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March 12, 2012

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Senator Dianne Feinstein  
Washington, DC Office  
331 Hart Senate Office Bldg.  
Washington, D.C. 20510

Re: HR 965 and S 1211

Dear Senator Feinstein:

There is a need to promote efforts to minimize conditions that encourage infectious agents to develop resistance to the medications we use to treat the infections they cause. It is for this reason that the California Conference of Local Health Officers (CCLHO) extends its support to two bills designed to help maintain the effectiveness of antibiotics used to treat infections in humans, HR 965 and S 1211, and recommends amended language that may improve the chances of passage of these two important bills.

The development of antimicrobial agents to treat life-threatening infections has been one of the most notable medical achievements over the past century. However, antimicrobial agents' effectiveness in treating infections is becoming compromised by increasing drug resistance. Drug-resistant organisms are plaguing Americans, including otherwise healthy adults and children, in healthcare settings and communities across the United States. Many factors contribute to the development of antimicrobial-resistant pathogens, including the inappropriate use of antimicrobial drugs in human and animal medicine and in food animal production.

Antibiotics are used in animal agriculture for judicious disease treatment, control and prevention purposes, but they are also used for growth promotion and feed efficiency. It has been established that this latter, non-therapeutic, utilization of antibiotics in the agriculture industry contributes to the development of antibiotic resistance in organisms in the natural environment.<sup>1,2,3</sup> The tendency for any reproducing organism to survive exposure to an antibiotic intended to eliminate it is driven by the environmental pressure exerted against the entire population of organisms by the antibiotic in question, particularly when the antibiotic doses are subtherapeutic. HR 965 and S 1211, by ending non-therapeutic uses in animals of those antimicrobials also used in humans, would reduce the development of resistance to antimicrobials among infectious disease agents.

<sup>1</sup> Alliance for the Prudent Use of Antibiotics (APUA). 2001. Antibiotic resistance: synthesis of recommendations by expert policy groups. WHO/CDS/CSR/DRS/2001.10. Geneva: WHO.

<sup>2</sup> CDC. 2001. Public Health Action Plan to Combat Antimicrobial Resistance. National Center for Infectious Diseases, Centers for Disease Control and Prevention. Atlanta, GA [Online]. Available: <http://www.cdc.gov/drugresistance/actionplan/html/index.htm>

<sup>3</sup> FDA (Food and Drug Administration). 2000. FDA Task Force on Antimicrobial Resistance: Key Recommendations and Report. Washington, DC. [Online]. Available: <http://www.fda.gov/oc/antimicrobial/taskforce2000.html>

The Food and Drug Administration (FDA) has taken important steps in recent years to address this problem, including guidance calling for phasing out of growth promotion and feed efficiency uses, and for veterinary oversight of all other uses of antimicrobials in animal production. The Administration is demonstrating a commitment to sound and science-based policies that are backed up by scores of scientific and medical publications. Nevertheless, these policies don't have the strength of law, so HR 965 and S 1211 are still needed.

While concerns have been raised that such restrictions on antimicrobial use would decrease food animal production, research in Denmark has documented that the elimination of non-therapeutic antibiotic use in animal husbandry practice did not diminish productivity or growth rate in animals or end products in the poultry or swine industry.<sup>4</sup> Nor was there an increase in the levels of bacterial colonization in swine and poultry after the discontinuation of growth promoting antibiotics.<sup>5</sup> Therefore, concerns from the industry regarding diminished productivity and increased risk of bacterial contamination appear unfounded. The impact upon the amount of feed needed per unit production ("feed-conversion ratio") may be minimally increased, but the answer to this question remains obscure.<sup>6</sup> Farmers in Europe have adapted to such a policy without undue disruption of production or increased consumer costs.

Support for HR 965 and S 1211 is far-reaching through the health care industry, in particular from infectious disease specialists and health organizations. Veterinarians themselves remain divided about the use of Antibiotic Growth Promoters. The Institute of Medicine's (IOM) Board on Global Health recommended in 2003 that "substantial efforts must be made to decrease inappropriate overuse of antimicrobials in animals and agriculture..." As noted in the IOM report, to accomplish this goal will require a partnership between the CDC, FDA, professional health organizations, academia, health care delivery systems, the healthcare industry and the entire population of consumers of agricultural products.

