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**Development of New Antibacterials: A Laudable Aim, But What Is the Value?**

As I recently discussed elsewhere [1], the likely solutions for the current paucity of new antibacterials may lie in the hands of a global initiative, whether this be led by the World Health Organization or the International Committee on Harmonization. It is clear that regulatory hurdles still present a major deterrent to the pharmaceutical industry; however, there is another issue that is often overlooked.

During the process of drug development, there are clear decisions made on the basis of the commercial viability of a candidate compound. The candidate’s viability is evaluated on the basis of many factors, including the potential number of uses (patients with a given infection or indication), the number of tablets given for each course of treatment, and the cost per dose. This all adds up to the net present value.

I would contend that currently there is a very poor perception of the value of antibacterials from the point of view of society, prescribers, pharmacists, and payers. What is the basis for this comment?

Falagas et al [2] compared 16 different drug classes in terms of their costs based on US prices in 2004. Using a range of elegant approaches to ensure comparable courses and relevant doses, the authors concluded that anti-infectives ranked fifth in terms of costs, with a median cost for a 10-day course of treatment of $137. Furthermore, of the antimicrobial agents examined from the period 1997–2003, several were approved for courses substantially shorter than 10 days, which suggests that the $137 estimate per course of treatment for antimicrobial agents is an overestimate. In addition, the reimbursement processes now applied in the European Union and elsewhere could make these estimates somewhat lower. In contrast, antineoplastic agents and respiratory and allergy drugs had median costs of $848 and $301 per course of treatment, respectively. These results underscore the net present value economic disadvantage of antimicrobial agents relative to other drug candidates and emphasize the need for economic incentives to bring a new antibacterial to the clinic on the basis of probable revenue.

In addition to this potential revenue downside, certain pharmacy companies in the United States have recently begun giving away the top 10 generic antibacterials, on the assumption that patients who collect their antibacterials for free will be encouraged to purchase the company’s wide array of supportive cough and cold remedies, which carry a much higher profit margin than do antimicrobials. This seemingly munificent approach merely sends patients the message that antibacterials are disposable, cheap items with little intrinsic value.

Antibacterials—indeed, anti-infectives as a whole—are unique in that misuse of these agents can have a negative effect on society at large. Misuse of antibacterials has led to the development of bacterial resistance, whereas misuse of a cardiovascular drug harms only the one patient, not causing a societal consequence.

Thus, in addition to bringing together various essential global organizations to agree on a unified and, it is hoped, simpler approval process for antibacterials, we must address the issue of the value of antibacterials. It is clear from the Infectious Diseases Society of America public policy statement [3], as well as from other observers [4], that the invention of antibacterials resulted in nothing less than a total revolution of health care, shifting medicine from a diagnosis and prognosis-oriented profession to a therapeutic-oriented profession.

We must not allow a lack of appreciation of the enormous intrinsic value of antibiotics to add further barriers to industry’s preexisting reluctance to reenter a vital field of research. Even with a better appreciation of “what antibacterials can do for you,” we must still seek ways to accelerate their development without compromising the overall standard of research and the eventual products.

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**References**


Letter in Response to the Infectious Diseases Society of America’s 10 × ‘20 Initiative

To the Editor—The Society of Infectious Diseases Pharmacists (SIDP) has read the 10 × ‘20 Initiative recently published by the Infectious Diseases Society of America (IDSA)’s Antimicrobial Availability Task Force in the 15 April issue of Clinical Infectious Diseases [1]. As clinicians working alongside our infectious diseases physician colleagues, we too are troubled and dismayed at the heightened morbidity and mortality associated with infections due to drug-resistant organisms [2]. The fact that there are too few drugs in the pharmaceutical pipeline that will be available to treat infections due to the so-called “ESKAPE” organisms (Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter species) is cause for a reevaluation of priorities by all stakeholders, including academia, pharmaceutical companies, professional societies, and government agencies around the world. A recent review by Spellberg et al [3] published in 2004 documented only 6 new antibiotics in the research and development pipeline among more than 506 drugs in development. In 2002, several companies halted or substantially reduced their anti-infective discovery efforts as a result of financial or technical issues in the discovery process [4]. In addition, the lack of diagnostic tests to identify resistant organisms necessitates new approaches, and the SIDP supports the idea of providing additional resources that would be needed to develop these diagnostic tests. The SIDP supports the development of initiatives that would repopulate the antibiotic pipeline and policies that would increase the long-term viability of these valuable resources.

To safeguard new antibiotics against misuse and overuse as they become available, antimicrobial stewardship programs are needed more than ever at every institution. The SIDP appreciates the recognition of the need for an infectious diseases–trained pharmacist as a key member of the antimicrobial stewardship team as described in the IDSA/Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship. Although the SIDP embraces the key role that infectious diseases pharmacists play in protecting the effectiveness of existing antibiotics as a nonrenewable resource and in preserving the viability of the new antibiotics as this biological resource becomes replenished through the 10 × ‘20 initiatives, we face a critical shortage of postgraduate antibiotic stewardship training programs to train the next generation of clinical pharmacists who will be qualified to take on this responsibility. The SIDP urges the IDSA to support provisions in regulations that would encourage institutional leaders to develop and maintain institutional programs for antibiotic stewardship and to support training programs before these new antibiotics come to the market.

The SIDP supports the 10 × ‘20 initiative and would be delighted to join the other societies that have also endorsed this initiative. We are committed to continuing to provide education, service, and research collaboration to our medical and surgical colleagues around the country to combat the dangers of resistant organisms and promote the 10 × ‘20 initiative. We stand beside you and are willing to assist with this initiative, including by selecting an SIDP member to serve on the Antimicrobial Availability Task Force. The SIDP also needs your help to ensure that institutional priorities are put in place to develop antibiotic stewardship training programs that will ensure that sufficient numbers of clinical pharmacists with training in infectious diseases are available to help protect the viability of these new precious resources.

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References