

## The Influence of Political Forces on Research Funding

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Non-defense research carried out in American universities is 60% federally funded, and most biomedical research is funded through the National Institutes of Health (NIH). We will address the effects of political forces on the awarding of individual grants and the overall level of research funding from the NIH.

The awarding of individual grants to university faculty and other researchers by the NIH is based mainly on peer review. The process of determining the yearly national research budget, including that of the NIH, is complex as congressional appropriations wind their way through to become law. These decisions are not insulated from political influence. A recent study reported the effect of representation on congressional or senate committees involved in the grants obtained by the state or congressional region. The process behind government appropriations involves the Appropriations Committees of the House and Senate, the Labor, Health and Human Services, Education-related Agencies Subcommittee and the subcommittee of the Senate Appropriations Committee.

It all begins with a budget which is presented by the President which NIH negotiates with the Department of Health and Human Services and the Office of Management and Budget within the Executive Office of the President. The various government committees mark-up the appropriations bill from the President, and present it to the House and Senate for a vote. The allocation and disbursement of approved funding

then occurs. A recent study found that from the years 1983 to 2002, the political effect on this process ranged from 2.85% to 6.74%. Clearly, this is a minor effect, and it is encouraging to know that peer review is the main mechanism by which NIH research and training awards are made.

Major, multi-year shifts in overall federal funding of biomedical research often comes through major economic crises such as the one we are in now, or major advocacy efforts of scientists, the biomedical industry and other groups, such as patient advocacy groups working closely with legislators. Two recent examples of this include the doubling of the NIH budget from 1998 to 2003, which came about largely because of well-reasoned and coordinated arguments from scientific organizations such as the American Association for the Advancement of Science, and from biomedical device and pharmaceutical companies as well as patent advocacy groups arguing that strong basic research was needed for a viable health care system.

The most recent major change in federal funding for research resulted from efforts to reverse the results of the recent economic crisis by passing the American Recovery and Reinvestment Act (ARRA) of 2009, which was signed into law by President Obama on February 17, 2009. The overall budget of the NIH rose from \$8.3 billion in fiscal year 1984 to \$28.7 billion in fiscal year 2008, and in 2009–2010 will increase another \$10 billion based on the ARRA. The National Institute of Dental and Craniofacial Research (NIDCR) has a series of programs supported by the ARRA, and these can be reviewed at [www.nidcr.nih.gov/Recovery/](http://www.nidcr.nih.gov/Recovery/). However, these are temporary funds, and their function is to support the best science while stimulating the economy. Our

most optimistic outlook is that these funds will be dispersed to individual scientists or groups of scientists using the effective peer review system already in place at the NIH, which is relatively insulated from the political process.

Advocacy efforts for dental research are carried out mainly by 2 organizations, which interact with the NIDCR: the Friends of the NIDCR, which is a group of individuals interested in promoting the strategic plan and other programs of the NIDCR to many different audiences, including legislators. The other group is the National Oral Health Advocacy Committee, which is a combined advocacy committee of the American Association for Dental Research and the American Dental Education Association. The primary purpose of these organizations is to increase and enhance the efficacy of advocacy efforts on behalf of dental research and dental education. To this end, there is a National Advocacy Network, which is the infrastructure through which members and advocacy coordinators can carry out joint advocacy and mobilize members of the House and Senate to take legislative action. Those interested in participating in this network should contact Monette McKinnon at [mckinnonm@adea.org](mailto:mckinnonm@adea.org). Advocacy organizations can be effective vehicles for those interested in promoting broad biomedical and dental research, as can participation in the efforts of patient advocacy groups. Also, local efforts can be effective in educating legislators. A simple measure such as inviting congressmen and other legislators to visit laboratories, clinics, dental or dental hygiene schools is often effective to help convince legislators on the value of our educational and research programs to oral and general health.

## Building Relationships from an Industry Perspective

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Much of the interest in fostering collaborations between academia and industry began in the 1980s, when the government encouraged collaboration that would foster a quicker pace of innovation. While industry sought out relationships with universities earlier, it became more widely accepted due to the “blessing” of institutions, such as the National Institutes of Health and Medical Research Council of Canada. University–industry collaborations foster economic growth, improve standards of living and extend humanity’s intellectual reach. With these lofty goals a long–term relationship mindset is essential.

Industry enters into collaborative relationships for many reasons. Most often it is to access a technology and gain expertise. Leveraging the credibility that an investigator brings and enabling the credentialing of the end result with the broader oral health community is highly desirable.

