in subsequent appropriations may be more pronounced when interest groups monitor agency adherence to Congressional suggestions and convey this information to Subcommittee members with whom the groups are well-connected.

5.3 Estimates of the effect of lobbying on NIH funding

How much of the NIH's overall allocations for rare diseases are related to the lobbying expenditures of interest groups? The aggregate additional NIH allocations for diseases associated with lobbying can be calculated by:

$$\sum_{i,t} e^{(\ln Y_{i,t}^{NIH} \, x \, \hat{\gamma}_3 \, x \, \widehat{\ln Y_{i,t-1}^{C}})} \qquad (9)$$

where $\hat{\gamma}_3$ is the estimated elasticity of NIH funding with respect to (lobbying-related) earmarks obtained by estimating equation (8) through two-stage least squares, as in the previous section. (as Column 4 of Table 5 shows, $\hat{\gamma}_3 = 2.21$). $\widehat{Y_{i,t-1}^{C}}$ are predicted values of Congressional earmarks obtained by estimating the effects of lobbying and other variables as described in equation (7) (recall that Column 1 of Table 3 presents the corresponding estimates). $Y_{i,t}^{NIH}$ are NIH allocations for disease i during year t.

Table 6 here

Table 6 shows our calculations of the effect of lobbying on NIH allocations for the years 2000-2008.[13] We find that each year between 3.5 and 11 million dollars in funding can be attributed to lobbying *via* earmarks. This amounts to 0.5 percent to 2.2 percent of NIH's overall allocations for new research on rare diseases during the years in our study. Given the small number of diseases that lobby and receive earmarks, and the dominance of investigator-initiated grants (which are less influenced by lobbying and earmarking) the share of overall allocations influenced by lobbying appears rather small. But it is perhaps more significant in light of the NIH's reputation of being insulated from political influences.

5.4 Robustness checks

The analyses above employed the number of deaths associated with diseases to measure disease burden, and the number of publications to measure the scientific opportunity associated with diseases. However, we acknowledge that the number of deaths captures just one dimension of disease burden, and the number of publications is a noisy measure of opportunity since articles vary in their quality.

To address these concerns, first, we examined an alternate measure of burden: the number of annual hospital discharges associated with the diseases in our study. This is a cost-weighted measure of prevalence and captures morbidity associated with debilitating, but non-fatal diseases. The data were obtained from the Agency for Health Research and Quality's "Healthcare Cost and Utilization Project (HCUP)." Second, we refined the scientific opportunity measure by weighing the publications by Journal Impact Factors for the journals where they appeared, *i.e.*, articles published in top-tier journals such as *Science* and *Nature* are weighted more heavily than those published in lower-tier journals. The results

[13] Lobbying expenditures in 1998 are used to predict earmarks in 1999 and the latter are used to calculate NIH allocations in 2000, and so on. Because 1998 is the first year for which we have data on lobbying expenditures, we are able to obtain estimates of the effect of lobbying on NIH funding starting 2000.

obtained by using these alternate measures (displayed in Tables A4 and A5 of the Supplementary Appendix) are qualitatively comparable to our original estimates from the disease-fixed effects models. These findings suggest the robustness of our measures, and also that disease-specific intercepts absorb a substantial amount of unobserved variation in disease-characteristics.

Finally, our opening anecdote about Rett Syndrome might suggest that rather than the lobbying expenditures of interest groups, celebrity advocacy for diseases draws Congressional attention and earmarks towards diseases. For each disease, we searched for media reports (on Factiva) about a celebrity's advocacy for the disease, disclosure of a celebrity's affliction, or death of a celebrity or a close relative due to the disease. We were able to identify nine diseases in our sample associated with significant celebrity-related events during the period of our study and estimated the models in Table 3 and Table 5 after including a dummy variable to indicate the diseases in years immediately following the celebrity events. The results (available on request) suggest that **c**elebrity involvement with a disease does not have a statistically significant impact on either Congressional earmarking or NIH allocations, and controlling for this does not affect our main findings about the effects of lobbying.

6 Discussion

The activities of interest groups that seek to influence the decisions made by experts for private gain has generated much controversy and debate, but little empirical evidence. Our study of disease interest group lobbying, Congressional soft earmarking, and NIH funding for research on rare diseases helps fill this gap by contributing three main findings.

