OUTLOOK

The profit problem in antibiotic R&D

Carl Nathan and Frederick M. Goldberg

Abstract | Economists, a biomedical researcher and a business executive have formulated three contrasting proposals to address the shortfall in antibiotic R&D. Their proposals, which emphasize advance purchase contracts, not-for-profit research, and tax incentives, respectively, share some features with provisions in bills pending before the US Congress that could potentially reshape the R&D landscape for this essential class of drugs.

The growing shortfall in antibiotic R&D[1] stems from economic, regulatory and scientific problems[2] that have been exacerbated by antibiotic resistance[3]. These adversities have convinced a significant portion of the pharmaceutical industry that antibiotic research and development are not competitively rewarding[4]. That is, it seems to be extremely difficult for an antibiotic to reap earnings above the cost of its development that are commensurate with those that the industry expects to attain by developing other kinds of products.

In April through June 2005, three bills were introduced in the US Congress to address aspects of this problem. These were the Preservation of Antibiotics for Human Use Act (S.742) introduced by Senators Kennedy (D), Snowe (R), Collins (R), Landrieu (D) and Reed (D), a reprise of an act introduced in 2003; Project Bioshield II Act of 2005 (S.666), introduced by Senators Lieberman (D), Hatch (R) and Brownback (R); and the Infectious Diseases Research and Development Act (H.R.3154) introduced by Representative Cubin (R) and eight colleagues. BOXES 1–3 summarize the features of these bills. Progress in directing the attention of elected officials to the growing antibiotic shortfall rewards the hard work of many scientists, physicians, government workers and foundation officers who have convened, conferred and issued reports and calls to action over the past decade. Particularly effective has been the public education campaign of the Infectious Diseases Society of America[5]. Another ray of hope shone forth in July 2005, when the US FDA acted for the first time to ban the use of an antibiotic, enrofloxacin (Baytril; Bayer), in healthy poultry, citing the risk to humans from dissemination of drug-resistant *Campylobacter*[6]. However, the bills face an uncertain fate. It is therefore timely to discuss the issues they address and the remedies they propose.

Here we consider three sets of views on these matters, formulated before the bills were introduced, and whose relevance has increased now that the bills exist. Michael Kremer, Professor of Developing Societies at Harvard, and Rachel Glennerster, director of the Poverty Action Lab at Massachusetts Institute of Technology, recently published a proposal for government incentivization of industrial vaccine and antibiotic development. Their book *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases*[7] recommends a different approach than one recently outlined by a medical scientist[2]. A businessperson (F.G.), with ties neither to academia nor pharma, recommends yet another solution. Below we summarize the status quo and then contrast these three distinct approaches to the profit problem in antibiotic R&D.

Status quo: for-profit antibiotic R&D

Large pharmaceutical companies have carried out most antibiotic R&D. Antibiotics must compete with all other products that these firms have under consideration, based on business decisions that affect the profitability, and therefore the fate, of the company. Infectious diseases do provide some attractive features for product development, particularly in a litigation-rich environment. Targeting microbial enzymes that lack a human homologue provides an opportunity to avoid mechanism-based toxicity. Toxicities are further reduced by short periods of administration. If toxicities are of low incidence, they may be considered acceptable in the treatment of life-threatening diseases. The downside risk for antibiotics might therefore be less than for drugs directed at human molecular targets in the long-term therapy of chronic ailments. Further, public gratitude, confidence and loyalty are bolstered by drugs that meet medical need by furnishing dramatically successful interventions in acute, life-threatening conditions.

