Medical News

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EPA Begins Testing Hospital Disinfectants as Sterilant Testing Program Nears Completion

The US Environmental Protection Agency (EPA) announced civil penalties totalling $3.1 million against the manufacturers (registrants) and distributors of several sterilant and hospital disinfectant products. Sterilant and disinfectant products play a critical role in infection control, and healthcare providers, consumers, and others rely on the licensing (registration) of these products as evidence that they work as claimed on the label. EPA has been conducting a testing program to determine the effectiveness of all antimicrobial products registered for use as sterilants, tuberculocidals, and hospital disinfectants. The testing has been divided into two phases: sterilant testing, and hospital and tuberculocidal disinfectant testing. In an effort to protect the public health, EPA has taken enforcement action to remove certain products from the market that have failed to perform effectively when used in accordance with the label directions. The enforcement actions have been levied against the manufacturers of eight ineffective sterilants that failed the EPA testing program, one registrant of two disinfectants that failed testing, and a number of distributors for selling unregistered sterilants and disinfectants. The Table summarizes the status of chemical sterilant products in the EPA efficacy testing program.

These actions will bring the enforcement component of the sterilant testing program nearly to completion, with emphasis shifting to validation tests of hospital disinfectants. EPA issued civil complaints, and a stop sale, use, or removal order, against the hospital disinfectant products Broadspec 128 and Broadspec 256 (Brulin and Co) for failing the agency's tuberculocidal and hospital disinfectant testing program. In addition, EPA has issued civil administrative complaints and proposed civil penalties against 10 distributors of seven unregistered Wipeout (disinfectant) products produced by Celltech Media, Inc (formerly Health Care Products, Inc) and one registered ineffective product (Wipeout Cold Sterilizing and Disinfecting Solution). The EPA recommends that holders discontinue use of existing stocks of any products that failed the testing program.

The EPA testing program was started in 1991 with sterilants. Testing began in 1992 on the 1,200 registered hospital disinfectants and 130 registered tuberculocides, and will be ongoing. The recent action against registrants of Broadspec 128 and Broadspec-256 is the first against a failed disinfectant or disinfectant with a tuberculocidal claim.

For additional information regarding the sterilant, hospital disinfectant, and tuberculocide testing programs, call EPA's toll-free hotline, the National Pesticide Telecommunications Network, at (800) 447-6349, from 7 AM to 6 PM (CST).

FROM: (1.) EPA Press Release: Sterilant and Disinfectant Enforcement Action; February 19, 1995. (2.) EPA Questions and answers: enforcement actions against registrants and distributors of ineffective and unregistered sterilants and disinfectants; February 15, 1995. (Table)

Tuberculosis-Related Hospitalizations Double in 3 Years and Cost Up to $8 Billion-HIV Infection Adds to Price Tag

The results of the first study to use a nationally representative sample of hospitals, combined with cost data, to estimate hospitalizations and their costs for HIV and tuberculosis (TB) care was reported by Dr. Lisa Rosenblum and colleagues at the Centers for Disease Control and Prevention (CDC).

Data were obtained from a survey of discharges from US nonfederal short-stay hospitals and from statewide billing information. Patients included in the survey were 15 to 44 years of age with a listed diagnosis of HIV infection (N = 418,200) or active TB (N = 77,700) during 1985 to 1990.

During 1985 to 1990, hospitalizations related to HIV infection increased six-fold, from 18 to 102 per 100,000 persons. During 1988 to 1990, hospitalizations related to TB increased twofold, from 8 to 16 per 100,000 persons. The prevalence of TB among HIV-infected patients increased from 2.4% from 1985 to 1988 to 5.1% from 1989 to 1990. The prevalence of HIV infection among patients with TB increased from 11% from 1985 to 1988 to 28% in 1989 to 39% in 1990.