Academia often needs expertise or capability that an industrial partner may provide. Industry has to operate efficiently to remain competitive and deliver desirable returns on investment for their shareholders. The introduction of process, a system to move towards goals efficiently, is a strength that industry cultivates in order to survive. This experience managing large programs from start to finish is a capability that industry brings to any academic and government relationship.

The classic pharmaceutical model of drug development is becoming less common, and industry is playing a lesser role in drug discovery. As universities and government develop core facilities and capabilities, the ability to leverage these

elements for the discovery phase is increasing. In order for these collaboration models to be sustainable and deliver the desired impact on oral health, they must be flexible and need proper funding from both government and industry sources to succeed.<sup>1</sup> The potential to develop common best practices is enormous and there is great need to publish the experiences with industry–university collaborations so that knowledge and experience may be disseminated appropriately.<sup>2,3</sup>

While collaborations between academia and industry are encouraged, there has been greater emphasis on whether these kinds of collaborations have the potential to create conflict of interest that may jeopardize the safety of study participants and the integrity of the data.<sup>4</sup> Escalating awareness is being driven by the intense focus of the media on these types of issues which cast an unfavorable light on many positive, productive relationships.

Over the past 20 years, fewer than a dozen dentistry–specific drugs have gained US Food and Drug Administration (FDA) approval. Only one area, locally delivered antimicrobials for periodontitis, has at least 3 new drug approvals and, sadly, none of these could readily be classified as a blockbuster. This reality has made industry question the return on investment of the drug development route. Instead, oral care research and development has more typically been focused on FDA monograph actives (fluoride for caries) and devices such as implants, toothbrushes or restorative materials.<sup>5</sup>

The risks associated with entering into university–industry collaborations on the part of a corporate entity is often framed around concerns about whether academia is unbiased and ethical, and whether the investigator or institution is respected. There are also concerns about the role of the broader university, especially when it comes to intellectual

property and publication rights. It is absolutely critical to have these elements defined up–front because this has been the cause of many irresolvable conflicts.

There are a number of potential strategies for building research relationships with industry. Enter into these relationships with eyes wide open. There will be big issues along the way that stall progress. In order to survive in the current research climate all parties need to roll up their sleeves and work through it with the end goal in mind.

The most common downfall when academia approaches industry regarding potential partnerships is a lack of understanding of the business which is targeted. Great ideas which are not framed appropriately are summarily dismissed because the audience is not understood. Identify partners with similar interests and complementary needs – all sides need to gain from the collaboration.

The most efficient way to build a research relationship is to find a way in. Champions are critical in these endeavors. Interestingly, many of these partnerships are forged through informal means such as networking during poster sessions at research conferences.

There is an increasing emphasis on translational research in the dental research community. The skill set to take the great inventions in the laboratory and make them relevant to the daily care of patients is unlikely to occur in a single individual. While dental hygienist scientists have the potential to play important roles in all phases of collaboration, this is the place where the hygienist has the highest potential. Given the close relationships that are forged between dental hygienist and their patients, the practicality and value of ideas can be fully vetted and honed into great ideas. Without the ability to leverage the outcomes of research, the return on investment for all parties is never enough.

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## Strategic Planning and Research Priorities in Private Industry

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Prior to any strategic planning of industry-supported research work, it is important to identify the priorities of the corporate organization. These priorities will be critical to understand in order to ensure that the research you are proposing is relevant to the corporation and meets their strategic needs.

Corporations will identify their priorities based on many different approaches. One approach might be to look at market research results to consider feedback and insights from both consumers and professionals. These studies might be conducted at conventions, through experts or key opinion leaders in the field, via advisory board meetings, through focus groups (qualitative research) and/or broad surveys (quantitative research). Often during these research studies, unmet consumer/patient needs may be uncovered or an unmet need within the profession may be revealed and explored.

Many companies will also review new and emerging trends in the marketplace. These can be either product or procedure trends. Some examples of emerging markets today might be dry mouth, erosion, sensitivity, minimally invasive dentistry or even spa dentistry.

In addition to considering what research needs to be conducted in the future, companies will look to explore the research that may already exist on a specific topic to date. This research may have been conducted within the company or outside of the organization. It may be research conducted on other products, on a specific ingredient(s) or on a specific subset of the population.

