United States General Accounting Office

GAO

Testimony

Before the Human Resources and
Intergovernmental Relations Subcommittee
Committee on Government Operations
House of Representatives

For Release
on Delivery
Expected at
10:00 a.m. EDT
Wednesday
August 5, 1992

FOOD SAFETY AND QUALITY

FDA Strategy Needed to Address Animal Drug Residues in Milk

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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss our report[1] on the Food and Drug Administration's (FDA) efforts to address animal drug residues in milk and on the agency's extra-label use policy that essentially allows veterinarians, under emergency circumstances, to treat dairy cows and other food-producing animals with a drug or dosage level not approved for the animal.

This is the second report to you on this subject, Mr. Chairman. Almost 2 years ago, in November 1990, we reported to you that because of sampling and testing limitations, FDA's surveys were not adequate to demonstrate that the milk supply was free from unsafe animal drug residues. At that time, we made a series of recommendations to FDA to improve its monitoring of the milk supply.

To their credit, Mr. Chairman, FDA and the National Conference on Interstate Milk Shipments--the cooperative state, federal, and industry body that oversees the Grade A Pasteurized Milk Ordinance --amended the Milk Ordinance in April 1991 to respond to our recommendations and your concerns and in recognition of the long-standing gap between animal drug usage and testing. The revisions were intended to increase the number of milk samples analyzed, drug residues tested for, and test methods the states and industry could use for monitoring milk. The report we are providing you today discusses FDA's progress on these issues to date.

SUMMARY

In brief, Mr. Chairman, because of ineffective federal leadership and the lack of a comprehensive FDA strategy for monitoring animal drug residues in milk, limited progress has been made in implementing program revisions. As a result, states are still testing, under the Milk Ordinance, for the same 4 drugs as they were in 1980, while up to 82 drugs that may leave residues in milk are known to be or suspected of being used in dairy cows. Furthermore, FDA has not evaluated and approved any additional screening tests to be used to test for any additional drugs, although states and industry have repeatedly stated their need for such tests. Development of a national data base to collect state and industry testing data is also behind schedule.

In the meantime, FDA has launched another survey to test for 12 animal drug residues in milk. However, because of statistical and testing limitations, FDA's survey cannot be used to draw conclusions about the presence of residues in milk. This survey, which is also being expanded to test for the same four drugs that

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[1]Food Safety and Quality: FDA Strategy Needed to Address Animal Drug Residues in Milk (GAO/RCED-92-209, Aug. 5, 1992).

the states and industry are already testing for, will cost about $500,000 this year.

Mr. Chairman, you also asked about FDA's extra-label use policy. We found that although FDA had intended the policy would be used only in emergency circumstances, such use is, in fact, routine. FDA cannot enforce its extra-label use policy effectively because it does not routinely monitor veterinarians' use of the policy and cannot detect residues of most drugs used in an extra-label manner on dairy cows. Consequently, FDA cannot control the use of animal drugs or ensure that illegal and possibly unsafe drug residues are not getting into milk, or the food supply in general. Furthermore, FDA's limited enforcement of extra-label uses undermines the federal drug approval process by discouraging animal drug companies from seeking FDA approval of those uses of their drugs that are now extra-label.

Before discussing the details of our findings, I would like to provide some background on the regulation of milk safety and animal drugs.

BACKGROUND

FDA oversees the safety of the nation's milk supply through a voluntary, collaborative federal/state program that dates back to the mid-1920s. Under the program, the states generally carry out most monitoring, enforcement, and other regulatory functions required by the Grade A Pasteurized Milk Ordinance--the basic milk sanitation standard in the United States, under which almost all milk is produced. For example, in 1991 the states tested under the Milk Ordinance about 1.2 million samples of milk for residues of four drugs. FDA oversees state regulators and selectively checks dairy farms and plants.