First, we find a positive and statistically significant effect of disease interest groups' lobbying expenditures on Congressional earmarking, after controlling for disease-specific effects and temporal variation in deaths and scientific opportunity. Hence, Congressional support for diseases appears responsive to the lobbying expenditures of disease advocates. Congressional responsiveness to lobbying appears to drop in the years immediately following changes in the leadership of the Congressional Subcommittee that appropriates funds to the NIH, suggesting that unobserved disease-specific variables influencing both lobbying and earmarking are unlikely to be driving our estimates of lobbying influence.

Second, two-stage regressions reveal that NIH's allocations respond to "soft" earmarks, specifically those associated with lobbying. This is, to our knowledge, the first quantitative assessment of the relationship between lobbying and soft earmarks. We also find evidence consistent with previous descriptions of the NIH allocation process that certain types of grants (RFAs and PAs) are particularly sensitive to political directives, thus revealing the mechanisms through which interest groups influence publicly funded biomedical research.

Finally, we show that the effect of lobbying on earmarks is most pronounced when accompanied by changes in our measures of disease burden and scientific productivity. Theories of interest group influence have debated whether politicians in committees favor powerful interest groups at the cost of the larger public, or instead gather information from lobbying groups to make evidence-based decisions. Our findings are consistent with the latter view. LHHE subcommittee members appear responsive to lobbying only when the diseases become salient – that is, when the diseases are associated with increases in burden or scientific opportunity. From this perspective, disease advocacy and Congressional oversight may be complements to, rather than substitutes for, the NIH's attempts to allocate funding based on scientific opportunity and disease burden.

Our study also informs the broader political economy literature on how interest groups influence policy when bureaucrats have their own preferences and procedures for policy-making. We highlight the importance of a novel channel through which such influence flows — soft earmarking — in a setting that is of fundamental importance for the health and well-being of millions of Americans.

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Figures and Tables

Figure 1a: Excerpt from the Congress Appropriations Conference Committee Meeting Report, FY2003 Appropriations (108th Congress, 1st Session House Report #108-10)

Rett syndrome is a neurological disorder seen almost exclusively in females; it affects approximately one in ten thousand live births per year. The conferees are pleased to learn of the discovery of the MECP2 gene as the main cause of this disorder and encourage the Institutes to expand their research efforts to learn how this gene affects other genes and tissues during the development of the nervous system. The conferees also encourage research to develop animal models of the disorder and to study the daily problems that afflict children with Rett syndrome, including autonomic disorders, as well as research on interventions for improved literacy and communication. Because Rett syndrome is a multi-faceted disorder, the conferees encourage NICHD, NINDS, NIDCD, and NIGMS to work in collaboration to maximize the outcomes from investments made in Rett syndrome research.

Figure 1b: NIH funds for Rett syndrome and the "average" rare disease (2001-2004) (in Millions of FY2010$)

