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## EPA Lacks Assurance That Disinfectants Kill Germs

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Environment, Energy, and Natural
Resources Subcommittee
Committee on Government Operations
House of Representatives

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss how well the Environmental Protection Agency (EPA) reassures doctors, nurses, and consumers that disinfectants are effective. EPA regulates the efficacy of disinfectants because users cannot see whether they kill germs, and the use of ineffective disinfectants could threaten public health. Moreover, ineffective disinfectants waste consumer dollars. About $1 billion per year is spent on disinfectants to kill disease-causing microorganisms on surfaces and objects in hospitals, schools, restaurants, offices, homes, and at many other locations. My testimony is based on our report on EPA's disinfectant program, which is being released today.[1]

In summary, we found that EPA lacks sufficient assurance that disinfectants kill germs as claimed for four reasons.

-- First, the validity of test methods and pass/fail performance standards used to assess the efficacy of disinfectants have been embroiled in scientific controversy over the last decade. However, EPA has made little progress in resolving the controversies.

-- Second, EPA has contributed to these controversies by accepting test methods and modifications to these methods without criteria and independent laboratory data for evaluating their validity.

-- Third, EPA lacks sufficient internal controls to ensure the quality and integrity of the data that registrants submit on disinfectant efficacy.

-- Fourth, EPA lacks an enforcement strategy to ensure that,

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[1]Disinfectants: EPA Lacks Assurance They Work (GAO/RCED-90-139, August 30, 1990).

once registered, disinfectants sold and distributed in the marketplace work as claimed.

Although the true extent to which ineffective disinfectants are marketed is unknown, evidence from EPA, the states, and others indicates that up to 20 percent of disinfectants on the market may be ineffective.

I will address each of these major program deficiencies in more detail, but first I would like to provide some background information on disinfectant efficacy regulation.

## BACKGROUND

EPA regulates disinfectants as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under FIFRA, disinfectants generally must be registered or licensed by EPA before they may be marketed. EPA may register a disinfectant only after determining that it is effective when used as claimed and does not cause an unreasonable risk to public health or the environment. EPA requires registrants of disinfectants intended to protect public health to submit efficacy data substantiating each claim about a product's performance and use. By contrast, EPA allows the marketplace to regulate product performance for most other pesticides because users can see whether the pesticide is effective against the target pest.

As defined by EPA, "disinfectant" refers to only one of several types of antimicrobial pesticides, which, with some exceptions, are substances intended to inhibit or destroy microorganisms (bacteria, fungi, and viruses). However, we have used the term disinfectant to broadly describe all antimicrobial pesticides intended to protect public health.

At the time of our review, about 4,100 disinfectants were registered by EPA for a variety of uses in many areas of the inanimate (i.e., nonliving) environment. Disinfectant types and uses range from products intended to kill bacteria on hard surfaces in bathrooms to products intended to chemically sterilize medical instruments in hospitals and doctors' offices. We focused on EPA's regulation of disinfectants registered for use on hard surfaces because over 75 percent of all disinfectants, or 3,200, were registered for such use. In addition, these disinfectants are most affected by the scientific controversies surrounding the test methods used to substantiate efficacy.

Infection control is a serious concern for health-care providers, the food industry, and consumers. In fact, health-care organizations recommend, and many public health ordinances require, the use of disinfectants. About 5 percent of all patients acquire an infection while hospitalized, according to the Centers for Disease Control. Although medical experts generally believe that most hospital-acquired, or nosocomial, infections are transmitted from person to person rather than from the inanimate environment, the role of the inanimate environment in transmitting infections has not been completely defined. However, research has linked at least some infections, including fatalities, to contaminated medical instruments.

## EPA LACKS ASSURANCE THAT EFFICACY TEST METHODS AND STANDARDS ARE VALID

Almost all of the EPA-recommended efficacy test methods and performance standards have been embroiled in scientific controversy for over a decade. Various scientists and officials from EPA, state governments, academia, industry, commercial laboratories, scientific associations, and user groups disagree over whether (1) the test methods produce inconsistent and nonreproducible results; (2) the existing laboratory test methods adequately simulate

performance of a disinfectant in actual use; and (3) the performance standards, or pass/fail criteria, for existing methods are valid or are too stringent. Nevertheless, EPA officials believe that the existing disinfectant efficacy test methods and performance standards are acceptable for registration and enforcement purposes. Most of the EPA-recommended methods were developed under the auspices of the Association of Official Analytical Chemists (AOAC). The AOAC is an independent standard-setting organization whose primary purpose is to develop and validate standardized chemical and biological analytical methods that are generally recognized as "official."

