

April 13, 2011

Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion
Office of Antimicrobial Resistance
Attn: Antimicrobial Resistance Action Plan
Docket No. CDC-2011-0002
1600 Clifton Rd., NE, Mailstop A-07
Atlanta, Georgia 30333

To Whom It May Concern:

I am writing to you on behalf of Trust for America's Health, a non-profit, nonpartisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. We believe that the new Draft Public Health Action Plan to Combat Antimicrobial Resistance is an important document that reflects detailed planning and true inter-agency collaboration in addressing the serious public health issue of antimicrobial resistance (AR). The plan, if implemented appropriately, will lead to significant improvements in understanding and mitigating the threat posed to human health in the United States and around the world.

We understand that the draft does not represent an exhaustive list of all activities that will be undertaken at the federal level to address AR. However, we believe that a number of key additions would strengthen the plan and ensure that key priorities are reflected in agencies' ongoing work. Our recommendations are detailed below.

1. Resources

Antimicrobial resistance poses a staggering health burden in the United States. And as resistant microbes continue to appear in both healthcare and community settings, the health and economic burdens will only increase. The problem demands a coordinated federal effort, as described in the draft plan. However, this effort will only succeed given appropriate resources for all four components: surveillance, prevention and control, research, and product development. While not all resources – or activities – should come from the federal government, there will have to be a significant and sustained federal investment to ensure that the plan yields results.

As drafted, the plan does not describe the resources that will be necessary for its implementation. We believe that it is crucial for such an assessment to be included. Key agencies and programs involved in the plan, including CDC and BARDA, have been seriously underfunded for years. Without a clear description of the necessary resources to meet the goals described in the plan, it is impossible for Congress and the public to understand the necessary investments that have to be made. The plan should include a professional judgment budget detailing the funds that will be necessary to support federal

efforts, as well as estimates of other resources (such as private sector investment in product development) and how those funds will leverage federal investments.

2. Status Report on Activities Described in the Plan

We were pleased to see that the plan breaks down specific activities not only by implementing agency but also by target year of completion. A number of the activities included were scheduled to be completed by the end of calendar year 2010. It would be helpful if the action plan, when finalized, were updated to make clear which of these activities were indeed completed in 2010 and which will be adjusted to be completed in 2011 or later.

3. Detailed Regulations on Veterinary and Agricultural Use of Antimicrobial Drugs

The overuse of antimicrobial drugs on food animals is a major contributor to antimicrobial resistance and thus a serious threat to human health. The draft plan appropriately acknowledges this, including attention to veterinary and agricultural antibiotic use under all four components (surveillance, prevention and control, research, and product development).

Unfortunately, the draft plan still calls for the formulation of “guidelines” rather than binding requirements for producers (Goal 3.5, “Identify factors that reduce transmission of drug-resistant pathogens, including infection control, in veterinary, agriculture and aquaculture settings, and formulate guidelines on ‘best practices’”; and Goal 4.2, “Promote, implement, and evaluate guidelines for appropriate antimicrobial use in agricultural and veterinary settings.”). We are very concerned that “guidelines” are unlikely to lead to meaningful changes in usage in this sector.

As we noted when FDA issued “Draft Guidance 209, The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,” nonbinding guidelines are unlikely to offer any incentive for food producers to adjust their practices. We believe that mandatory regulations here are crucial, and that the action plan should clearly reflect this need.

Further, we believe that any such regulations should:

- Clearly define “judicious use” of antimicrobials in veterinary and agricultural settings;
- Require veterinary prescriptions or veterinary feed directives for therapeutic provision of medically important antimicrobial drugs to food animals;
- Eliminate off-label use of antimicrobial animal products; and
- Implement strict monitoring once regulations are established.

These goals could be met by adding a specific goal 4.2(e): “Develop, disseminate for comment, and implement regulations regarding the use of antimicrobial drugs in food-producing animals, including a clear definition of ‘judicious use,’ requirements for the

use of veterinary prescriptions or feed directives, and prohibitions on the off-label use of antimicrobial animal products.”

4. Insurance Payment Mechanisms

Goal 3.3 in the draft plan is to “Identify and promote successful AR prevention and control programs in healthcare settings that utilize existing recommendations for preventing transmission of AR organisms.” We believe that this goal could be furthered by ensuring that existing CMS payment and tracking systems are being fully leveraged to address the impact and causes of antimicrobial resistance in healthcare settings. For example, CMS tracks healthcare-associated infections (HAIs), and already includes some measures of appropriate antibiotics use in its Annual Payment Update database. The agency could begin tracking appropriate antibiotic use as it does HAIs, and use reimbursement to penalize providers that prescribe inappropriately. This kind of effort could be encouraged by adding a new goal 3.3 (e): “Assess and pilot a range of reimbursement-based approaches to reduce inappropriate antibiotic use in healthcare settings, to be applied by CMS and other payers.”

5. Product Development and Domestic and Global Access

The draft plan appropriately emphasizes new product development as a key component of the fight against antimicrobial resistance. We were pleased to see the comprehensive, multi-agency efforts proposed in section IV, including the publication of detailed FDA guidance documents for product development related to clinical trial design, relevant medical devices, and diagnostic assays.

However, a key issue that we believe is missing from this section is that of access. New drugs, assays, or vaccines will be ineffective if they are not accessible to the public. It will be important to ensure that the public will benefit from the products described in the plan, particularly given the extent of public effort and resources that will likely go into their development.

Access concerns should not be limited to our borders. As the draft plan notes, fighting antimicrobial resistance will require sustained collaborations with partners worldwide. Antimicrobial resistance cannot be addressed without addressing the health of all global citizens. From a public health perspective – as well as an ethical one – product development should address plans for access to relevant drugs, diagnostics and vaccines, especially in the poorest countries.

The action plan should add a goal 11.4: “From the earliest stages of product development, develop plans that address intellectual property and distribution issues to ensure expedient and affordable access to relevant drugs, diagnostics, and vaccines both within and outside the United States.” Collaborating agencies should include FDA, NIH, CMS, CDC, WHO, and USAID.

Conclusion

Thank you for the opportunity to comment on the Draft Action Plan to Combat Antimicrobial Resistance. We hope that these recommendations are helpful, and look forward to working with CDC and all the participating agencies in the ongoing development and implementation of the plan.

If you have any questions, please do not hesitate to contact Dara Lieberman, TFAH's Government Relations Manager, at 202-223-9870 ext. 20 or via email at dliberman@tfah.org.

Sincerely,

A handwritten signature in black ink that reads "Jeffrey Levi". The signature is written in a cursive style with a large initial "J".

Jeffrey Levi, PhD
Executive Director