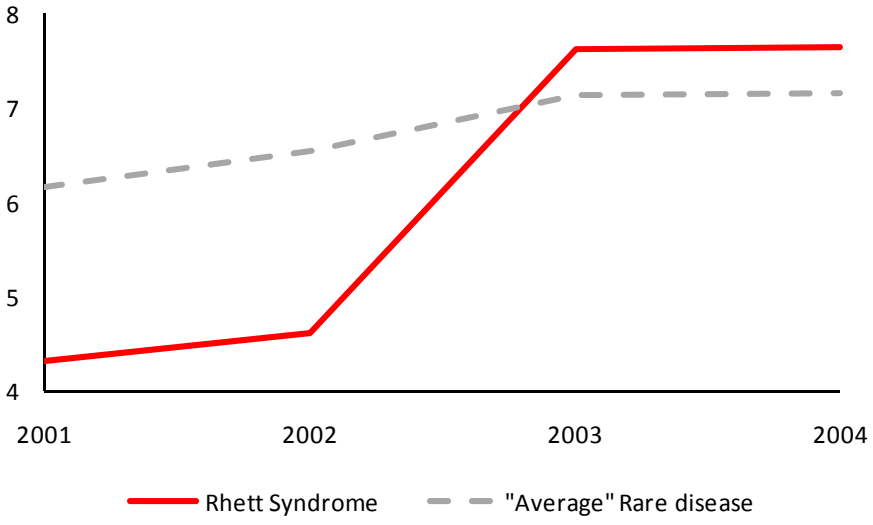
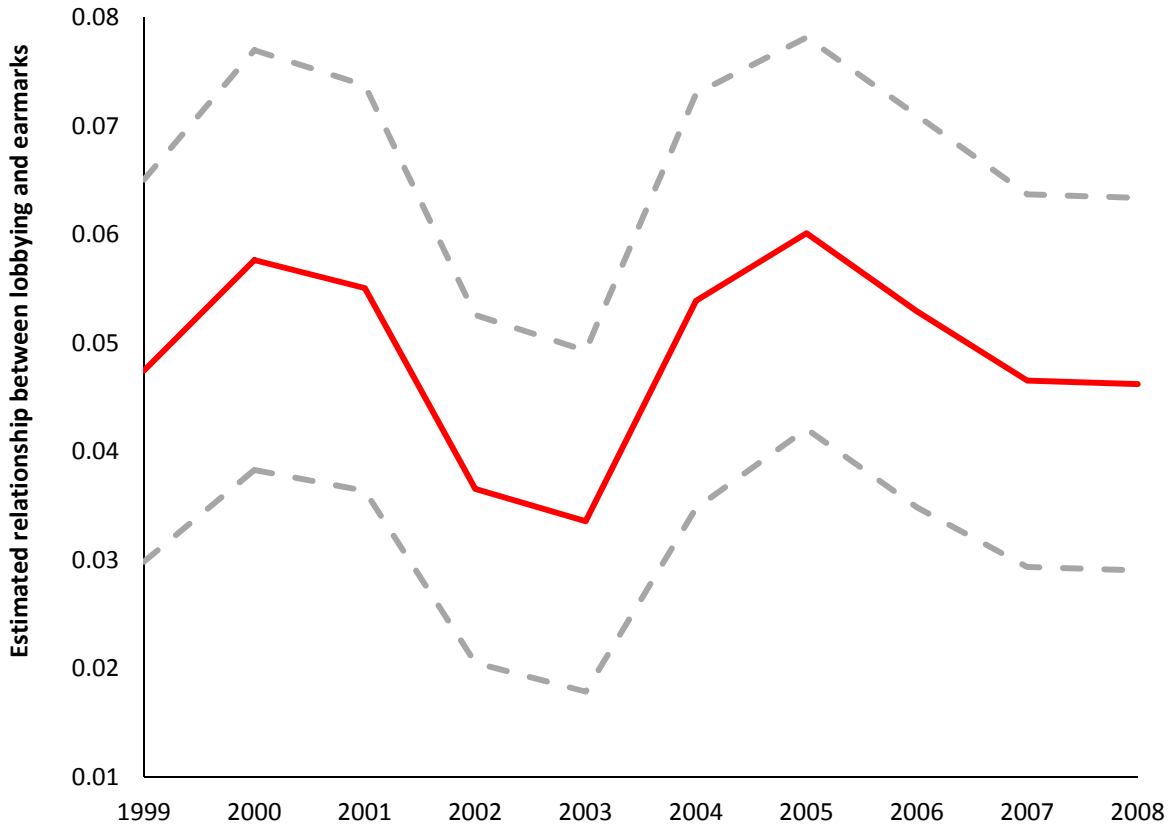


Figure 1b notes: This figure shows NIH funding for research on Rett Syndrome, and the average funding for each of the rare diseases that received NIH grants at least once during the 1998-2008 period.

Figure 2: Estimated responsiveness of earmarks to lobbying, 1998-2008



Year	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
House	Porter	Porter	Regula	Regula	Regula	Regula	Regula	Regula	Obey	Obey
Senate	Specter	Specter	Harkin	Harkin	Specter	Specter	Specter	Specter	Harkin	Harkin

Figure 2 notes: This figure shows estimates of the elasticity of current year earmarking with respect to lagged lobbying, by year. It is based on regression results reported in Table 4. The table below the graph indicates Chairmanship of the House and Senate LHHE Subcommittees by year. The dotted lines indicate 95% confidence intervals.

