Decontamination Alternative

To the Editor:

As a fellow nurse consultant, I've enjoyed listening to Ms Crow on the lecture circuit. In AMSCO's opinion, the "Product Commentary" (Vol 10:220-221) left much unsaid. Let me start by clearly stating that AMSCO makes both washer/sterilizers and washer/decontaminators. We believe that both can be effective decontamination methods when applied appropriately.

Ms Crow makes a strong point of the need for cleaning as part of a decontamination process. She also points out that protection of personnel should be a vital concern when selecting decontamination procedures. We whole-heartedly agree.

From an infection control viewpoint, it is essential to remember that the decontamination process consists of cleaning and the application of an effective biocidal process.[1] In the case of a washer/sterilizer, the biocidal process is steam sterilization, providing a sterility assurance level (SAL) approaching a 10^{-9} chance of a survivor. For the washer/decontaminator, the biocidal process may be exposure to hot water (180°F, minimum maintained) or that in combination with a short exposure to a chemical disinfectant. In AMSCO's equipment, we have set the SAL for the washer/decontaminator at about 10^{-4} possibility of a survivor. The generally accepted SAL for declaring an item sterile is 10^{-6}.

Ms Crow addresses only the flooding chamber type of washer/sterilizer in drawing her conclusions. Such units are usually found only in operating room suites where the machine may be used to decontaminate instruments immediately following use before soil has an opportunity to dry. Such units can be used in either the wash/sterilize mode or in the "flash" gravity displacement steam sterilization mode only.

Washer/sterilizers used in central processing departments and installed within the past 25 years are generally of another type. These employ rotating spray arms to create water jets as Ms Crow described for washer/decontaminators. Most units begin their cycle with a cool water rinse to remove gross debris without coagulating it. Then follows a wash cycle using a detergent of appropriate pH for contact with passivated stainless steel. The wash cycle concludes with a rinse and the machine then goes into a steam sterilization cycle at 285°F. This cycle produces clean, safe instrumentation, with no further need for manual or ultrasonic cleaning unless organic material was allowed to become encrusted on the instruments prior to processing, which will cause difficulty for any cleaning system. This can be prevented by following the Association for the Advancement of Medical Instrumentation (AAMI) recommended practice of keeping surgical instruments from becoming thoroughly dry prior to processing.[2]

By mid-1990, AMSCO washer/sterilizers of either type will have the capability of selecting the length of wash cycle, depending on the amount of soild present. Surgical instruments processed through such a system will easily meet both of Ms Crow's requirements (for cleaning and personnel safety) without manual cleaning.

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Vice President,
Education and Professional Relations
AMSCO, Erie, Pennsylvania

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2. Association for the Advancement of Medical Instrumentation. *Good Hospital Practice: Steam Sterilization and Sterility Assurance.* Arlington, Virginia; 1988.

Sue Crow, MSN, RN, CIC, was asked to respond to this letter.

I have had several companies inform me that they have washer/decontaminators on the market. That is certainly good to know. The primary characteristic the user must look for in purchasing such a product is that it does indeed clean-that it removes all organic material and does not bake on soil. The cheaper one can buy this mechanism the better. Most