Animal drugs used to treat sick dairy cows or increase milk production may leave residues in milk. FDA, under the Federal Food, Drug, and Cosmetic Act (FFDCA), is responsible for determining whether animal drugs are safe and effective for those animals and whether the food products derived from treated animals will be safe for human consumption. Generally, FDA must approve new animal drugs and set legal limits on the residues that may remain in food before drugs may be legally marketed in the United States. Use of an animal drug in a manner inconsistent with its approved labeling is illegal and can result in FDA's taking regulatory action against the veterinarian, dairy farmer, or other persons involved. However, in 1984 FDA established guidelines for veterinarians to treat food-producing animals in a manner not in accordance with approved labels, under emergency circumstances.

GAP BETWEEN ANIMAL DRUG USAGE AND TESTING IS LONG-STANDING

Since 1980 the states have routinely tested milk under the Milk Ordinance for only 4 of the 82 animal drugs that are known to be or suspected of being used on dairy cows and that may leave residues in milk. On the basis of tests for these four drugs, FDA estimated in 1991 that up to 1 percent of the nation's milk supply was contaminated with excess residues and was discarded. The actual extent of contamination is not known but is probably greater because many of the drugs that are not routinely tested for are widely used. FDA data indicate that 64 of the 82 drugs are commonly used on dairy cows or may leave residues that raise health concerns. Moreover, 35 of these 64 drugs have not been approved for use on dairy cows, and still others are not approved for use in any food-producing animals.

Although some states and parts of the milk industry are supplementing the tests required under the Milk Ordinance with other tests, no reliable data are available on the number or types of tests done, the drugs tested for, or the test results. In addition, neither FDA nor the states have collected data from the results of these supplemental tests in a uniform manner that would allow analysis.

LIMITED PROGRESS IN IMPLEMENTING PROGRAM REVISIONS

FDA and the states have made limited progress in implementing program revisions to improve milk monitoring. In particular, implementation of the 1991 revisions to the Milk Ordinance is behind schedule and uncertain. In addition, FDA's new program to monitor drug residues in milk is not providing conclusive information and FDA has not resolved how this program fits into the overall state/federal monitoring effort. Overall, FDA lacks a comprehensive strategy for monitoring animal drugs in milk.

In April 1991 FDA, the states and industry revised the Milk Ordinance to increase industry and state monitoring and surveillance of animal drug residues in milk. In January 1992 industry began testing raw milk from all milk tankers as they enter dairy plants, but only for selected beta lactams, a class of antibiotics. As of July 1992 the states were responsible for monitoring industry's compliance with the new testing requirements, and dairy farmers were required to participate in an industry-developed quality assurance program when drug residues found in their milk products exceed permitted levels. FDA is required to identify additional drugs to test for and recommend additional test methods for the states and industry to use. In particular, FDA and the AOAC Research Institute, a nonprofit standard-setting organization, were to develop a program to evaluate and recommend additional rapid-screening test methods by July 1992. State

monitoring efforts depend heavily on identifying and using new test methods.

Yet, implementing the revisions to the Milk Ordinance has proven to be more difficult and time consuming than initially envisioned. For example, lack of communication within FDA and between FDA and the Institute, as well as unanticipated difficulties delayed the start-up of the new AOAC Research Institute/FDA program. Assuming that FDA and the Institute formally sign a memorandum of understanding--which they have not to date--the Institute now estimates that it will be fall 1992 before it can evaluate new methods. As a result, new screening methods will not be available until 1993 at the earliest. Subsequently, FDA will need to train and certify state regulators who, in turn, will have to train and certify industry personnel in the use of the tests.

The outcome of the program is also uncertain because it is a novel venture for both FDA and the Institute and because FDA has not yet resolved the type of test methods the states and industry may use under the Milk Ordinance. FDA is developing and validating regulatory methods to specifically identify and measure the residues of 48 animal drugs in milk. While these methods can yield definitive information about the identity and quantity of a drug residue, they require specialized laboratory equipment and are time consuming to run.

