

True Facts About the MUMS Legislation (S 741 and HR 2079)

Several entities have presented misinformation to members of Congress asking them to oppose MUMS. They are asserting that the legislation would fast track transgenic animals or drugs, prevent FDA from ensuring antibiotic safety, and weaken the Federal Food, Drug and Cosmetic Act. While untrue, this has a few members of Congress concerned.

The MUMS Coalition will continue to work diligently on correcting this misinformation but it is equally important that you provide correct information to your members of Congress if concerns are raised.

Q: Is the MUMS legislation a vehicle for the approval of genetically engineered animals (including transgenic salmon)?

A: No, the MUMS legislation was never intended to authorize approvals of transgenic animal drugs. The bill's sponsors are prepared to offer a specific amendment to clarify this and the MUMS Coalition concurs.

Q: Will the bill allow the unsafe use of drugs, including animal antibiotics?

A: No, drugs authorized under the bill must meet appropriate standards for human, animal and environmental safety. There is no "fast-tracking" of public health safety assessment. FDA's draft *Guidance for Industry (#152): Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern*, ensures food safety regarding antibiotic resistance.

Q: Are there loopholes in the MUMS bills?

A: No, the MUMS bill is sound legislation. The legislation has been developed with the line-by-line technical review of the Food and Drug Administration. The bill is the result of Congress' mandate to the Secretary of Health and Human Services in the Animal Drug Availability Act of 1996 (Public Law 104-250) to announce proposals for "legislative and regulatory options for facilitating the approval under section 512 of the Federal Food, Drug and Cosmetic Act of animal drugs intended for minor species and minor uses." The FDA has provided assurance to Congress that loopholes are not present.

Q: What is MUMS really about?

A: According to the National Organization for Rare Disorders, about 25 million people in the United States suffer from an estimated 6,000 uncommon or rare conditions known as "orphan diseases"¹ A similar situation exists in animals but is compounded many times over by the needs of many hundreds of species. The purpose of the MUMS bill, as was the purpose of the human Orphan Drug Act, is to help correct this situation and promote animal health and welfare of minor species and alleviate suffering from uncommon or rare diseases for all animals.

While there is currently little to no incentive for pharmaceutical companies to get drugs approved by FDA for relieving the problems of minor medical conditions in any species or for medical conditions in minor species, the MUMS legislation is but a small step to correct the problem without compromising public or environmental health in any way. Indeed, passage of the MUMS legislation would strengthen the Federal Food, Drug and Cosmetic Act and greatly benefit animals and the people who care for them.

Further Information

Individuals wanting to examine the actual legislation or obtain additional information should visit <http://www.avma.org/scienact/mums>. Members of Congress should be encouraged to contact Barron Avery in Senator Sessions' office (202-224-4124), John Rounsaville in Representative Pickering's office, (202-225-5031) and/or FDA-CVM for their independent assessment of the MUMS bills.

¹ Villarreal, M.A. 2001 Orphan Drug Act: Background and Proposed Legislation for the 107th Congress. CRS Report for Congress. Congressional Research Service, The Library of Congress, Code RS20971. July 25, 2001