EPA officials have acknowledged that the existing disinfectant efficacy methods and standards need to be improved; yet the agency has made limited progress in resolving the controversies because of problems in conducting needed research. Between 1983 and 1989, EPA spent about $384,000 on two consecutive cooperative agreements with the University of North Carolina at Chapel Hill (UNC) to update and improve certain disinfectant test methods, but this work did not accomplish EPA's intended objectives. EPA officials and the UNC researchers have disagreed over UNC's research results and conclusions. Our review indicated that EPA did not manage and monitor the UNC cooperative agreements well. In addition, the dispute between EPA and UNC over the research may have been compounded by a lack of communication and coordination within EPA and a lack of top management involvement in the early years of the agreements.

We do not know whether EPA's criticisms of UNC's research are valid, reflect reasonable differences in scientific judgment, or reflect a lack of acceptance of research results critical of an existing program. However, if EPA is ever to resolve the scientific controversies, it must do a better job of managing the research. In April 1990, EPA announced that it would spend $600,000 for research on certain disinfectant efficacy methods.

However, EPA believes it may need to spend an additional $1.2 million to completely research the alleged problems with the disinfectant methods and standards.

Over the years, EPA has contributed to the controversies by accepting test methods and modifications to methods that have not been independently validated through laboratory evaluation. EPA has accepted the methods and modifications on the basis of internal, and in some cases external, scientific peer review and regulatory judgment. However, EPA lacks criteria for assessing the validity of proposed test methods or significantly modified test methods. For example, EPA accepts three different test methods to demonstrate that disinfectants kill tuberculosis bacteria. In effect, the registrants may choose which of the three methods they will use to support the registration of their products, even though the test, such as the length of time a surface is exposed to the disinfectant (referred to as contact time), differ significantly.

We found that one product was tested under two of the test methods and was deemed to be effective after 10 minutes under one method and effective after 55 minutes under a second method. Naturally, the registrant chose to maintain the product's registration by using the method that produced the shorter contact time. However, EPA was unable to explain to us the differences in the test results between the methods for this product.

## CONTROLS OVER QUALITY/INTEGRITY OF EFFICACY DATA QUESTIONABLE

Even with improvements in its programs to ensure the validity of the test methods used to support the efficacy of disinfectants, EPA would continue to lack assurance that disinfectants work as claimed. This is because of problems with the quality and integrity of registrant-submitted disinfectant efficacy data. EPA relies on registrant-submitted efficacy data to register

disinfectants and on its data review, lab inspection, and data audit programs to ensure the quality and integrity of the data. However, we found weaknesses in each of these programs. We also found that a pre-registration testing program is needed to supplement these programs because they generally do not enable EPA to identify cases in which registrants have selectively submitted incomplete disinfectant efficacy data or have deliberately submitted invalid data. We believe EPA's lack of sufficient control over the quality and integrity of registrant-submitted disinfectant efficacy data is a material weakness in EPA's internal controls that should be, but has not been, reported to the President, as required by the Federal Managers' Financial Integrity Act of 1982.

Specifically, we found that (1) EPA had inspected/audited only about 10 percent of all the labs that performed disinfectant efficacy studies submitted to EPA over a period of about 4 years and had identified only about 13 percent of all the labs that performed these studies; (2) EPA's inspectors and auditors may be unable to evaluate adequately the capability of labs to perform these studies; (3) EPA has been slow to prepare and process reports from inspections and audits at labs performing these studies; and (4) EPA lacks program guidance for conducting data reviews, lab inspections, and data audits relating to these studies. I will now discuss just one of the weaknesses we found to illustrate the extent of the problems.

We found that EPA had not inspected most of the labs that performed disinfectant efficacy studies. Between January 1, 1985, and September 30, 1989, EPA's lab division inspected labs and audited studies at 9 individual labs, representing only 10 percent of the 92 labs that had generated disinfectant efficacy data EPA received over about this same time period. What is distressing is that the lab division was unaware of most of the labs, including some high-volume labs. The lab division had identified only 12 of

the 92 labs because it had not used a readily available EPA data system that contains a central archive of studies that registrants submit to EPA to support their registrations.