State and industry officials told us that FDA's regulatory methods are not suitable for and not responsive to their needs for quick, reliable, and inexpensive screening tests that can be used in the field to check raw milk before processing. On the other hand, FDA officials believe that the more detailed regulatory methods are needed as a standard or reference against which to evaluate the performance of screening methods, as well as to confirm positive results obtained from these methods. Frustrated by FDA delays, some states and parts of the milk industry have in the meantime started using screening tests on their own.

In addition to not resolving questions about test methods, FDA has not effectively planned and implemented other elements of the Milk Ordinance revisions. For example, industry was required to begin retaining and reporting residue data to the states in January 1992, and the states were required to begin auditing these data in July 1992. However, the start-up of the national residue data base has been delayed, in part, because of resource constraints. Without a national residue data base, FDA cannot develop and analyze information from state and industry screening tests to help target monitoring and enforcement efforts and ensure effective oversight.

FDA'S New Monitoring Program Does Not Provide Conclusive Information

In February 1991 FDA started the National Drug Residue Milk Monitoring Program. During the first year of the program, which cost about $250,000, FDA tested about five raw milk samples a week nationwide from selected milk processing plants for residues of 12 drugs. FDA expanded the program in 1992 to increase the yearly sample size from 250 to 500 and the number of methods used to test for five additional drugs, including the four beta lactams that the states have been testing for. The expanded program will cost about $500,000 in fiscal year 1992. As of May 1992 the program, using sophisticated regulatory methods, had confirmed the presence of five sulfa drug residues in milk samples tested, but the residues were all below levels of concern.

However, no meaningful conclusion can be drawn from these test results. The program's small sample size and the limited number of drugs tested for preclude drawing any statistically valid conclusions about the presence of residues in milk. Although FDA officials agree that the results of the program are not statistically projectable, they believe that the program can provide an indication of whether animal drug residues are present in milk. We believe that the statistical and testing limitations raise questions about the value of this program, as well as about how it fits into the overall federal/state milk monitoring effort, especially considering the anticipated increase in monitoring efforts by the states and industry under the revised Milk Ordinance. For example, FDA decided to expand its monitoring program to test for the same four drugs that the states and industry are already testing for.

Comprehensive FDA Strategy Needed

Overall, FDA lacks a comprehensive strategy for monitoring animal drug residues in milk. Initial efforts to implement the Milk Ordinance revisions were impeded by a lack of internal FDA communication, coordination, and agreement. In May 1992 FDA created a Milk Working Group to formally establish links between key offices. While the Group is a step in the right direction, FDA still lacks a comprehensive strategy. Lacking clear federal leadership, some states and parts of the milk industry have taken actions on their own. While commendable, these efforts do not represent a comprehensive, uniform, or required system that will provide consumers with assurance that the milk supply is free of excess and unsafe animal drug residues. If consumers are uncertain about the risks of animal drug residues in their milk because they perceive a breakdown in milk monitoring they may decrease their consumption of milk products, regardless of the actual health risk imposed by residues in milk.

We believe that FDA needs to develop a comprehensive strategy to monitor milk for animal drug residues that optimizes state and industry monitoring under the Milk Ordinance, outlines FDA offices' roles and responsibilities, and integrates the various efforts to improve milk monitoring.

Mr. Chairman, let me now address FDA's extra-label use policy.

EXTRA LABEL USE UNDERMINES CONTROLS OVER ANIMAL DRUGS

Use of an animal drug other than specified on the FDA-approved label--called extra-label use--is a violation of FFDCA. However, in 1984 FDA established a policy under which it will generally not pursue enforcement action when veterinarians treat food animals, such as dairy cows, in an extra-label manner when the animal's life is in danger and no other effective approved drugs are available. For example, a veterinarian could use or prescribe a drug approved for use only on horses to treat dairy cows. Although FDA officials intended that extra-label uses under its policy would be rare, evidence indicates that veterinarians are routinely using and prescribing drugs in an extra-label manner for dairy cows. Several veterinarians who treat dairy cows told us that 40 to 85 percent of their drug prescriptions for dairy cows are extra-label use prescriptions.