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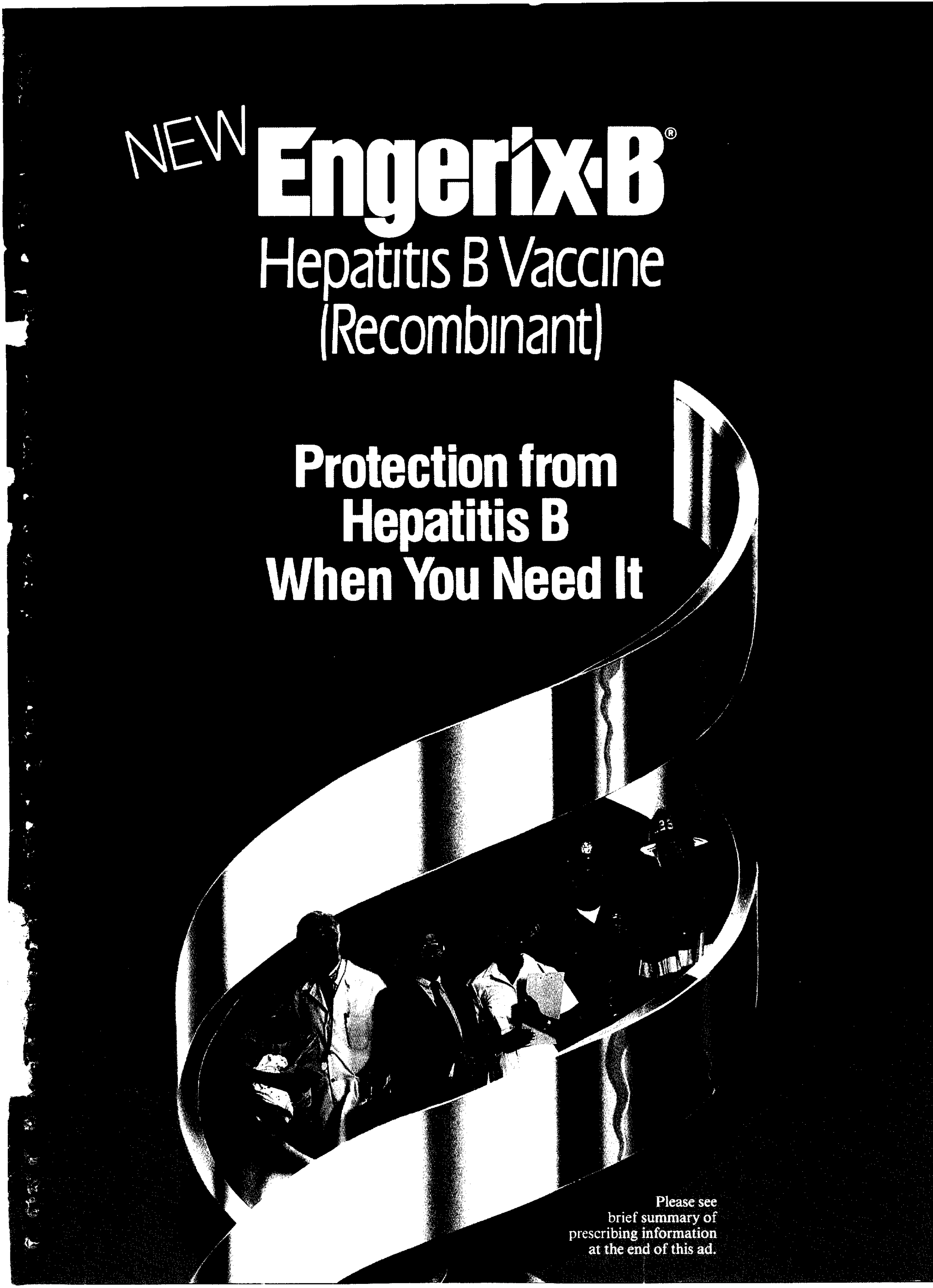

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New 0, 1, 2 Month Dosing Regimen for Certain Populations*

New 20 mcg Recombinant Dose

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Standard dosing regimen (0, 1 and 6 months)	Yes	Yes
New 0, 1, 2 month dosing regimen*‡ for certain populations	Yes	No
Published efficacy data: Neonates born of infected mothers'	Yes	Yes
VACTRAC™–computer software for vaccination tracking and compliance	Yes	No
Bar-coded, unit-dose vials	Yes	No
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†Hepatitis B Vaccine (Recombinant), MSD.
‡When prolonged maintenance of protective antibody titers is desired, a booster dose at month 12 is recommended.

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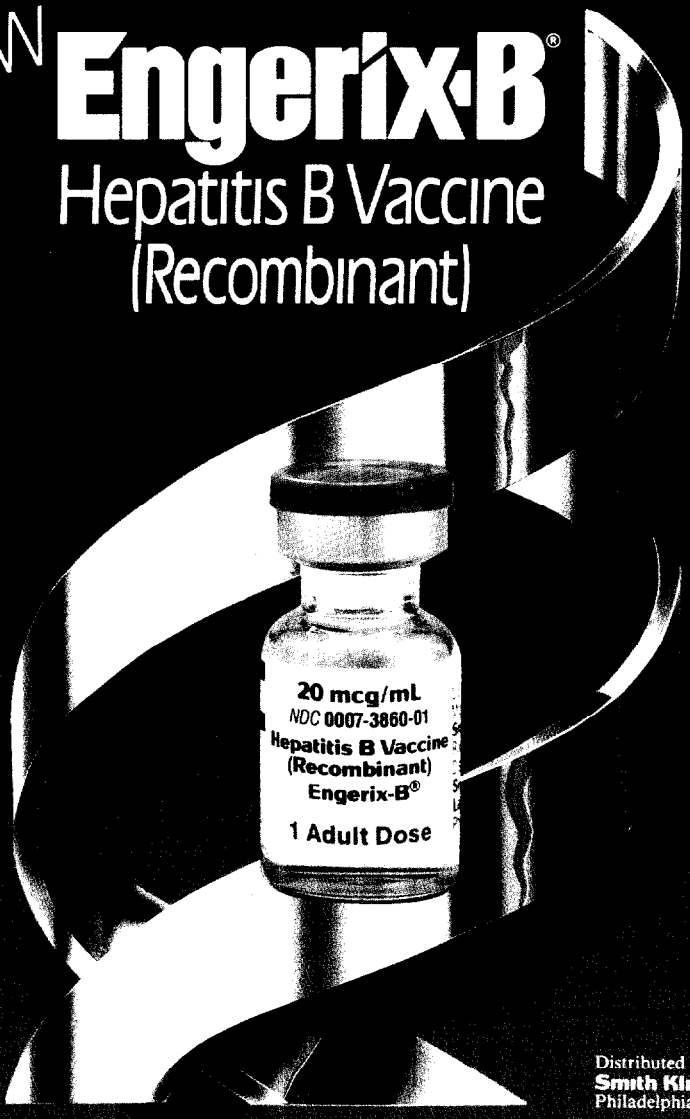