Antibiotics are usually designed to be used singly. Most firms make no effort to develop products collaboratively to exploit synthetic lethality (that is, killing a pathogen by inhibiting two pathways at once); instead, knowledge of the chemistry, target and mechanism of action is kept secret until clinical trials commence. Once antibiotics are developed, marketing efforts sometimes aim to maximize sales in a situation in which the primary target market (people with a specific bacterial infection) is considered too small to reward the cost of product development. As a result, secondary target markets can assume particular importance. These sometimes include healthy food animals, which are fed an estimated 50–70% of antibiotics produced in the US in an effort to boost their growth[2], and people with infections that occasionally demand broad-spectrum therapy but more often qualify for broad-spectrum therapy on the basis of

Box 1 | **Bill S.742: Preservation of Antibiotics for Medical Treatment Act**

- Requires the FDA, 2 years after the bill comes into force, to withdraw approval of non-therapeutic use of seven major classes of antibiotics in feed and water given to food-producing animals
- Allows use of these drugs for sick animals and pets
- Defrays costs to livestock producers, particularly family farms and small farms
- Funds research, demonstration and education projects

imprecision in microbiological diagnosis at the time of prescription. Development of technology for rapid, accurate, pretreatment microbiological diagnosis is not part of most firms' portfolios, and might even undercut sales.

Because a given antibiotic is often distributed as widely as possible, including throughout the food chain, and usually used singly, antibiotic resistance arises quickly, which shortens its market life[2]. Although major firms match superb expertise with enormous resources, fundamentally new classes of antibiotics are hard to discover using older approaches and sources; instead, companies usually seek variants on older agents. Even if the goal is an agent in a new class, insistence on developing singly-acting, broad-spectrum agents severely limits the number of potential new targets. To make matters worse, antibiotics seem to be a special case with respect to contemporary combinatorial chemical libraries: the hits discovered in these collections rarely lead to useful anti-infectives.

Finally, regulatory requirements for approval of a new antibiotic do not take into account that the new compound's superiority over existing agents might be confined to its ability to kill pathogens that have become resistant to the existing drugs. It takes a very long time and is exceedingly expensive to conduct clinical trials in patients infected with drug-resistant organisms who have not already been treated with another anti-infective agent before the drug resistance has been detected. Companies have little choice but to conduct trials in patients most of whom are infected with organisms sensitive to existing antibiotics. In this setting the new agent might not show any superiority over existing agents. Moreover, regulatory requirements make it very difficult to win approval for new agents whose advantage over existing antibiotics is expected to be evident only when two or more new agents are used in combination. Overall, then, the ratio of costs to earnings is often perceived as adverse when compared with drugs for other indications.

The foregoing considerations pertain to infections prevalent in relatively wealthy markets. Targeting infectious diseases that are primarily prevalent in poor societies is a non-starter for most firms.

Model 1

In Model 1, the incentive to undertake for-profit antibiotic R&D is provided by government via guaranteed purchase of products[7]. In this model, government intervenes to improve the profit outlook for antibiotics in competition with other product lines. The incentive is based on advance-purchase contracts; that is, commitment to purchase a fixed quantity of antibiotics at a rewarding price, provided that the drugs meet certain specifications. Alternatively, government commits to purchase patent rights to the new antibiotics, with the intent of placing the patent rights in the public domain in order to open the manufacturing and marketing processes to competition.

Paradoxically, the competitive basis of awarding the purchase commitment might be a powerful disincentive to participation. Normally, any number of antibiotics useful for a given indication can emerge as successful products; they contend in the marketplace in part on the basis of differences in performance that cannot always be anticipated and which are only perceived after extensive clinical use. By contrast, under the 'pull' model[7], the government is likely to buy only one product for each indication for which a competitive purchase bid is posted. This increases rather than decreases the risk of financial loss faced by a company as it considers embarking on an expensive programme of R&D. Not only does the usual risk remain that a product might not emerge; there is the additional risk that even if a product is developed, it might not be the one selected for government purchase, even if subsequent clinical experience would have proved that it was superior to other options.

Moreover, when government draws up specifications for antibiotics, a crucial decision becomes centralized: which infectious diseases represent the top priorities? What lobby would speak up for infectious diseases that chiefly afflict people in impoverished regions? What mark-up would government allow when it sets such contracts, and how would the public respond to large cash transfers from deficit-plagued public treasuries to one of the world's most profitable industries? Pressure would be high to award only a small number of contracts. If incentives could be provided for the development of only a few antibiotics, the specifications would probably call for broad-spectrum agents. This would direct research back to the same targets that have been so extensively mined with rapidly diminishing results.