Table 1: Deaths, Publications and Lobbying expenditures associated with rare diseases: 1998-2008

Year	Deaths	Publications	Lobbying Expenditures (in thousands of 2010 $)
1998	288,091	15,494	7,232
1999	284,365	16,203	5,548
2000	293,734	16,716	6,536
2001	300,241	18,660	8,244
2002	307,843	19,858	8,958
2003	313,562	20,675	9,437
2004	311,877	22,975	11,189
2005	323,183	23,994	12,168
2006	321,791	25,144	12,843
2007	327,133	18,636	12,267

Table 1 notes: Column 1 shows the number of U.S. deaths associated with the 955 diseases. Column 2 shows the number of publications associated with the diseases. Column 3 shows the lobbying expenditures by disease groups associated with these diseases, in thousands of 2010 dollars. The deaths data were collected from the National Vital Statistics System of the National Center for Health Statistics. The publications were extracted from information in raw MEDLINE XML files. NIH funding data were constructed from information in the agency's CRISP and RePORTER databases. The lobbying expenditures for organizations associated with these diseases were obtained from the Center for Responsive Politics.

Table 2: Descriptive statistics for disease-year observations

Variable	Mean	Std. Dev.	Min	Max
Earmarks (#)	0.09	0.64	0	13
NIH grants (in 1000s of FY2010$)	2,991	18,573	0	488,617
Lobbying expenditures (in 1000s of FY2010$)	10.1	37.8	0	1,060
Deaths (#)	292.4	2,644.1	0	74,648
Publications (#)	18.9	101.1	0	2,770

Table 2 notes: This table reports descriptive statistics for the 10,505 disease-year observations in the sample. We analyze data on 955 rare diseases over an eleven-year period from 1998-2008.

Table 3: OLS estimates of the relationship between lobbying and earmarks

Dependent variable ("e" represents # of Earmarks)	[1] log(1+e)	[2] log(1+e)	[3] log(1+e)	[4] e	[5] (e > 0?)
Log Lobby Expenditure (1000's FY2010$; 1-yr lagged)			0.048**	0.207**	0.018**
			[0.009]	[0.039]	[0.006]
Log Deaths (No. of deaths; 1-year lagged)	0.016**	-0.001	-0.002	0.012	-0.004
	[0.002]	[0.005]	[0.005]	[0.014]	[0.004]
Log Publications (No. of pubs; 1-year lagged)	0.016**	0.014*	0.012*	0.023+	0.013*
	[0.001]	[0.006]	[0.006]	[0.013]	[0.006]
Log NIH Funds (1000 of FY2010 $; 1-year lagged)			0.001	0.001	0.001
			[0.001]	[0.001]	[0.000]
Constant	-0.017	0.012	-0.035	-0.200	-0.008
Year effects (11 years)	Y	Y	Y	Y	Y
Disease effects (955 diseases)	N	Y	Y	Y	Y
Adjusted-R2	0.065	0.658	0.665	0.605	0.613
N	9,550	9,550	9,550	9,550	9,550
Robust S.E. in brackets; + p<0.1; * p<0.05; ** p<0.01					

Table 3 notes: This table reports Ordinary Least Squares (OLS) estimates of the effect of lagged NIH funding, deaths, and publications on the number and probability of current year earmarks. Column 1 is the baseline model, without disease effects. Column 2 adds disease fixed effects. Column 3 adds lobbying expenditures of interest groups associated with each disease. The dependent variable in Columns 1-3 is log (1 + earmarks). Column 4 reports estimates of a model with the number of earmarks for a disease-year as the dependent variable. Column 5 reports estimates of a linear probability model with a dummy indicator for whether a disease was the subject of an earmark in a disease-year as the dependent variable. We use the full sample of 955 rare diseases and eleven years, but the year 1998 drops out of the estimating sample because our explanatory variables are lagged by a year, and our data begin in 1998.

Table 4: OLS estimates of the relationship between lobbying and earmarks with interaction terms

Dependent variable = Number of Earmarks (e)	[1] log(1+e)	[2] log(1+e)
Log Lobby X Log Deaths		0.006*
		[0.003]
Log Lobby X Log Publications		0.009**
		[0.003]
Log Lobby Expenditure	0.048**	0.002
	[0.009]	[0.006]
Log Deaths (No. of deaths; 1-year lagged)	-0.002	-0.012+
	[0.005]	[0.006]
Log Publications (No. of publications; 1-year lagged)	0.012*	0
	[0.006]	[0.007]
Log NIH Funds (1000 of FY2010 $; 1-year lagged)	0.001	0.001
	[0.001]	[0.001]
Constant	-0.035	0.015
Year effects (11 years)	Y	Y
Disease effects (955 diseases)	Y	Y
Adjusted-R2	0.665	0.669
N	9,550	9,550
Robust S.E. in brackets; + p<0.1; * p<0.05; ** p<0.01		

Table 4 notes: This table reports ordinary least squares (OLS) estimates of the effects of lobbying expenditures (logged, and with a one year lag) on the log of earmarks. Column 2 reports the estimated effects of two interactions (lobbying X deaths and lobbying X publications; all variables logged and lagged) on this variable. Column 1 reproduces the estimates from a specification without the interaction terms, for comparison.