Even if EPA corrected the weaknesses we found in its data review, lab inspection, and data audit programs, it would be unable to identify cases in which registrants have selectively submitted incomplete disinfectant efficacy data. EPA's position is that registrants are required by FIFRA to submit all data indicating that a disinfectant may not be effective as registered when they are aware that such data exist. However, evidence indicates that registrants have submitted to EPA efficacy test data indicating that their disinfectants work but may have withheld other test data indicating that these disinfectants do not work. Furthermore, if a registrant deliberately submitted invalid data to EPA, or a commercial lab deliberately submitted invalid data to a registrant, EPA's data reviewers, lab inspectors, and data auditors probably would be unable to tell. Neither lab inspectors nor data auditors can practically observe these tests in progress, and no physical evidence remains from the tests once they are completed. As a result, EPA relies on a registrant's word about the procedures followed in a test, the disinfectant formulation tested, and the test results reported.

During our review we also found evidence that registrants had submitted selective data to EPA. For example, by chance, one data auditor found evidence of selective data--passing and failing data on a high-volume, household disinfectant whose registration file contained only passing data. In addition, representatives of two registrants told us that they had obtained both passing and failing results on disinfectants but had submitted only passing results to EPA.

The belief that registrants submit selective data to EPA is widespread. In fact, members of the disinfectant industry openly

joked about submitting selective data to EPA at a widely attended national meeting on disinfectant efficacy test methods that we and EPA officials attended. Industry representatives and others explained that the disinfectants are "effective," but selective data had been submitted to EPA because EPA's performance standards are too stringent.

What can EPA do to fix this situation? We believe that the only way for EPA to determine whether a registrant has submitted selective data or has deliberately submitted invalid data is for EPA to sponsor independent testing of the disinfectants. Although EPA tested selected product claims at one time, it no longer does so. EPA discontinued testing disinfectants primarily because of competing program priorities. However, remaining records from EPA's limited testing program show that, in at least some cases, federal government testing before registration led to more protective label claims. We are not suggesting that EPA test all disinfectants for efficacy before registering them. Instead, EPA could target such a program to those disinfectant claims of greatest importance to public health and/or products with suspected efficacy problems.

## LIMITED MONITORING/ENFORCEMENT OF REGISTERED DISINFECTANTS

I would now like to turn to our last point--EPA lacks an enforcement strategy to ensure that, once registered, disinfectants sold and distributed in the marketplace work as claimed. Even if EPA were to implement improvements in its processes for registering efficacy claims and for ensuring the quality and integrity of registrant-submitted data, these improvements would not provide sufficient assurance that disinfectants on the market work as claimed. Registrants could, intentionally or inadvertently, manufacture and sell ineffective batches of disinfectants after registering them.

Until 1982, EPA operated a limited post-registration testing program to verify certain efficacy claims of marketed disinfectants at its laboratory facilities in Beltsville, Maryland. According to previous EPA congressional testimony, EPA discontinued the program primarily because (1) the level of testing was inadequate and was creating a false sense of security among users and the public about the efficacy of disinfectants on the market and (2) budget constraints prevented EPA from conducting what it considered to be an adequate level of testing. Since it stopped testing disinfectants, EPA has looked to the states, the user community, and the disinfectants industry to ensure the efficacy of marketed disinfectants. However, we found that few states and no user groups were routinely monitoring disinfectants and that industry self-regulation was ineffective. Furthermore, EPA lacks a strategy to channel complaints about potentially ineffective disinfectants from various sources to take appropriate enforcement action against disinfectants found to be ineffective.

We identified only three states--Florida, North Carolina, and Mississippi--that were monitoring the efficacy of disinfectants in the marketplace under their pesticide enforcement programs, and these states have decreased the amount of testing they have performed in recent years. Only two states--Wisconsin and Virginia--were testing disinfectants under other state programs. These five states test for only a limited number of efficacy claims. Other states have been reluctant to start testing programs because they too lack the resources needed to establish and operate a testing facility, according to selected state officials we interviewed.

Also, states do not have the authority to regulate the efficacy of disinfectants in the marketplace outside of their boundaries. In at least two cases, registrants have responded to state enforcement action by recalling disinfectants from the marketplace within the state or by deleting specific efficacy

claims from disinfectant labels while continuing to market the disinfectants or make the claims in other states. For example, a producer agreed to recall from a single state market a disinfectant marketed under nine different brand names after the product failed state efficacy tests. However, the disinfectant, which is registered for use on floors, walls, and other hard surfaces in hospitals, nurseries, rest rooms, telephone booths, and elsewhere, continues to be sold in all other states, according to the registrant's customer service representative.