Another alternative discussed (but not favoured) by Kremer and Glennerster[7] is for government to reward antibiotic development by extending patent life on another product of the company's choosing, the so-called 'wild-card patent extension'. Some who are eager to entice large pharmaceutical firms back to antibiotic development feel that the wild-card option is the only attraction that the industry values highly enough to ensure that it responds. Nonetheless, the wild card would be unfair, because it would

Box 2 | **Bill H.R.3154: Infectious Diseases Research and Development Act**

Provides incentives for pharmaceutical, biotechnology and medical device companies to invest in R&D with respect to antibiotics, antivirals, diagnostic tests and vaccines. Specifically:

- Extends relevant patents by the time taken for regulatory review
- Allows extension of another ('wild card') patent by 2 years
- Allows Department of Health and Human Services (DHHS) to designate infectious disease products for fast-track approval
- Provides a tax credit equal to 35% of research expenses on infectious diseases from private sources
- Provides a tax credit equal to 20% of investment in construction of manufacturing facilities for infectious-disease products
- Requires the President to appoint a Commission on Infectious Disease Product Development to advise DHHS as to which pathogens pose a significant threat to public health and to recommend specific actions
- Requires the DHHS via the FDA to issue guidelines for clinical trials of anti-infectives

transfer the costs of developing drugs for one kind of disease to patients with another kind of disease; it would be counter-productive, because it would reward companies that have developed blockbuster drugs, the over-pursuit of which is a root cause of insufficient antibiotic R&D; and it would be anticompetitive, because firms would contend for the reward only if they already had a patent whose extension was likely to be exceptionally lucrative. This would freeze out most start-up companies focused on anti-infectives, the very firms most likely to take a fresh scientific approach. Another way that this incentive might backfire is if it enticed a large firm not interested in marketing antibiotics to purchase a small one that had been developing antibiotics so that the large firm could acquire the small firm's wild-card patent extension.

Model 2

In model 2, not-for-profit antibiotic research is coupled with for-profit development[2]. After society's needs for increased antibiotic R&D are experimentally addressed on a small scale by philanthropic foundations, government takes responsibility for stepping in, recognizing that society has an exceptionally compelling medical need that is not being met by the business sector. Government alone or together with foundations sets up a not-for-profit antibiotic research operation and encourages business participation through tax incentives and gifts of intellectual property to the for-profit sector. Scientists working under the direction of scientists, rather than marketing executives, experiment with new approaches to making antibiotics. They target infectious diseases that present the greatest medical need rather than the best opportunity for profits; develop technology for pre-treatment diagnosis; share results at the earliest opportunity; and work toward specific, combination therapy. They figure out how to culture new species of antibiotic-producing microorganisms, perhaps from among the thousands of bacterial species that live in the intestines of healthy humans, in which the normal microbiota helps to exclude disease-causing bacteria. The scientists experiment with inhibitor chemistries, such as natural-product-based combinatorial libraries and target-templated synthesis. The facilities are open to academics intent on building chemical tools for biological investigation. These workers validate a new list of drug targets in infectious agents and provide proof of principle, reducing industry's costs.

Box 3 | **Bill S.975: Project Bioshield II Act**

The act includes 29 titles (major topics) in 360 pages. Many important provisions, including those focused on vaccine development, are not covered here. It provides incentives to increase private-sector research into the prevention, detection and treatment of diseases related to biological, chemical, nuclear or radiological attack or an infectious disease outbreak, including the following features:

- **Gives the Department of Homeland Security (DHS) a 'Terrorism and Infectious Disease Countermeasure Purchase Fund' to contract for products and their R&D in a manner similar to Department of Defense (DOD) contracts**
- **Authorizes DHS to fund private R&D if approval of the product can be anticipated within 8 years**
- **Authorizes National Institutes of Health (NIH) to award 'partnership challenge grants' for NIH scientists, NIH-funded grantees and for-profit entities to work together on countermeasures and research tools**
- **Appropriates new funds for NIH for studies of infectious disease in animal models, including primates**
- **Confers fast-track status for approval of contracted products**
- **Requires the Department of Health and Human Services (DHHS) via the FDA to issue guidelines for clinical trials of anti-infectives**
- **Authorizes fees to vendors for maintaining a 'warm industrial base' (excess manufacturing capacity) for emergencies**
- **Allows grants to build up to 10 more Biological Safety Level 3 or 4 facilities**
- **Authorizes Centers for Disease Control and Prevention (CDCP), in consultation with DHS and DOD, to award grants and scholarships to train scientific and technical personnel for infectious disease research to remedy shortages, with awardees obligated to serve as directed for at least 2 years after training**
- **Extends relevant patents by the time taken for regulatory review**
- **Allows DHHS to reward providers with a 'wild card' patent extension of 0.5–2 years**
- **Allows indefinite extension of unexploited patents on NIH-funded intellectual property until commercialization, without interim fees**
- **Provides tax incentives for small-business R&D partnerships**
- **Provides capital-gains tax exclusions and equity tax credits for investors in 'countermeasure' research**
- **Provides a tax credit equal to 35% of research expenses on countermeasures**
- **Assigns liability to the US government for claims arising out of manufacture, clinical trial or use of a contracted product; caps awards for non-economic losses**
- **Supports small companies to participate in the 'national biodefence industry'**
- **Exempts participants in planning meetings from antitrust laws**
- **Creates within NIH a National Center for Healthcare Technology Development to foster transfer of NIH-funded intellectual property to companies, the director to be appointed by the President**
- **Permits DHS to contribute to procurement pools organized by the United Nations, foreign governments or non-profit entities**
- **Allows DHHS to attempt to persuade DOD and DHS to add a broad range of specified infectious agents to the product procurement lists in the national interest, ranging from HIV to *Escherichia coli***
- **Allows DHS to block publication of information pertaining to biological agents**
- **Establishes in DHHS an Office of Public Health Countermeasure Development headed by an Assistant Secretary appointed by the President to set priorities including those for 'basic and applied research' related to a 'national preparedness' plan devised by Secretary of DHHS in consultation with DOD and DHS**
- **Includes in the 'national preparedness plan,' for every five countermeasures dealing with 'exotic pathogens', another two or more dealing with non-bioterror infections of high incidence in the US, and another two or more dealing with non-bioterror infections of high incidence in developing countries**
- **Establishes in CDCP a 'Global Disease Detection Trust Fund' of up to US$250 million per year for infectious disease detection and control activities abroad**

Government and universities donate or license intellectual property to industry for product development, including medicinal chemistry, pharmacology, clinical trials and regulatory affairs. Specific combination therapy shrinks markets but extends product life. To compensate, government extends patent life for drugs developed through public–private partnerships, so that industry can anticipate profits that, although they accrue only slowly, are substantial in the long term.

Intent on preserving its investment, government also legislates tax policy that favours food producers who refrain from administering antibiotics to healthy animals. The legislation is crafted in such a way that antibiotic administration to healthy animals adds nothing to the profit margin for the food industry, and so the practice should fade out.

The incursion of government into the pharmaceutical and agribusiness spheres is necessarily preceded by public debate. During that debate, major institutional investors become aware of their extraordinary influence over decision-making in the pharmaceutical industry. Recognizing a personal medical risk to their families from inaction, and perceiving an opportunity to reverse a growing perception of ethical laxity in their own industry, major investment firms opt to support pharmaceutical companies that accept moderate profits in association with improvements in public health. In fact, recognition grows that this is a good business decision, because returns on almost all other investments will fare better if antibiotic R&D are resumed than if economic life is disrupted by incurable infectious diseases.

Of course, there are major impracticalities and disadvantages to such an approach. Government might find it difficult to engage in an activity traditionally claimed by pharmaceutical firms, among the most active contributors to political campaigns[8], even though the goal is to help industry resume that activity itself. Public-sector administrative practices might be less efficient than industrial approaches, for example, in cutting off non-productive lines of investigation. As in industry, most 'leads' would not pan out, and a large proportion of investigational resources will be wasted, but here, the waste would be a matter of public record. Budget masters might not tolerate a process that at its best is remarkably inefficient.