From 1985 to 1990, inpatient care costs increased 7.7-fold for HIV and 3.2-fold for TB hospitalizations. During this period, HIV and TB hospitalizations resulted in 5.7 and 1.1 million days of care, respectively, with an estimated direct cost of $5.7 to $7.4 billion and $0.89 to $1.07 billion, respectively. Estimated national costs of inpatient care for HIV infection or TB or both totaled $6.4 to $8.1 billion, 5% of which was used for patients with both HIV infection and TB.

These findings suggest that the convergence of the HIV and TB epidemics has had an increasing effect on morbidity and the cost of care among young adults in the United States. The authors conclude that the increasing prevalence of comorbidity of HIV infection and tuberculosis in inpatients underscores the need for strict infection control of tuberculosis on the part of hospitals, increased attention to prevention, and early identification and treatment of HIV and tuberculosis to reduce morbidity, hospitalizations, and the cost of care.

FROM: Rosenblum LS, Castro KG, Dooley S, and Mor-

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TABLE†
STATUS OF THE CHEMICAL STERILANT PRODUCTS IN THE EPA ANTIMICROBIAL EFFICACY TESTING PROGAM, FEBRUAY 1995

Product Name	lest Results	status
Cidex aqueous solution (70781)	Passed	On the market
Cidex Formula 7 (70784)	Passed	On the market
Cidex Plus 28 (707814)	Passed	On the market
Actril (52252-7)	Passed	On the market
Omnicide (46851-2)	Passed	On the market
Omnicide 14 (468514)	Passed	On the market
Spar-o-Syl (67539)	Passed	On the market
Renalin dialyzer reprocessor (52252-6)	Passed	On the market
Renalin (52252-5)	Passed	On the market
3M Glutarex (7182-4)	Failed	Canceled registration due to registrant's failure to pay maintenance fees. No longer on the market.
Warexin (61404)	Not tested	Registrant voluntarily canceled registration before EPA testing program began. No longer on the market.
Sonacide (8991-11)	Failed	Registrant voluntarily canceled registration. No longer on the market.
Sporicidin (8383-5)	Failed	Registrant voluntarily canceled registration. Enforcement action taken to remove from market.
Actril (soluble) (52252-3)	Not tested	Registrant voluntarily canceled registration. No longer on the market.
Sterx Cold Sterilant (52252-2)	Not tested	Registrant voluntarily canceled registration before EPA testing began. No longer on the market.
Coldcide 2 (551851)	Not tested	Not in production during EPA testing program. Registrant removed all sterilant claims. Currently marketed as a hospital disinfectant.
Steris 20 (587791) Steris 20-D (587792)	Not tested	Special chamber required to test-FDA to test Currently on the market.
Harvey's Vapo Steril (106481)	Not tested	Special chamber required to test-FDA to test Currently on the market.
Scopas Steril System (567961)	Not tested	Canceled registration due to registrants failure to pay maintenance fees. Not on the market.
Wipeout (58994-l)	Failed	Enforcement action taken to remove from market. Currently under stop sale order. Notice of intent to cancel issued and cancellation proceedings underway.
*Cetylcide G (3150-4)	Failed	EPA has accepted new data and label changes showing efficacy at 10 hours at 20°C. Currently on the market.
Bionox (465061)	Failed	Canceled registration due to nonpayment of maintenance fees. No longer on the market.
*Metricide activated dialdehyde (46781-1)	Failed	EPA accepted new data and label changes showing efficacy at 10 hours at 25°C. Currently on the market.
Metricide Plus 14 (46781-3)	Failed	Enforcement action taken to remove from market. Currently under stop sale order.
*Metricide Plus 30 (46781-4)	Failed	EPA accepted new data and label changes showing efficacy at 10 hours at 25°C. Currently on the market.
*Coldcide 10/Coldspor (551952)	Failed	EPA accepted new data and label changes deleting all sterilant claims. Currently marketed as a hospital disinfectant.
Minncare (52252-4)	Failed	Registrant removed all sterilant claims. Currently marketed as a hospital disinfectant.
Ucarcide 602 (10352-29)	Failed	Registrant voluntarily canceled registration. No longer on the market.
● Matricide 28 (46781-2)	Failed	EPA accepted new data and label changes showing efficacy at 10 hours at 25°C. Currently on the market.
Clidox-S (87148)	Failed	Restricted use to veterinary and animal research sites. Currently on the market.