Veterinarians and officials from FDA and the American Veterinary Medical Association told us that extra-label use is routine and necessary because there are not enough approved drugs to effectively treat all dairy cow diseases. However, there are no empirical data on the need for extra-label uses to treat dairy cows. Without such data, it is difficult to determine whether dairy farming practices and economics contribute to the perceived need to use drugs in an unapproved manner. For example, despite the policy restrictions, some veterinarians choose to use drugs not approved for dairy cows to treat certain diseases because they consider them to be more effective or less costly than drugs approved for these same uses.

When a drug is used in an extra-label manner, important safeguards against marketing unsafe animal drugs are bypassed. In particular, health and safety data are usually not available. Consequently, veterinarians may lack sufficient information on the dosage levels and milk discard times needed to ensure that illegal and/or unsafe residues do not occur in milk and other food products. The potential lack of information is of particular concern when extra-label use involves a drug not approved for use on any food animal because FDA may not have any data on the potential human health risks from consuming residues of the drug in food. In addition, approval of a drug in one food animal does not necessarily provide sufficient information for safe use of the drug in an unapproved manner in another animal because of differences in

the animals' systems. One drug manufacturer, for example, sent letters to 7,000 dairy veterinarians warning that no safety data were available for a certain drug when used in an extra-label manner and that illegal residues could result. FDA lacks data to show that veterinarians have sufficient knowledge and information to make informed decisions about extra-label uses, especially those involving drugs not approved for use in any food animal.

Furthermore, when a drug is used in an extra-label manner, test methods to detect possible residues in milk are usually not available. FDA and state milk regulators lack acceptable test methods to detect most drugs used in an extra-label manner. FDA officials acknowledge that without the ability to detect residues in milk from the extra-label use of animal drugs on dairy cows, the agency generally cannot enforce the policy. In addition, we found that FDA does not routinely monitor veterinarians' use of drugs under the policy. For example, FDA has not attempted to obtain data on veterinarians' extra-label use of drugs under the policy.

Veterinarians' routine practice of treating dairy cows in an extra-label manner, coupled with FDA's inability to ensure that the conditions of the policy are followed, may discourage animal drug manufacturers from seeking additional approvals of their drugs. According to officials from FDA and the Animal Health Institute, animal drug companies have little incentive to pursue FDA approval for all possible uses of an animal drug because of the cost of approval and limited return on investment, especially when a drug is no longer protected by a patent. In addition, without data on how and to what extent veterinarians are using drugs in an extra-label manner, FDA generally cannot develop a sufficient case to compel drug manufacturers to seek approval of those uses of their drugs that are used routinely in an extra-label manner.

Veterinarian involvement also does not ensure that no illegal residues remain in milk following extra-label use of an animal drug on a dairy cow. For example, FDA has frequently warned dairies and veterinarians about residues resulting from extra-label uses of drugs found in dairy cows sent to slaughter. Also, veterinarians acknowledge that they cannot ensure that animal owners and producers, who typically administer drugs to their animals, follow veterinarians' directions for extra-label uses. In addition, many of the drugs used by veterinarians for extra-label uses are available over the counter. Although FDA's policy does not permit nonveterinarians (such as dairy farmers) to treat food-producing animals with drugs in an unapproved manner, dairy farmers may copy veterinarians' extra-label uses to treat dairy cows by using over-the-counter drugs.

Mr. Chairman, the issues surrounding extra-label use drug use are complex and highly controversial. Recent proposals to address extra-label use problems and FDA's policy all have limitations because of the persistent lack of data on the need for extra-label

uses and whether veterinarians have sufficient information to make informed decisions on extra-label uses. We believe that data from a scientific source could help policy makers decide whether to keep, revise, or eliminate the policy. The National Academy of Sciences is in the process of establishing a standing panel of experts on animal health and veterinary medicine that may be able to address this issue as part of this overall effort. In the interim, we believe that FDA can further restrict extra-label uses and begin to collect data on such uses to better control the unapproved use of drugs on food animals.

This concludes my prepared statement. I would pleased to respond to any questions that you or members of the Subcommittee may have.

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