Model 3

In the third model, tax allowances provide the incentive to undertake for-profit antibiotic R&D. The underlying principles of this approach are that public markets reward the most efficient use of capital, and tax efficiencies are a major driver of decisions about capital allocation. Accordingly, tax incentives are legislated for firms of any size that invest in antibiotic R&D. The tax incentives can be bought and sold. Antibiotic R&D becomes a sound investment for firms that could face a need for cash with limited options for obtaining it, such as biotech start-ups. The purchaser of tax incentives must qualify by likewise investing in antibiotic R&D. The tax incentive is deferrable and can be invested. The enabling legislation attracts additional support because it stipulates that the R&D spurred by the tax incentive must be carried out in the home country in order to promote job growth. In the United States, products developed under this programme are accorded another incentive: front-of-the-line status for FDA review.

Another tax provision provides incentives for discounts and the distribution of new antibiotics in low-income countries. That is, taxes on profits from sales in high-income countries are lowered in proportion to the discount applied (so-called 'tiered pricing') and sales achieved for product distribution in low-income countries. This attracts additional public support because it helps improve the moral force of the donor nation's foreign policy.

In this plan, industry remains in control of antibiotic R&D, but small firms can participate as well as large ones. Profits are market-driven, not government-decreed. Government intervenes in pricing indirectly and only for low-income markets. Finally, the tax incentives could include those described above that aim to stop the feeding of antibiotics to healthy animals.

Conclusion

To hold ground against the growing threat from infectious diseases, society needs a coordinated approach involving both vaccines and antibiotics. In both cases this means coming to grips with a profit problem. However, the development of vaccines faces different research challenges and regulatory restrictions than the development of antibiotics, and society needs to devise different solutions for each.

Vaccine availability would be advanced enormously by Model 1 ('pull' by government-funded advance-purchase contracts), government's financial support of a 'warm' industrial base for vaccine production and the transfer of product liability from manufacturers to government. The Project Bioshield II Act combines these features and would provide extensive support for crucially important public-health measures.

However, Bioshield II's military-style 'pull' approach, and its concentration of control in a non-science agency and focus on 'exotic pathogens' that might be used by terrorists, is not likely to produce solutions to the economic, regulatory and scientific problems that deprive us of the ongoing ability to treat a wide variety of already prevalent infections. For this, we need elements of all three bills and more besides. The Preservation of Antibiotics for Medical Treatment Act of 2005 would extend to the US the good practices regarding antibiotic use in animals that were introduced so effectively in Europe in 1999. However, restricting what is now the bulk use of antibiotics would lower antibiotic-based profits substantially and hasten the retreat of the pharmaceutical industry from antibiotic development. It is therefore extremely important that Congress pass the Preservation of Antibiotics for Medical Treatment Act in conjunction with the Infectious Diseases Research and Development Act. The latter would introduce tax credits with some of the features of Model 3, along with other incentives, and establish a much needed national coordinating body. The American public should urge their Representatives and Senators to become informed about these bills, debate them, improve them, and to pass not one but all three.

Although the introduction of these bills is cause for celebration, they face an uphill battle even to come to a vote. Even if these bills are passed, they represent just the beginning. For one thing, they pertain only to the United States. The shortfall in antibiotic R&D is global, as are many of the firms in a position to remedy the situation. Governments need to promote solutions in all countries where pharmaceutical R&D are carried out.

In our view, the most effective approaches to meeting society's needs for antibiotics will combine features of Models 2 and 3. Government-supported, long-standing, not-for-profit antibiotic research should proceed in parallel with for-profit antibiotic research. Both research streams should feed into for-profit antibiotic development, with tax incentives attracting commercial firms both large and small, experienced and innovative. Antibiotics should enter a regulatory system for approval and post-approval review that is tailored to address emerging antibiotic resistance and the need for new antibiotics as inseparable, unending and a special case.