In addition to supporting these bills, CCLHO recommends limited edits to the "nontherapeutic use" definition in the bills (See Attachment A). We believe these edits improve the clarity and specificity of the definition and, by clearly targeting only growth promotion and feed efficiency uses, may improve the chance of passage. The suggested amendment is detailed in the Attachment.

The emerging specter of antimicrobial resistance and the potential negative impacts on human health is well-recognized in the health care field.<sup>7</sup> The dollar cost of inpatient treatment with the most recently developed antibiotics and in driving research to develop new antibacterial weapons is enormous. The scientific evidence supports the measures proposed in HR 965 and S 1211.

Strengthening antimicrobial stewardship is critically important to the health of both humans and animals and is essential if we are to protect the long-term effectiveness of these severely threatened therapeutic agents.

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<sup>4</sup> Emborg H, Ersbøll A, Heuer O, Wegener H. The effect of discontinuing the use of antimicrobial growth promoters on the productivity in the Danish broiler production. *Prev Vet Med* 2001;50:53-70.

<sup>5</sup> Evans, M and Wegener, H. Antimicrobial growth promoters and *Salmonella* spp., *Campylobacter* spp. in poultry and swine, Denmark, *Emerging Infectious Diseases* April 2003, Vol. 9, No. 4

<sup>6</sup> Emborg et al, 2001

<sup>7</sup> Bancroft, E *Antimicrobial Resistance*, Journal of the American Medical Association, Vol. 298, No. 15, October 17, 2007

Senator Dianne Feinstein  
Page 3  
March 12, 2012

CCLHO was established in statute in 1947 to advise the California Department of Health Services (now California Department of Public Health), other departments, boards, commissions, and officials of federal, state and local agencies, the Legislature and other organizations on all matters affecting health. CCLHO membership consists of all legally appointed physician health officers in California's 61 city and county jurisdictions.

If you have questions, please feel free to contact me at [wilma.wooten@sdcounty.ca.gov](mailto:wilma.wooten@sdcounty.ca.gov) or 619-542-4181.

Sincerely,

*Original signed by:*

Wilma Wooten, MD, MPH  
President, California Conference of Local Health Officers

cc:

Senator Barbara Boxer  
Kathleen Sebelius, U.S. Secretary of Health and Human Services  
Margaret Hamburg, M.D., Commissioner, U.S. Food and Drug Administration  
Congresswoman Louise McIntosh Slaughter  
California Delegation

Attachment

## **ATTACHMENT A:**

### **CCLHO-recommended amended language to H.R. 965 and S. 1211, SEC. 4. (a), lines 19-25 (on p.10 of both bills)**

#### **Suggested edits:**

“(tt) NONTHERAPEUTIC USE.—The term ‘nontherapeutic use’, with respect to a critical antimicrobial animal drug, means any use of the drug ~~as a feed or water additive~~ for an animal in the absence of any clinical sign of disease or a documented risk of disease in the animal for growth promotion, feed efficiency, weight gain, ~~routine disease prevention,~~ or other routine purpose.”.

#### **Suggested final language for this paragraph (with edits accepted, and wording rearranged for better readability):**

“(tt) NONTHERAPEUTIC USE.—The term ‘nontherapeutic use’, with respect to a critical antimicrobial animal drug, means any use of the drug in an animal for growth promotion, feed efficiency, weight gain, or other routine purpose in the absence of any clinical sign of disease or a documented risk of disease in the animal.”.

#### **Explanation for the proposed language revision:**

The key result of the changes is to clarify the focus on growth promotion and feed efficiency uses and not eliminate appropriate prevention/prophylaxis uses (which can be judicious uses, as in human medicine). The FDA, AVMA, and Codex Alimentarius Commission (the international standard setting body for food safety) define therapeutic uses as treatment, control, and prevention. The terms "non-therapeutic" or "sub-therapeutic" are presumably other uses (i.e., growth promotion and feed efficiency), but are not used by these entities and have been ill-defined and used inconsistently elsewhere. The changes to this paragraph will clarify the definition of "nontherapeutic" in the legislation, with a clear focus on growth promotion and feed efficiency uses without ambiguity that could be interpreted to put judicious therapeutic uses at risk, which may help garner broader support (or, in some cases, toned down opposition) for these bills.