Organizations seeking to identify priorities must also be aware of

competitive activity within the category they may be exploring. They need to understand the activities and products in the competitive landscape that are gaining traction. In addition, the internet can be a wonderful tool to acquire knowledge about trends and fads via Google, YouTube and various blogs.

Understanding technology, activities, products and procedures that are approved and available in other parts of the world can also be a key driver in identifying research priorities. In some cases this learning may come from a competitor, but often times it is a result of exploring worldwide trends, fads and emerging sciences.

Finally, and probably most importantly, a corporate organization must be mindful of its core competencies, but must also understand if there is opportunity to move beyond the competencies that exist today to a competency that may be acquired. Ultimately, any new competencies would need to be a strong strategic fit in order to avoid potential disastrous results.

Once the corporate priorities are identified, they must then be prioritized in order to come to a key decision on what research should be pursued. For example, recognizing the corporate strategy for the study (i.e. long or short term, local, regional or global) will be critical to the design of the study. In addition, the core competency of the organization is critical to the decision making and prioritizing process. In reviewing this aspect, it is important to determine how the option expands the current portfolio and if it does so in a meaningful way. In looking at the possibility of a product line extension, a company must consider whether the additional products in the line will contribute meaningful product benefits or will move the product line into a different or new and meaningful area. Finally, the timeline to get the results, the cost of getting those results and the re-

turn on the investment will all need to be considered.

If it is determined that the research priority will be in a non-core competency or new area, then it is important to first evaluate the cost of entry. This can be accomplished by reviewing and applying Michael Porter's "Five Forces" in his 1998 publication *On Competition*.<sup>1</sup> The company must also consider how this expansion of the corporate brand image would be perceived and what the options to entry are. For example, is it in the organization's best interest to research and develop a new product or procedure alone? Or is a strategic partnership the better choice? Is an acquisition of the product/procedure/technology the best approach? Once the plan of entry is decided, a plan after entry must be formulated including a timeline, cost and return on investment.

Now that the key priorities have been listed, they need to be prioritized in rank order. Strategic plans, both short and long term, must then be developed around these priorities. It will be important to ensure that the appropriate resources are allocated for all proposed research and that key performance indicators are in place in order to consistently monitor the progress of the research project.

It is important to consider both the advantages and challenges associated with merging research interests between academia, government and industry. Several advantages do exist, including the fact that these types of collaborations are relationship based and develop as a result of solid relationships between academia and industry. Because of this platform, funding support is usually straightforward and predictable. In addition, there is solid support for proposed methodologies and techniques, as well as a dedicated, reliable team of corporate research and development employees who are always available as an ongoing

resource. Once the data has been collected, an additional advantage to this type of collaboration is that there are corporate employees who are able to run the statistical analyses that are needed for final report and article submissions. Finally, the end result of this type of collaboration can lead to even more interaction between these groups, such as additional studies, consulting or ongoing long-term collaborations.

The challenges with these merging research interests include the need for common interests, the fact that the priorities of either team may change mid-stream or the economic pressures that may exist as the research study progresses, as well as the level of oversight the corporation may choose to impose on the researcher. Overall, however, the advantages far outweigh the challenges and great opportunities exist

from these types of academic, government and industry research interactions and collaborations.

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## The Academic/Industry Relationship: Common misconceptions about bias.

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Criticisms of bias in sponsored research programs regularly generate media interest, both in the academic world and beyond. This climate of mistrust has been fueled by reports of negative study results being withheld by industry as well as falsified data being presented by academic investigators, thus questioning the validity of support for drugs and devices.

Inherent industry bias is the assumed culprit, suggesting that active sponsor involvement in study design, analysis, control of databases and publication set the stage for biased research results. Financial considerations also play an important role in the conduct of clinical trials. Product development costs, especially for drugs, can run into the millions of dollars. This financial burden relies mainly on industry. In fact, over 70% of funding from clinical trials comes from industry.<sup>1</sup> Researchers pressured to obtain funding increasingly look to industry in this era of shrinking federal dollars. Interestingly, two thirds of academic medical centers hold an equity interest in companies that sponsor research at their institution.<sup>2</sup> New approaches in the evaluation of drugs have been suggested, such as an Institute for Prescription Drug Trials within the National Institutes of Health (NIH), which would administer clinical trials sponsored by industry.<sup>3</sup> While most of the negative media is related to prescription drug trials, bias towards industry sponsored trials for oral health products exists as well. Although dental clinicians are wary of product claims when research is sponsored by industry,

one must ask who else would pay for this research. It is only through education and understanding of the research process that some of these misconceptions can be cleared.

