

**House Committee on Energy & Commerce  
Subcommittee on Health  
Hearing on “Promoting the Development of Antibiotics and  
Ensuring Judicious Use In Humans”  
Testimony of Jeffrey Levi, Ph.D.  
Executive Director, Trust for America’s Health  
June 9, 2010**

Thank you, Mr. Chairman. I would like to commend you for holding this timely and important hearing. My name is Dr. Jeffrey Levi and I am the Executive Director of Trust for America’s Health, or TFAH, a nonprofit, nonpartisan public health advocacy organization dedicated to saving lives by working to make disease prevention a national priority. I appreciate the opportunity to testify before you today to discuss an ongoing public health crisis, the growing resistance of microbes to existing antibiotics.

This is a problem that has concerned our organization for some time. In fact, this critical issue was highlighted in our 2008 report, *Germs Go Global: Why Emerging Infectious Diseases are a Threat to America*,<sup>1</sup> which found that the growing rise and spread of antimicrobial resistance (AMR) has led to the development of resistant pathogens and allowed many diseases formerly treatable with drugs to resurge and take hold with new vigor. I ask that a copy of this report be included in the hearing record.

As you know, antibiotics are one of the greatest public health developments of the past 70 years. However, nature and biology keep challenging our biggest accomplishments. In your April 28<sup>th</sup> hearing, Dr. Thomas Frieden, the director of the Centers for Disease Control and Prevention (CDC), summed up the challenge before us very well. He stated that we are headed toward a “post-antibiotic world in which we have few or no clinical interventions for some infections.”

This is not an abstract concern. We are already living in a world where antibiotic resistance is believed to be responsible for over 90,000 deaths a year in the United States. That’s more than die of diabetes or Alzheimer’s or HIV. This comes at a great human toll and poses a totally unnecessary burden on the U.S. health care system. The CDC estimates that the health care costs associated with AMR range from \$28 billion to \$45 billion<sup>2</sup> -- money that could be saved by public and private insurance plans. Yet, we have not made the level of investment needed to address this crisis.

Despite the size of the problem, AMR has not attracted private sector interest and investment on the scale of other biomedical challenges. When there is market failure to address a major public health concern, it becomes incumbent upon the government to

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<sup>1</sup> Also available from: <http://healthyamericans.org/report/56/germs-go-global>

<sup>2</sup> Scott, R. Douglas, “The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention,” Centers for Disease Control and Prevention, March 2009. [http://www.cdc.gov/ncidod/dhqp/pdf/Scott\\_CostPaper.pdf](http://www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf)

create the climate and, if need be, provide the resources, to address this challenge. And that requires a multi-faceted approach that includes:

- Leadership by the federal government at a level that recognizes that this is a public health problem that requires immediate national and international attention and requires setting ambitious, but achievable goals if we are committed – such as the 10 by 20 goal of bringing to market 10 new antimicrobials by the year 2020;
- Prevention campaigns, policies, and strategies that assure prudent use of existing antimicrobial agents and reduce transmission of drug-resistant strains; and
- Research and development that creates the incentives for the best minds and the most successful companies to invest their talents and their capital in finding new diagnostics and new antimicrobial agents.

I will now address each of these elements in turn, but let me emphasize one very important overarching point. In the current situation, the burden of antimicrobial resistance is borne by the health care system and by consumers --- paying the price in avoidable death, illness, and health care costs. That needs to change.

### **Leadership**

Successful response to AMR requires leadership at the federal level. The proposed Strategies to Address Antimicrobial Resistance (STAAR) Act identifies the key elements of the federal response: a government-wide strategic plan, a comprehensive research agenda, and increased coordination among the federal agencies with roles to play in AMR response. We are pleased to see that the Administration has not waited for passage of the STAAR Act to begin to address its goals in several ways.

The recent appointment of Dr. Ronald Valdiserri to the newly created position of Deputy Assistant Secretary for Health, Infectious Diseases, creates a locus for leadership for a cross-governmental AMR strategy. Prior to this appointment, there was no official in charge of coordinating infectious disease policy across the agency.<sup>3</sup> We also look forward to the updated Public Health Action Plan to Combat Antimicrobial Resistance and hope that this strategy will be coordinated with other efforts, including the forthcoming medical countermeasures strategy being developed by the Assistant Secretary for Preparedness and Response. We also hope that there will be recognition on the part of the Administration – both through the work of ASPR and through engagement of the National Security Staff at the White House – that AMR is not just a traditional public health threat, but one that has serious bioterrorist potential as well.