Individuals and organizations both within and outside of the health-care industry told us that they were not aware of any hospitals, doctors, or dentists that test disinfectants for efficacy. Likewise, the restaurant and food-processing industries generally do not test the efficacy of disinfectants on the market. Some researchers affiliated with users and others have tested disinfectants, or are planning to test disinfectants, but have not established monitoring programs.

Although several researchers and others have complained or submitted data to EPA indicating that specific disinfectants do not work as claimed, EPA has not established the system for processing these complaints, a system that it proposed as part of its 1987 disinfectant strategy to improve its program. Furthermore, EPA lacks an adequate laboratory facility or provision to contract for laboratory services to verify the complaints and take appropriate enforcement action against disinfectants found to be ineffective.

Market forces cannot be relied upon to control disinfectant efficacy problems because users cannot visually identify ineffective products. Furthermore, although registrants can test competitors' products and have challenged competitors' claims, EPA has been unable to resolve conflicting claims because it lacks the laboratory facilities necessary to do so.

Although the scientific controversies cloud the issue somewhat, historical data on specific products from EPA and the states, along with data from industry, academia, and other sources, indicate that some disinfectants on the market do not work. The true percentage of ineffective disinfectants on the market is unknown. Although historical data on product failure rates from EPA and the states are not comparable because of differences in sampling schemes, performance standards, and testing procedures, EPA officials and others believe that up to 20 percent of marketed disinfectants may be ineffective. Some disinfectants have failed enforcement tests by a wide margin, and some have failed repeatedly in a single state, in multiple regulatory labs, or in tests performed by registrants themselves at regulatory labs. For example, one registered disinfectant used in hospitals, nursing homes, and schools failed efficacy tests on multiple occasions in EPA's lab and in two state labs.

Without an enforcement strategy to channel complaints about potentially ineffective disinfectants from industry, users, and others and to take appropriate enforcement action against the producers of disinfectants found to be ineffective, EPA may be jeopardizing public health and wasting consumer money. In light of federal budget constraints, EPA may need to explore options for pooling resources from the states, user groups, and industry to implement such a strategy.

Although there are other options, a federal or federally supported independent laboratory facility could conduct post-registration testing to verify selective disinfectant efficacy claims and assist in enforcement cases. However, EPA's existing facility in Beltsville, Maryland, is obsolete and in disrepair. Options exist for operating an independent laboratory facility; however, EPA has not explored these options. EPA officials have objected to reopening a federal facility because they claim EPA cannot afford to test disinfectants because of its limited budget

and competing pesticide program priorities, and they do not believe the federal government should test these products. Although fees charged for the privilege of obtaining a disinfectant registration could help offset the costs of a disinfectant laboratory facility, the Congress would need to provide EPA with additional authority to establish these fees.

## CONCLUSIONS AND RECOMMENDATIONS

Our work shows that EPA does not know whether disinfectants work and that its disinfectant efficacy program needs a major overhaul. When consumers purchase disinfectants with EPA registered labels to use in their homes, they expect that the products will kill the germs claimed on the labels. When people are admitted to hospitals or go to their doctors' offices for treatment, they expect that their doctors and nurses will use disinfectants that work and that their treatment will not expose them to germs that disinfectants should have killed. Unfortunately, these expectations are not being fully realized because of deficiencies in EPA's efforts to regulate disinfectant efficacy. In short, EPA's policy of "let the buyer beware" for disinfectants may be compromising public health and wasting consumer dollars. It is clear to us that EPA needs to exercise greater leadership to resolve these problems.

Our report makes several recommendations to EPA to correct the deficiencies we identified and restore credibility to the disinfectant program, including (1) developing a plan to resolve the scientific controversies that surround disinfectant efficacy test methods and performance standards; (2) developing and publishing a policy that establishes criteria for evaluating the validity of new test methods and modifications, including criteria for determining when independent laboratory data are needed for validation; (3) improving internal controls over its current programs to ensure the quality and integrity of registrant-

submitted efficacy data and conducting preregistration tests to selectively verify registrant claims; (4) establishing an enforcement strategy in conjunction with the states, user groups, and industry to ensure that marketed disinfectants work as claimed; and (5) preparing a cost-benefit analysis of alternatives for a laboratory facility to research and test the efficacy of disinfectants, including the option of charging fees to register disinfectants to help finance such a facility.

Mr. Chairman, this concludes my prepared statement. I would be glad to respond to any questions that you or members of the Subcommittee might have.