Any scientist appreciates that reduction in bias is a basic part of the scientific method. While practicing professionals have been far removed from their basic science classes, most have forgotten that there are internal and external threats to the validity of research results. Internal threats include subject selection, history, repeated testing (learning over time) and maturation (aging process, fatigue). External threats including randomization, masking and multicenter participation are controlled so that results can be applied to other populations. Individuals involved in research consciously account for these confounding issues by rigorous approaches to study design and analysis.

There are also other, more subtle forms of bias, for example:

- Publication Bias – studies with positive findings are published more often and faster than those with negative results<sup>4</sup>
- Funding Bias – biases in research design, outcome and reporting may be influenced by the source of funding or the desire to obtain continued funding
- Outcome Bias – studies that collect many types of data often report only the significant results
- Grey Literature Bias – results appear in many forms that are not referenced in journals. This includes abstracts, working papers, conference reports, patents and progress reports that can contain conflicting data

Efforts to reduce these types of bias with the aim of “increased transparency” have been initiated by regulatory agencies, professional organizations, academic institutions and journal editors. Clinical Trial Registries, use of Consolidated Standards

of Reporting Trials (CONSORT) and Conflict of Interest statements are all initiatives created to limit bias and increase transparency in clinical trials. Regulatory efforts include established federal, professional and advertising guidelines.

The Clinical Trial Registry ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) is a repository of federal and privately funded studies conducted in the U.S. allowing consumer, industry and investigator access to clinical trials. At this time, trial registration is voluntary, except for federally funded clinical trials.

Publications in peer reviewed journals have now adopted use of CONSORT ([www.consort-statement.org](http://www.consort-statement.org)) to address publication bias. Most journals, including dental health journals, require authors reporting on clinical trial data to follow these guidelines when publishing. Use of CONSORT makes published clinical trial data more amenable to systematic reviews as the full data are included for easy access and meta-analysis.

Conflict of Interest or statements of financial disclosure are now required of investigators by most organizations. The NIH states “This regulation promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting of research funded under NIH grants, cooperative agreements or contracts will be biased by any conflicting financial interest of an Investigator.”<sup>5</sup>

It seems that most of these efforts described have focused on the bias of the investigator. Actually, industry sponsors of clinical trials must adhere to regulations imposed by government and professional organizations. All clinical trials involving human subjects adhere to the U.S. Code of Regulations (CFR), which defines the procedures that must be met for studies involving drugs, medical devices and over the counter health products. International agencies, including Health

Canada, also provide regulations for marketing of products and approval of advertising claims. Claims used in advertising are regulated by the Federal Trade Commission (FTC) and the National Advertising Division (NAD) of the Better Business Bureau. These agencies have jurisdiction over national advertising, including print, packaging and labels, broadcast in TV, radio and infomercials, direct mail and the internet. Advertisers must substantiate all claims, whether overt or implied. For “clinically proven” claims, the FTC, working in partnership with the FDA, requires industry to supply 2 clinical trials in support of the claim. Professional associations may also oversee product claims. The American Dental Association

requires clinical claim support for all advertising. In addition, clinical study guidelines adopted by the profession often dictate what study designs are accepted for product evaluation and claim approval.

In summary, elimination of bias in clinical research is a shared responsibility. As professionals, we are called upon to be both supportive of new product development and critical of claims validity.

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## Exploring the Government/Industry Interface – the NIH SBIR STTR Program

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The National Institutes of Health (NIH) participates in 2 Congressionally-mandated programs that offer funding explicitly for small U.S. companies to do innovative research work in the biomedical and behavioral sciences that have the potential for commercialization. These are the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs.

SBIR was enacted in 1982 and has 11 federal agencies participating. In order of their SBIR budgets (largest to smallest), they are:

- The Department of Defense
- The Department of Health and Human Services (which includes NIH)
- The National Aeronautics and Space Administration
- The Department of Energy
- The National Science Foundation
- The Department of Homeland Security
- The U.S. Department of Agriculture
- The Department of Commerce
- The Department of Education
- The Environmental Protection Agency
- The Department of Transportation

SBIR's sister program, STTR, was enacted in 1992 and includes the top 5 SBIR-participating agencies.