Because of this twin threat – the health care challenges of AMR and the potential for weaponizing AMR – strategies and plans will not suffice. We will need the Administration and Congress to empower the relevant federal agencies to carry out their strategies by giving them the financial resources they need. This is particularly important

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<sup>3</sup> “Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections,” GAO-08-673T April 16, 2008.

in the area of research and development, which I will discuss later, where we are only providing a fraction of what is needed. Strategies without resources are pieces of paper that give false hope to those at risk to AMR-related conditions.

## **Prevention**

Development of new antimicrobial agents will take time. However, we are not without options in containing the spread of antimicrobial resistance. We have at our disposal prevention strategies that can achieve two critical goals – we can reduce the spread of new infections through appropriate infection control, and we can reduce development of further resistance through the more prudent use of antibiotics.

Addressing AMR must be a central part of the new national effort to ensure health care quality. HHS should make maximum use of its new authorities under health reform to combat this problem. Everyone in our country has the right to expect that health care acquired infections (HAIs) should be “never” events. We applaud the steps already taken by the Center for Medicare and Medicaid Services (CMS) to end reimbursement for HAIs, and are pleased that many private payers are following suit. This provides hospitals the incentive to lower infection rates.

CMS also includes some measures of appropriate antibiotics use in its Annual Payment Update database, where hospitals report certain quality measures.<sup>4</sup> CMS could implement tracking of prudent use of antimicrobials, as it does for HAIs, and withhold reimbursement for providers and facilities that regularly inappropriately prescribe. Health IT could be an important mechanism for HHS to track use, if appropriate antimicrobial prescribing is included as a quality measure under the regulations for meaningful use of electronic health records.

Consumers also have a responsibility in fighting AMR. We are pleased that the CDC is expanding its Smart Use campaign to educate consumers about prudent use of antibiotics. We hope that sufficient resources can be identified to assure that this is truly a national education campaign. If consumers learn when they may need antibiotics and when to avoid them, providers are likely to feel less pressure to inappropriately prescribe.

Consumers should also be educated about and empowered to demand non-pharmaceutical protections in the health care setting, such as hand-washing and glove wearing. Health professions and public health associations and schools should similarly educate their constituencies on the prudent use of antibiotics and provide them with the necessary tools to say no to patients who request antibiotics for non-bacterial infections.

That said, the President’s FY 2011 proposed budget for prevention does not reflect the severity of the problem. Indeed, the proposed budget cuts the CDC’s prevention and

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<sup>4</sup> GAO, 2008.

education efforts by \$8.6 million, which would decrease the number of health departments receiving grants to track and control antibiotic resistance from 48 to 20.<sup>5</sup>

We recommend that this committee ask CDC for a professional judgment budget that would define the resources needed to support federal, state, and local efforts as well as to support a national campaign addressing both sides of the AMR equation: prudent use and consumer empowerment about non-pharmaceutical protections. Under the health reform law, Congress has authorized, and the Prevention and Public Health Fund has the resources to support, a national prevention campaign. This would be an excellent focus for part of that campaign.

### **Research and Development of New Products**

Ultimately, the problem of antimicrobial resistance will not be resolved until we have better diagnostics, new antimicrobial agents, and new vaccines to prevent the diseases that are associated with resistance. But few new products are in the pipeline – certainly nothing on the scale reflected in the Infectious Diseases Society’s 10 by 20 campaign. This is primarily because the market has failed: there are insufficient financial incentives for industry or academia to divert their current research and development efforts from more profitable enterprises. We need to change that equation.

To date, the largest federal investment in creating incentives is through the Biomedical Advanced Research and Development Authority (BARDA), and we are pleased to see them at the hearing today. Unfortunately, their programs are chronically underfunded. BARDA’s FY 2010 funding is \$341 million, with \$476 million requested by the President in FY 2011. But even with the proposed FY 2011 increase, this does not come close to what BARDA needs to incentivize development of a range of countermeasures, not just antimicrobials. Indeed, the Center for Biosecurity has estimated that BARDA would need \$3.39 billion to have a 90 percent chance of successfully developing medical countermeasures identified in HHS’ Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan.<sup>6</sup>

With scarce funding, the federal government has been unable to demonstrate to industry that they will be full partners in developing and procuring new antimicrobials. We have seen that small pharmaceutical companies are more willing to contract with BARDA. Larger companies see a bigger return on investment for pharmaceuticals to treat chronic disease than for new medical countermeasures. However, due to their size, these small companies assume tremendous risk to their survival if contracts fall through, so predictability of funding is key to maintaining private sector involvement.

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<sup>5</sup> Department of Health and Human Services, “Fiscal Year 2011: Centers for Disease Control and Prevention, Justification of Estimates for Appropriation Committees,” p. 111.