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TABLE† (continued)
STATUS OF THE CHEMICAL STERILANT PRODUCTS TESTED IN THE EPA ANTIMICROBIAL EFFICACY TESTING PROGRAM, FEBRUARY 1995

Product Name	Test Results	status
Alcide Exspor (45631-3)	Failed	Restricted use to veterinary and animal research sites. Currently on the market.
Alcide ABQ (45631-6)	Failed	Restricted use to veterinary and animal research sites. Currently on the market.
Wavicide-01 (151361)	Failed	Enforcement action pending. Products remain on the market.
Wavicide-01 Concentrate (151362)	Failed	Enforcement action pending. Products remain on the market.

• EPA has allowed this failed sterilant back on the market because the registrant has reformulated the product, changed the use directions (time and temperature required for sterilization), increased the percentage of active ingredient, and retested the product. New data have been submitted to EPA by the registrant showing that the product is effective according to the new label. EPA carefully reviewed the new data and determined that the product is effective as stated on the label.
† From reference 2.

gan M. Effect of HIV infection and tuberculosis on hospitalizations and cost of care for young adults in the United States, 1985 to 1990. *Ann Intern Med* 1994;121:786-792.

Remarkable Discovery Has Implications for HIV Treatment

Until recently, HIV infection has been thought of as a gradual process in which the virus slowly invades the immune system. Findings from two recently published studies report that the virus and the immune system engage in a battle from the very beginning of infection.

Each day, millions of new HIV virus particles are produced and killed. But the immune system's losses also are staggering, with up to 1 billion infected T cells dying and being replaced each day. This battle continues with the immune system losing ground each day. These findings were reported in two independent studies by two leading AIDS researchers, Dr. David Ho, director of the Aaron Diamond AIDS Research Center in New York, and Dr. George Shaw, University of Alabama in Birmingham.

The major discovery is that the half-lie of the circulating virus and the cells producing the virus is only 2 days-not weeks or months, as previously thought. However, within 2 to 4 weeks, a new and drug-resistant strain of the virus takes over. One of the key factors behind the new findings was new drugs that stop the activity of HIV-enabling researchers to measure how fast the virus population declines and recovers. Dr. Shaw and his team studied 22 patients given three new drugs that block the activity of two viral enzymes required for viral replication. One drug, nevirapine (NVP), inhibits reverse transcriptase. The others, ABT-538 and L-735,524, inhibit the protein-cleaving enzyme the virus uses to manufacture protein coats for new virus particles. In the New York study, Dr. Ho and his team had similar results with the use of ABT-538 on 20 patients.

The two teams found that within two weeks, all the virus in a patient's body was resistant and that between 100 million and 1 billion new viruses were being produced each day. The continuous production of large amounts of infective viruses drives the rapid turnover of the immune system's susceptible T cells.

However, the investigators noticed that when they halted virus production with a drug, the immune system worked full throttle to produce new T cells, approximately 1 billion per day. It is believed that the HIV virus gradually gains ground, killing a few more T cells each day than are being replaced, causing a noticeable decline in T cells over time.

This new picture of HIV infection, the researchers note, suggests new strategies for dealing with the virus. The baffle between the immune system and the virus is so close that any drug that weakens the virus and gives the immune system an edge might be enough to tip the balance.

FROM Ho DD, Neumann AU, Perelson AS, et al. Rapid turnover of plasma virions and CD4 lymphocytes in HIV-1 infection. *Nature* 1995;373(6510):123-126. Wei X, Ghosh SK, Taylor ME, et al. Viral dynamics in human imnmnodeficiency virus type 1 infection. *Nature* 1995;373(6510):117-122. Kolata, G. New AIDS findings on why drugs fail. *New York Times* January 12, 1995.