Each agency is required to set aside 2.5% of their extramural R&D budget for SBIR and three-tenths of 1% for STTR. Combined NIH budgets over the past several years have been approximately \$650 million (\$580 million SBIR, \$70 mil-

lion STTR). Current budgets (fiscal year 2009) are \$600 million for SBIR and \$72 million for STTR (The fiscal year 2009 budgets for the National Institute of Dental and Craniofacial Research (NIDCR) are \$7.8 million and \$0.9 million).

There are 3 phases to both SBIR and STTR with federal funds available for Phases I (a feasibility study) and II (full research/R&D). Phase III is the commercialization stage and awardees are responsible for obtaining the necessary following on funding and strategic partnerships to bring the SBIR/STTR-developed products or services into the marketplace. No SBIR or STTR funding is available for Phase III.

Both of these programs share the following goals:

- Stimulate technological innovation
- Use small businesses to meet Federal R&D needs
- Foster and encourage participation by minorities and disadvantaged persons in technological innovation
- Increase private-section commercialization innovations derived from Federal R&D

There are 2 major differences between the programs that must be considered when deciding which is best. They are the amount of subcontracting needed and the principal investigator's (PI's) employment.

The SBIR program allows collaborations with private industry, universities, foundations or other U.S. entities. However, the STTR program requires a collaborative effort between the small business and a non-profit research institution. The small business must perform a minimum of 40% of the effort and the collaborating institution a minimum of 30%. The remaining 30% may be allocated to either of these entities or an additional third party, leaving the possibility of as much as 60% of the effort to be performed by the non-profit research institution. Generally, the

maximum amounts subcontracted for the SBIR program are one-third in Phase I and one-half in Phase II. Those research projects needing substantial support by a non-profit research institution usually consider the STTR program.

The other major difference between the programs involves the PI. SBIR requires that the PI be primarily employed with the small business awardees and STTR permits the PI to be employed with either the small business or the collaborating research institution. Those projects for which the expertise, leadership and technical guidance are to be provided by a university employee usually find the STTR program is a better fit.

NIH has exercised great flexibility in the implementation of its SBIR and STTR programs to maximize their use. The following are just a few of the many nuances that have helped to make these programs not only effective, but also viable sources of funding for small businesses to consider as part of their business plans to fund their research and R&D efforts:

- NIH offers both grant and contract opportunities with most (95%) of its awards being grants. As an assistance mechanism, grants offer more flexibility than contracts which is a procurement mechanism
- NIH offers 3 grant application submission dates each year: April 5, Aug. 5 and Dec. 5
- An applicant may exceed the budgetary and project duration period guidelines, providing they are adequately justified and the research plans warrant doing so. These guidelines are:
  - SBIR Phase I – \$100,000 for 6 months
  - SBIR Phase II – \$750,000 for 2 years
  - STTR Phase I – \$100,000 for 12 months
  - STTR Phase II – \$750,000 for 2 years

- Grant applicants must respond to the NIH mission of improving human health rather than a narrowly focused scientific technical topic. This allows for submission of investigator-initiated projects for which the investigator is encouraged to “think outside of the box” to provide innovative solutions to real problems
- All applications are peer reviewed and applicants receive the reviewers’ comments. These comments are especially useful when an applicant decides to revise and resubmit their application for review and consideration again
- Applications may be given assignments to multiple NIH institutes and centers for funding consideration. For those appli-

cations that are deemed scientifically and technically meritorious, this allows for greater chance of being selected for an award

- NIH offers Phase II Competing Renewals that provide additional Phase II funding for complex instrumentation projects, clinical research tools, behavior interventions/treatments or clinical projects preparing for FDA approval
- NIH offers the opportunity to submit FastTrack applications (combined Phase I and Phase II applications). Funding gaps between phases can be dramatically reduced or perhaps eliminated for FastTrack applicants
- NIH offers technical assistance programs to help transition SBIR-developed products into

the marketplace

Only small businesses may apply and receive SBIR and STTR funds, but university involvement is also encouraged. University individuals may serve as consultants or as key personnel on subcontracts to the small businesses. In the case of STTR, they may serve as principal investigators. University individuals who own their own small companies may also apply and receive awards. However, they and their universities must be cognizant of the conflict-of-interest issues that may arise and properly handle them.

Additional information about the NIH SBIR and STTR programs and how to submit an application is available from the NIH Small Business Research Funding Opportunities Web site <http://grants1.nih.gov/grants/funding/sbir.htm>.