[http://www.cdc.gov/fmo/topic/Budget Information/appropriations\\_budget\\_form\\_pdf/FY2011\\_CDC\\_CJ\\_Final.pdf](http://www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY2011_CDC_CJ_Final.pdf)

<sup>6</sup> Center for Biosecurity of UPMC, “Center for Biosecurity Recommendations for BARDA Funding for FY 2009,” March 31, 2008. Available from: [http://www.upmc-biosecurity.org/website/resources/commentary/2008-03-31-barda\\_funding\\_fy09\\_burr.html](http://www.upmc-biosecurity.org/website/resources/commentary/2008-03-31-barda_funding_fy09_burr.html)

The existing options beyond BARDA – including potential expansion of the Orphan Drug Act, prioritization vouchers for companies that focus on neglected tropical diseases, and advance purchase arrangements – are all necessary but, we believe, probably insufficient to create the research and manufacturing capacity and/or the demand for developing new antimicrobial agents. These financial and regulatory incentives may continue to attract small companies, but we worry that they will not attract the larger companies with the manufacturing and marketing capacity to bring new products to scale. Existing protections under the Orphan Drug Act are relatively generous. But they have not brought broad investment in antibiotics. We believe it is unknown whether extended exclusivity would change the equation. On the one hand, these are new drugs that may have a short lifespan if resistance develops, and so extended exclusivity may not reduce the risk for the investor. On the other hand, if the new drug is truly one that overcomes the problem of resistance, then the market should be large enough to draw in industry without additional exclusivity.

Even if we successfully address the market issues, we still face a major challenge: we need a comprehensive approach that will also create the intellectual capital in the academic-based biomedical research community – along with interest in the major pharmaceutical and biotech companies – to answer the range of basic research questions and then develop the diagnostics, treatments, and vaccines that will effectively prevent or treat AMR.

Given the combined public health and bioterrorist threat associated with AMR, we hope that the forthcoming Public Health Action Plan to Combat Antimicrobial Resistance will include a national plan that defines in a comprehensive way the appropriate role, and new incentives needed, for the key players who can resolve this problem:

- What is the right mix of direct financial incentives and regulatory protections such as extended market exclusivity to bring new companies to the table?
- What policies and incentives can the government create that will result in a willingness of venture capital to invest in development of new antimicrobial agents? Government financing alone does not need to be the answer. We saw the beginning of venture capital playing a role in development of new influenza-related products. Can we learn from this experience and bring more players to the table? Similarly, can we learn from the experience of other government agencies, such as the CIA, which has chartered a venture capital fund (In-Q-Tel) to foster commercial development of IT products that would serve the CIA's strategic needs?<sup>7</sup> In-Q-Tel is an outside entity that brings together industry, academia, venture capitalists, and others to foster the development of new technologies.<sup>8</sup> This model has been successful because of robust government funding, strategic investments, and the opportunity for profit for other venture capitalists.

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<sup>7</sup> In-Q-Tel, History, Available from: <http://www.iqt.org/about-iqt/history.html>.

<sup>8</sup> Yanuzzi, Rick, "In-Q-Tel: A New Partnership Between the CIA and the Private Sector," *Defense Intelligence Journal*, CIA, 2000. Available from: <https://www.cia.gov/library/publications/additional-publications/in-q-tel/index.html#snapshot>

- What policies and incentives – beyond those in place today – can bring larger pharmaceutical and biotech companies to join in the research and development effort?
- What investments does the NIH need to make to incentivize biomedical researchers to re-engage with the field of antimicrobial development? This needs to go beyond traditional support for specific research efforts so that individual researchers and institutions see a long-term future in this field.
- What policies can FDA put in place in advance so that potential investors in research know the pathway to approval?
- What basic research do NIH and CDC need to conduct to provide the intellectual base for industry investment in new products?
- And just as important, what policy and financial arrangements will assure that new products developed with special federal financial support or regulatory incentives such as extended patent exclusivity will be accessible and affordable to domestic consumers, reflecting the taxpayers' early investment in their development? We also need to assure that these products are available globally.

Any plan should come with a professional judgment budget – estimating what the public sector costs of this plan would be and what level of investment from the private sector can reasonably be incentivized – so that Congress and the Administration can make appropriate estimates of the potential return on an increased federal investment.

If the HHS plan fails to address these issues properly, we would urge Congress to require that a contract with an independent entity – which is empowered to bring all the relevant stakeholders to the table: government, industry, academia, and consumer representatives – to develop such a plan.

### **Conclusion**

Antimicrobial resistance is both a public health and a national security threat. It is causing unnecessary death and illness – some that can be prevented with existing capacities and some that will require new authorities and funding. But it is a solvable problem – if we are creative enough in our policies and our investment strategies. As the bugs adapt, so must we.

Thank you again for the opportunity to share our views today. I look forward to any questions you and members of the committee may have.