Table 5: Estimates of the relationship between earmarks/lobbying and NIH allocations

DV = Log NIH New Grants (1000 FY2010$)	[1] OLS	[2] OLS	[3] OLS	[4] OLS	[5] 2SLS
Log (1 + # Earmarks) 1-year lagged				0.188	2.443*
				[0.123]	[0.994]
Log Lobby (1000's FY2010$; 1-year lagged)			0.087		
			[0.045]		
Log Deaths (No. of deaths; 1-year lagged)	0.235**	-0.039	-0.038	-0.036	-0.034
	[0.016]	[0.077]	[0.077]	[0.077]	[0.078]
Log Publications (N of publications; 1-year lagged)	0.478**	0.062	0.07	0.071	0.062
	[0.016]	[0.069]	[0.068]	[0.069]	[0.077]
Log NIH Funds (1000s of FY2010 $; 1-year lagged)			-0.047**	-0.046**	-0.066**
			[0.014]	[0.014]	[0.016]
Constant	0.264	1.688	1.73	1.814	1.810
Year effects (11 years)	Y	Y	Y	Y	Y
Disease effects (955 diseases)	N	Y	Y	Y	Y
Instrument for Earmarks	N	N	N	N	Y
Adjusted-R2	0.209	0.692	0.658	0.693	0.703
N	9,550	9,550	9,550	9,550	8,595
Robust S.E. in brackets; + p<0.1; * p<0.05; ** p<0.01					

Table 5 notes: This table presents ordinary least squares (OLS) and two-stage least squares (2SLS) estimates of the effect of past year (logged) earmarks and (logged) lobbying expenditures on (logged) current year NIH funding for diseases. Columns 1-4 provide estimates of the effects of the explanatory variables on all new NIH funding each year. The OLS estimates capture the direct effect of lobbying, as well as direct effect of earmarks on NIH grants. Column 5 displays 2SLS estimates of the effects of earmarks on NIH funding. The 2SLS estimation instruments for earmarks with lobbying: the resulting estimate on the earmark coefficient can be interpreted as the effect of lobbying-related earmarks on NIH grants. Since we instrument for earmarks with past-year lobbying, the estimating sample loses an additional 955 observations.

Table 6: Estimates of the effect of lobbying-driven earmarks on NIH funding for rare diseases (2000-2008)

Year	NIH Funds (in FY2010 M$)	NIH Funds related to lobbying (in FY2010 M$)	% of NIH Funds related to lobbying
2000	367.10	4.63	1.26
2001	419.36	4.12	0.98
2002	475.58	4.27	0.90
2003	656.98	3.45	0.52
2004	537.38	7.03	1.31
2005	537.90	9.22	1.71
2006	474.55	10.18	2.15
2007	558.84	10.96	1.96
2008	572.40	9.86	1.72

Table 6 notes: This table uses the coefficient estimates of the effect of lobbying on earmarks and the effect of lobbying-related earmarks on NIH allocations for new research proposals to estimate the amount of NIH funds related to lobbying. Estimates of lobbying-related earmarks are obtained from the first-stage of the 2SLS equation (Column 1 of Table 5) and the predicted earmarks (lagged by a year) from the first stage are used in the second stage to calculate estimates of NIH allocations related to lobbying (Column 4 of Table 6). Column 2 displays NIH funding for research (for new projects only) in the 955 rare diseases; Column 3 displays our estimates of NIH funding related to the lobbying expenditures of interest groups (via earmarks); Column 4 displays the percent of NIH funding related to the lobbying expenditures of interest groups (via earmarks).

