



## Union of Concerned Scientists

Citizens and Scientists for Environmental Solutions

October 28, 2010

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Submitted electronically via [www.regulations.gov](http://www.regulations.gov) to docket no. FDA-2010-N-0506

Re: FDA's Fiscal Year 2011-2015 Strategic Priorities

Dear Commissioner Hamburg:

On behalf of the Union of Concerned Scientists (UCS) and Keep Antibiotics Working (KAW), we are pleased to submit comments on the Food and Drug Administration's (FDA's) Draft Strategic Priorities Fiscal Year (FY) 2011-2015 document<sup>1</sup> announced in the October 1, 2010, *Federal Register*.<sup>2</sup>

Founded in 1969, UCS is an independent, science-based nonprofit working for a healthy environment and a safer world. KAW is a coalition of health, consumer, agricultural, environmental, and other advocacy groups with more than eleven million dedicated supporters. Both UCS and KAW have long worked to protect the efficacy of our limited arsenal of antibiotics by advocating the reduction in their unnecessary use. We value the role of the FDA as a leader in public health and look to the Strategic Priorities as a road map for the initiatives the agency plans to embark on over the next five years.

Beginning in FY 2011, according to its draft strategic plan, the FDA will focus on four cross-cutting strategic priorities: 1) advance regulatory science and innovation; 2) strengthen the safety and integrity of the global supply chain; 3) strengthen compliance and enforcement activities to support public health; and 4) address the unmet public health needs of special populations.<sup>3</sup>

To address the four cross-cutting strategic priorities, the FDA formulated four strategic program goals: 1) advance food safety and nutrition; 2) promote public health by advancing the safety and effectiveness of medical products; 3) establish an effective tobacco regulation,

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<sup>1</sup> Food and Drug Administration (FDA), "Strategic Priorities: 2011-2015," draft 9/29/10. Online at [www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/StrategicActionPlan/UCM226907.pdf](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/StrategicActionPlan/UCM226907.pdf).

<sup>2</sup> 75 *Federal Register* 60767-8, October 1, 2010.

<sup>3</sup> FDA, Strategic Priorities, 5-12.

prevention, and control program; and 4) manage for organizational excellence and accountability.<sup>4</sup>

These cross-cutting strategic priorities and program goals lay out a robust five-year plan for the FDA. We were, therefore, disappointed to find that the strategic priorities and program goals ignore the serious public health issue of antibiotic-resistant bacteria. *In fact, the term “antibiotic resistance” does not even appear in the document — a jarring omission considering the importance of the issue.*

Under the second program goal promoting public health with safe and effective medical products, the strategic plan fails even to note the loss of effectiveness of antibiotics to treat human diseases.<sup>5</sup> In the section dealing with animal drug safety and effectiveness, where one would expect the agency to address the contribution of animal antibiotic overuse to antibiotic-resistant diseases, the agency’s sole mention of antibiotics inexplicably has to do with residue testing.<sup>6</sup> Antibiotic residues in milk and meat are a public health issue, but the threat is minor compared to the looming crisis of drug-resistant diseases. It is difficult to reconcile an elevation of residue concerns over the antibiotic resistance crisis with the FDA’s “solemn responsibility to protect and promote the public health”<sup>7</sup> and the many public statements made by FDA and others in the Obama administration on the importance of the antibiotic resistance issue.

In a Congressional hearing in March 2010, for example, Commissioner Hamburg said that antibiotic resistance was, “one of the foremost health concerns in the nation.”<sup>8</sup> Additionally, the FDA’s recent draft guidance on the judicious use of medically important antibiotics described antimicrobial resistance as a “mounting public health problem of global significance.”<sup>9</sup>

Just this past summer, representatives of the FDA, Centers for Disease Control, and the U.S. Department of Agriculture all testified at a Congressional hearing affirming the scientific connection between antibiotics used on the farm and the reduced efficacy of antibiotic drugs in human medicine.<sup>10</sup>

After years of working on this issue, UCS and KAW welcomed the apparent renewed commitment to the problem of antibiotic resistance, as did a number of leading medical

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<sup>4</sup> FDA, Strategic Priorities, 13-33.

<sup>5</sup> FDA Strategic Priorities, 18-28.

<sup>6</sup> FDA, Strategic Priorities, 27.

<sup>7</sup> FDA, Strategic Priorities, 9.

<sup>8</sup> Philip Brasher, “FDA mulling restrictions on livestock antibiotics,” *Des Moines Register*, March 10, 2010. Online at <http://blogs.desmoinesregister.com/dmr/index.php/2010/03/10/fda-mulling-restrictions-on-livestock-antibiotics>.

<sup>9</sup> FDA Center for Veterinary Medicine, *Draft Guidance: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* (June 28, 2010), 4. Online at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>

<sup>10</sup> Helena Bottemiller, “Debate over Antibiotics in Ag Rolls On,” *Food Safety News*, July 19, 2010. Online at <http://www.foodsafetynews.com/2010/07/debate-over-antibiotics-in-ag-rolls-on/>

organizations, including the American Medical Association, American Nurses Association, the Infectious Diseases Society of America, and the American Public Health Association. But the FDA's urgent rhetoric means little if the agency fails to include antibiotic-resistant disease among its strategic priorities.

We strongly urge the FDA to revise its Draft Strategic Priorities document to address the important public health crisis of antibiotic resistance, including implementing steps leading to the timely reduction of the unnecessary use of antibiotics in food animal production.

Thank you for the opportunity to comment on this important public health issue.

Sincerely,



Margaret Mellon, Ph.D., J.D.  
Director, Food & Environment Program  
Union of Concerned Scientists



Richard Wood  
Steering Committee Chair  
Keep Antibiotics Working