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Despite superbug crisis, progress in antibiotic development 'alarmingly elusive'

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Despite the desperate need for new antibiotics to combat increasingly deadly resistant bacteria, the U.S. Food and Drug Administration (FDA) has approved only one new systemic antibiotic since the Infectious Diseases Society of America (IDSA) launched its 10 x '20 Initiative in 2010—and that drug was approved two and a half years ago.

In a new report, published online today in *Clinical Infectious Diseases*, IDSA identified only seven new drugs in development for the treatment of infections caused by multidrug-resistant gram-negative bacilli (GNB) bacteria. GNB, which include the "nightmare bacteria" to which the Centers for Disease Control and Prevention (CDC) alerted the public in its March 2013 Vital Signs report, represent the most pressing medical need. Importantly, there is no guarantee that any of the drugs currently in development to treat GNB will make it across the finish line to FDA approval and none of them will work against the most resistant bugs we're worried about today.

"In the past, the 10 x '20 goal would have been considered modest, but today the barriers to approval of nine additional antibiotics by 2020 seem insurmountable," said Henry Chambers, MD, chair of IDSA's Antimicrobial Resistance Committee (ARC). "Some progress has been made in the development of new antibiotics, but it's not nearly enough, and we absolutely must accelerate our efforts."

"We're losing ground because we are not developing new drugs in pace with superbugs' ability to develop resistance to them. We're on the

precipice of returning to the dark days before antibiotics enabled safer surgery, chemotherapy and the care of premature infants. We're all at risk," said Helen W. Boucher, MD, lead author of the policy paper and a member of IDSA's Board of Directors and ARC.

Entitled "10 x '20 Progress: Development of New Drugs Active against Gram-negative Bacilli: An Update from the Infectious Diseases Society of America," the paper outlines actions that must be taken to address the synergistic crises of an anemic antibiotic pipeline coupled with an explosion in multi-drug resistant pathogens. A multi-pronged approach is needed, including new economic incentives to encourage antibiotic research and development (R&D); clarification of FDA's requirements for antibiotic approval; increased research funding; improved infection prevention; and new public health efforts including better data collection and surveillance of drug resistance and use of antibiotics. We also need to encourage "antibiotic stewardship," which includes measures that health care facilities, providers and even patients can take to preserve the life-saving power of antibiotics by limiting their inappropriate use.

IDSA leaders have been exploring with other stakeholders specific solutions to address the pipeline problem including the creation of a Limited Population Antibacterial Drug (LPAD) approval pathway to speed drugs to approval as well as new R&D tax credits and reimbursement models. Congressional Republican leaders in the U.S. House of Representatives announced last month their intent to make fixing the antibiotic R&D pipeline a priority for the 113th Congress.

Ironically, at this urgent time of greatest need, the number of pharmaceutical companies investing in antibiotic R&D has plummeted. Pharmaceutical companies typically put R&D resources into the development of chronic disease drugs – including those to treat high cholesterol, diabetes, and cancer – which provide significant financial rewards, partly because they are intended to be taken for long periods of

time. Antibiotics, which are intended to be taken for short courses, just can't compete. The results are playing out in real time, with the smaller pharmaceutical company Polymedix – which has one of the seven drugs in development noted in the 10 x '20 paper – filing for bankruptcy protection in early April 2013. Moreover, the policy update reports that only four large multinational companies remain in antibiotic R&D. One of these, AstraZeneca, which has two of the seven drugs in development, plans to reduce its future investments in antibiotics, its CEO, Pascal Soriot, recently announced. The current pipeline of antibiotics is fragile indeed, and the dwindling roster of antibiotic developers has dire consequences for public health, patient care and national security.

New antibiotics are critically necessary to save the lives of people such as Josh Nahum, a healthy 27-year-old man who died from an overwhelming Enterobacter aerogenes infection as he was recovering in the hospital after a skydiving accident. Although his doctors tried desperately to save Josh, they ran out of antibiotics to treat this virulent bug. Read more about Josh's story and the experiences of others whose lives have been devastated by antibiotic resistance: http://www.idsociety.org/Joshs_Story.aspx.

IDSA first warned of the looming antibiotic apocalypse with its 2004 report, "Bad Bugs, No Drugs." Nearly 50 other medical societies and organizations, including the American Medical Association, have endorsed the 10 x '20 initiative so far.

"IDSA is committed to ensuring proper use of currently-available antibiotics to make certain we can continue to count on them. But that is not enough. Simply put, the antibiotic pipeline is on life support and novel solutions are required to resuscitate it – now," said IDSA President David A. Relman, MD. "In the past year, the heads of CDC and the World Health Organization, along with the United Kingdom's chief medical officer, have all sounded the alarm about rising rates of

antibiotic resistance. The lack of new antibiotics to treat these potentially life-threatening infections signals the end of modern medicine as we know it."

More information: See a fact sheet on antimicrobial resistance here: www.idsociety.org/AntibioticRe … tSheet-April2013.pdf

Provided by Infectious Diseases Society of America