Supplementary Appendix

Figure A1: Comparison between the funding numbers for diseases obtained through our keyword search algorithm, and the numbers reported by NIH-RCDC

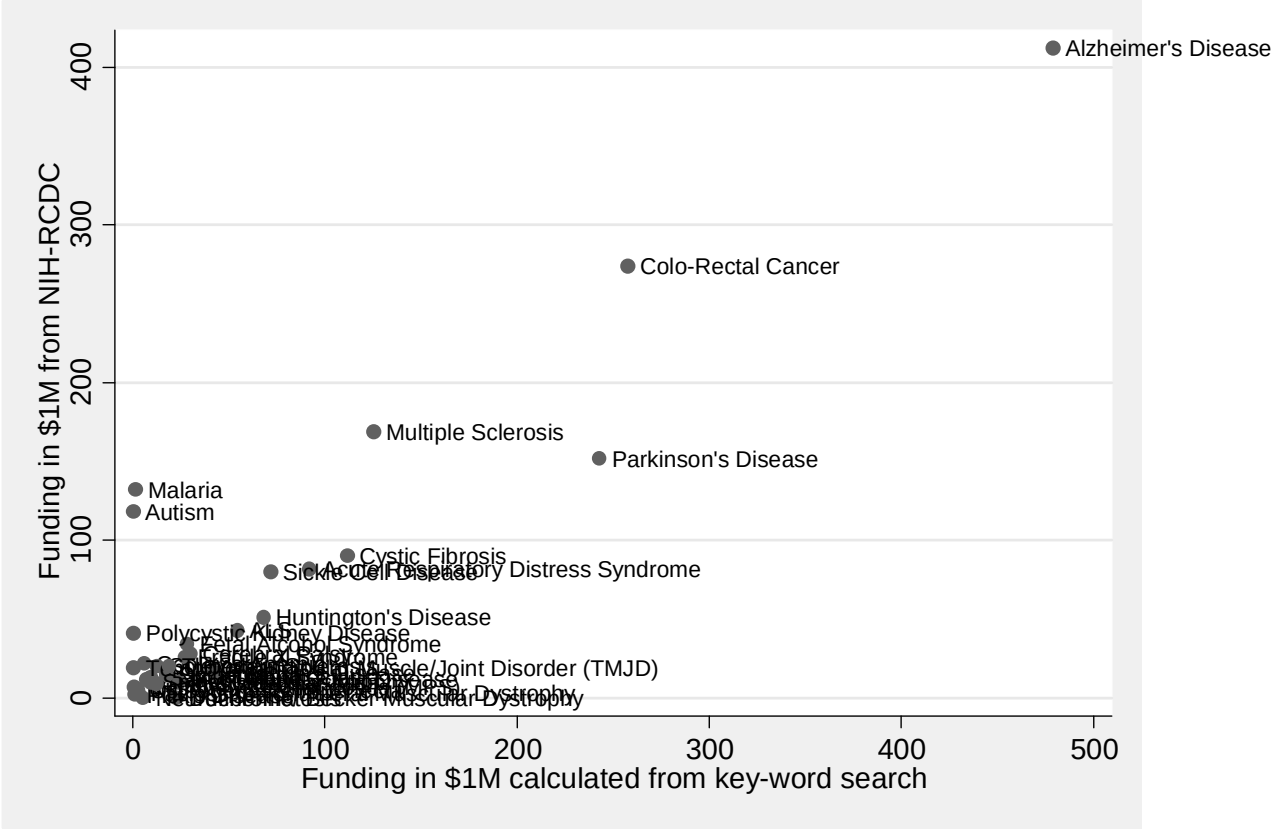


Figure A1 notes: This figure shows NIH funding numbers for 33 rare diseases as calculated by our keyword search (on the X-axis) and as reported by NIH's Research and Conditions Disease Categorization (RCDC) initiative for the year 2008. Both funding numbers are in millions of dollars.