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Competing interests statement
The authors declare no competing financial interests.

OUTLOOK

Finding improved medicines: the role of academic–industrial collaboration

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Abstract | This paper reviews models of academic–pharmaceutical industry collaboration and debates the value of such partnerships so that those contemplating an alliance can reflect *a priori* on the purpose, nature and process that will provide a constructive outcome. The scope is confined to the biomedical discipline, because collaborations in other fields, such as physics and engineering, have not suffered as a result of the concerns associated with biomedicine.

The scientific community has, by nature, a strongly competitive culture. Competition for peer recognition, funding and professional preferment is embedded in academia, yet progress in modern scientific research is achieved predominantly by collaborative teamwork. In the early nineteenth century, the concept of fundamental research was exemplified, especially in Germany, as "a dedicated scientific pursuit of natural phenomena without seeking any practical application." This was the implication of the scientific philosophy of German *Wissenschaft* — that is, 'pure research'. This scientific philosophy is still widely held today. For example, Dean Ross of John Hopkins University, in reflecting on academic and pharmaceutical industry relationships, emphasized that academic scientists have as their goals the acquisition and dissemination of knowledge as full-time independent 'scholar scientists'. He contrasted this role with the pharmaceutical industry's goal of profit arising from the full-time employment of scientists[1]. Given these differing goals and cultures, it is obvious that the possibility for misunderstandings as to the nature of a specific collaborative venture is high. Advances in biochemistry and pharmacology from the 1930s onwards, and the creation of research departments within pharmaceutical companies, radically changed the balance of competence and scientific credibility, so that by the 1950s productive scientific research collaboration became feasible. However, during that decade, collaboration within the United States between industry and academia seems to have fluctuated in relation to the availability of public funding for biomedical research[2]. Blumenthal speculated that the increase in this type of collaboration was due to a reduction in grant-sponsored research. If this interpretation is true, it raises the important issue of what the real motivations were for such collaborations. If the motivation of academic researchers is a mixture of survival, desperation or even greed, then this does not bode well for the quality or outcome of the collaboration. Similarly, the motivation for industry to sponsor external research efforts, ranging from tax-benefits to marketing and public relations to genuine knowledge exchange, needs to be explored. It is therefore timely to reflect on the nature and purpose of scientific research collaboration between academia and the pharmaceutical industry, particularly in light of current concerns about its purpose and even validity[3,4], including views that the academic, government and industrial complex has a detrimental effect on the culture and motivation of academic research[5–8].

In this review we focus on the biomedical discipline. It would seem that academic–industrial collaborations in the fields of physics and engineering have generally enjoyed a constructive and fruitful relationship over many years, without raising the concerns associated with biomedicine[9]. Even this restricted focus provides a broad topic. Given the breadth of the subject, it is necessary to apply some definitions and constraints. We largely confine ourselves to collaborations in the preclinical, discovery phase rather than clinical development. By collaboration we mean "to work together, especially in a joint intellectual effort" or, less elegantly, "to team up"[10]. The terms 'relationship'[3] and 'alliance', on the other hand, although suggestive of a certain connectivity, do not necessarily imply "a joint intellectual effort". It is therefore important to reflect on what the reasons for collaboration are, because these will usually determine the motivation and structure of any collaboration. We come back to this fundamental question in the section on areas of potential discord. A question for the future is how academic–pharmaceutical industry research collaborations should be arranged in order both to meet society's needs for advancing knowledge towards novel and improved medicine and to reassure those constituencies that decry such arrangements? Such issues are explored in greater detail in the later sections of this review. Before that, however, we outline some common academic–industrial relationships.

Types of relationships

There are many variations of academic–industrial relationships, ranging from expert individual consultation to academic–industry–government liaisons. Models which fall under the 'collaboration' rather than 'relationship/alliance' description are asterisked.

Consultations and fee for service, including contract research outsourcing. Under this model, academics/clinicians consult for industry for a stated term on a particular project. The expertise delivered varies