Table A1: OLS estimates of the relationship between lobbying and earmarks (House and Senate)

Dependent variable = log(1+number of earmarks)	House	Senate
Log Lobby Intensity (1000's FY2010$; 1-year lagged)	0.030**	0.039**
	[0.007]	[0.007]
Log Deaths (No. of deaths; 1-year lagged)	-0.005	0.003
	[0.003]	[0.004]
Log Publications (No. of publications; 1-year lagged)	0.002	0.011+
	[0.002]	[0.006]
Log NIH Funds (1000 of FY2010 $; 1-year lagged)	0.001	0
	[0.000]	[0.000]
Constant	-0.009	-0.043
Year effects (11 years)	Y	Y
Disease effects (955 diseases)	Y	Y
Adjusted-R2	0.515	0.64
N	9,550	9,550
Robust S.E. in brackets; + p<0.1; * p<0.05; ** p<0.01		

Table A1 notes: This table reports Ordinary Least Squares (OLS) estimates of the effect of lagged NIH funding, deaths, and publications on the number and probability of current year earmarks. The dependent variable in Columns log (1 + earmarks). Column 1 displays estimates of the effects of the explanatory variables on earmarks by the House LHHE subcommittee, and Column 2 displays estimates of the effects on earmarks the Senate LHHE subcommittee.

Table A2: Yearly estimates (OLS) of the relationship between lobbying and earmarks

Dependent variable = Earmarks (e)	log(1+e)
Log Lobby Expenditure X Y1999	0.047**
	[0.011]
Log Lobby Expenditure X Y2000	0.058**
	[0.012]
Log Lobby Expenditure X Y2001	0.055**
	[0.011]
Log Lobby Expenditure X Y2002	0.037**
	[0.010]
Log Lobby Expenditure X Y2003	0.034**
	[0.010]
Log Lobby Expenditure X Y2004	0.054**
	[0.012]
Log Lobby Expenditure X Y2005	0.060**
	[0.011]
Log Lobby Expenditure X Y2006	0.053**
	[0.011]
Log Lobby Expenditure X Y2007	0.047**
	[0.010]
Log Lobby Expenditure X Y2008	0.046**
	[0.010]
Log Deaths (No. of deaths; 1-year lagged)	-0.003
	[0.005]
Log Publications (No. of publications; 1-year lagged)	0.012*
	[0.006]
Log NIH Funds (1000 of FY2010 $; 1-year lagged)	0
	[0.001]
Constant	-0.033
Year effects (11 years)	Y
Disease effects (955 diseases)	Y
Adjusted-R2	0.667
N	9,550
Robust S.E. in brackets; + p<0.1; * p<0.05; ** p<0.01	

Table A2 notes: The table reports ordinary least squares (OLS) estimates of the effects of lobbying on Congressional earmarking for each of the years during the 1999-2008 period. The coefficients on the interaction terms are yearly elasticities.

Table A3: OLS and 2SLS estimates of the relationship between earmarks and RFA/PA allocations

D.V. = Log NIH Grants (1000 FY2010$)	OLS	2SLS
Log (1 + # Earmarks)	0.398*	2.609*
	[0.188]	[1.099]
Log Deaths (No. of deaths; 1-year lagged)	0.115*	0.091
	[0.057]	[0.059]
Log Publications (No. of publications; 1-year lagged)	0.092*	0.056
	[0.046]	[0.050]
Log NIH Funds (1000 of FY2010 $; 1-year lagged)	-0.008	-0.015
	[0.009]	[0.009]
Constant	0.277	0.385
Year effects (11 years)	Y	Y
Disease effects (955 diseases)	Y	Y
Adjusted-R2	0.591	0.612
N	9550	8595
Robust S.E. in brackets; + p<0.1; * p<0.05; ** p<0.01		

Table A3 notes: This table presents ordinary least squares (OLS) and two-stage least squares (2SLS) estimates of the effect of past year (logged) earmarks on (logged) current year NIH funds through RFAs and PAs. The first column displays OLS estimates (which capture the direct effect of earmarks on NIH grants) and the second column reports 2SLS estimates (which instrument earmarks with lobbying and can be interpreted as the effect of lobbying-related earmarks on NIH grants). Since we instrument for earmarks with past-year lobbying, the estimating sample loses an additional 955 observations in the 2SLS regressions.

Table A4: OLS estimates of the relationship between lobbying and earmarks (with alternate measures of disease burden and scientific opportunity)

Dependent variable ('e' represents no. of earmarks)	[1] log(1+e)	[2] log(1+e)	[3] log(1+e)	[4] e	[5] (e > 0?)
Log Lobby Intensity (1000's FY2010$; 1-year lagged)			0.048**	0.208**	0.018**
			[0.009]	[0.039]	[0.006]
Log Deaths (No. of deaths; 1-year lagged)	0.015**	-0.001	-0.002	0.012	-0.004
	[0.002]	[0.005]	[0.005]	[0.014]	[0.004]
Log Days of Hospital Utilization (1-year lagged)	0.001*	0.004	0.004	0.016*	0.001
	[0.001]	[0.003]	[0.003]	[0.007]	[0.002]
Log Publications (JIF-weighted publications; 1-year lagged)	0.014**	0.008+	0.006+	0.011	0.007*
	[0.001]	[0.004]	[0.004]	[0.008]	[0.003]
Log NIH Funds (1000 of FY2010 $; 1-year lagged)			0	0	0
			[0.001]	[0.001]	[0.000]
Constant	-0.020	0.012	-0.042	-0.242	0.002
Year effects (11 years)	Y	Y	Y	Y	Y
Disease effects (955 diseases)	N	Y	Y	Y	Y
Adjusted-R2	0.066	0.658	0.665	0.605	0.613
N	9,550	9,550	9,550	9,550	9,550
Robust S.E. in brackets; + p<0.1; * p<0.05; ** p<0.01					

Table A4 notes: This table reports Ordinary Least Squares (OLS) estimates of the effect of lagged NIH funding, deaths, hospital utilization, and publications (weighted by the impact factors of the corresponding journals) on the number and probability of current year earmarks. Column 1 is the baseline model, without disease effects. Column 2 adds disease fixed effects. Column 3 adds lobbying expenditures by interest groups associated with each disease. The dependent variable in Columns 1, 2, and 3 is log (1 + earmarks). Column 4 reports estimates of a model with the number of earmarks for a disease-year as the dependent variable. Column 5 reports estimates of a linear probability model with a dummy indicator for whether a disease was subject of an earmark in a disease-year as the dependent variable. We use the full sample of 955 rare diseases and eleven years, but the year 1998 drops out of the estimating sample because our explanatory variables are lagged by a year, and our data begin in 1998.

Table A5: Estimates of the relationship between earmarks/lobbying and NIH allocations (with alternate measures of disease burden and scientific opportunity)

DV = Log NIH New Grants (1000 FY2010$)	[1] OLS	[2] OLS	[3] OLS	[4] OLS	[5] 2SLS
Log (1 + # Earmarks) 1-year lagged				0.187	2.126*
				[0.123]	[0.981]
Log Lobby (1000's FY2010$; 1-year lagged)			0.079+		
			[0.041]		
Log Deaths (No. of deaths; 1-year lagged)	0.209**	-0.039	-0.038	-0.036	-0.035
	[0.016]	[0.077]	[0.077]	[0.077]	[0.078]
Log Days of Hospital Utilization (1-year lagged)	0.022**	0.004	0.004	0.003	0.019
	[0.007]	[0.026]	[0.026]	[0.026]	[0.029]
Log Publications (JIF-weighted pubs; 1-year lagged)	0.443**	0.069	0.076	0.076+	0.086+
	[0.014]	[0.046]	[0.046]	[0.046]	[0.051]
Log NIH Funds (1000 of FY2010 $; 1-year lagged)			-0.047**	-0.047**	-0.066**
			[0.014]	[0.014]	[0.016]
Constant	0.199	1.640	1.596	1.776	1.675
Year effects (11 years)	Y	Y	Y	Y	Y
Disease effects (955 diseases)	N	Y	Y	Y	Y
Instrument for Earmarks	N	N	N	N	Y
Adjusted-R2	0.222	0.693	0.693	0.693	0.703
N	9,550	9,550	9,550	9,550	8,595
Robust S.E. in brackets; + p<0.1; * p<0.05; ** p<0.01					

Table A5 notes: This table presents ordinary least squares (OLS) and two-stage least squares (2SLS) estimates of the effect of past year (logged) earmarks and (logged) lobbying expenditures on (logged) current year NIH funding for diseases. Columns 1-4 provide estimates of the effects of the explanatory variables on all new NIH funding each year. The OLS estimates capture the direct effect of lobbying, as well as direct effect of earmarks on NIH grants. Column 5 displays 2SLS estimates of the effects of earmarks on NIH funding. The 2SLS estimation instruments for earmarks with lobbying: the resulting estimate on the earmark coefficient can be interpreted as the effect of lobbying-related earmarks on NIH grants. Since we instrument for earmarks with past-year lobbying, the estimating sample loses an additional 955 observations.