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*Please see brief summary of prescribing information at the end of this ad for a complete listing of adverse reactions, contraindications, warnings and precautions.

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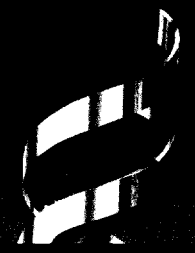

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See complete prescribing **information** in **SK&F literature or *PDR*. The following is a brief summary.**

INDICATIONS AND USAGE: 'Engerix-B' is indicated for immunization against infection caused by all known subtypes of hepatitis B virus Immunization is recommended in persons of all ages, especially those who are or will be, at Increased risk of exposure to hepatitis B virus.

CONTRAINDICATIONS: Hypersensitivity to yeast or any other component of the vaccine is a contraindication for use of the vaccine

WARNINGS: Do not give additional injections to patients experiencing hypersensitivity alter an 'Engerix-B' injection (See CONTRAINDICATIONS.)

Hepatitis B has a long incubation period Hepatitis B vaccination may not revent hepatitis B infection in individuals who had an unrecognized hepatitis 5 infection at the time of vaccme administration Additionally, it may not prevent infection in individuals who do not achieve protective antibody titers

PRECAUTIONS: General: As with any percutaneous vaccme. keep epinephrine available for use in case of anaphylaxis or anaphylactoid reaction

As with any vaccme, delay administration, if possible, in persons wdh any febrile illness or active infection.

Pregnancy: Pregnancy Category C Animal reproduction studies have not been conducted with 'Engerix-B'. It is also not known whether 'Engerix-B' can cause fetal harm when administered lo a pregnant woman or can affect reproduction capacity Give 'Engerix-B' to a pregnant woman only if clearly needed

Nursing Mothers: It is not known whether 'Engerix B' is excreted in human milk Because many drugs are excreted in human milk, use caution when giving 'Engerix-B' to a nursing woman

Pediatric **Use:** 'Engerix-B' has been shown to be well tolerated and highly immunogenic in infants and children of all ages Newborns also respond well maternally transferred antibodies do not interfere with the active immune response to the vaccme

ADVERSE REACTIONS: 'Engerix B' is generally well tolerated During clinical studies involving over 10,000 individuals distributed over all age groups. no serious adverse reactions attributable to vaccme administration were **reported** As with any vaccme, however, it is possible that expanded commercial use of the vaccme could reveal rare adverse reactions not observed in clinical studies

Ten double-blind studies involving 2.252 subjects showed no significant difference in the frequency or severity of adverse experiences between 'Engerix B' and plasma dewed vaccines In 36 clinical studies a total of 13.495 doses of 'Engerix B' were administered lo 5,071 healthy adults and children who were initially seronegative for hepabbs B markers, and healthy neonates. All subjects were monitored for 4 days post-administration Frequency of adverse experiences tended to decrease with successive doses of 'Engerix B' Using a symptom checklist,* the most frequently reported adverse reactions were injection site soreness (22%). and fatigue* (14%) Other reactions are listed below

Incidence 1% to 10% of Injections: Induration erythema; swelling; fever (> 37 5°C). headache'. dizziness.*

'Parent or guardian completed forms for children and neonates Neonatal checklist didnot include headache, fatigue or dizziness

Incidence < 1% of Injections: Pain; pruritus; ecchymosis; sweating; malaise; chills. weakness, flushing; tingling; hypolension; influenza like symptoms; upper respiratory tract illnesses nausea, anorexia; abdominal pain/cramps vomiting; constipation; diarrhea lymphadenopathy; pain/stiffness in arm, shoulder or neck arthralgia; myalgia; back pain; rash; urticaria petechiae; erylhema, somnolence, insomnia; irritability; agitation

Additional adverse experiences have been reported with the commercial use of 'Engerix B' outside the United Stales Those listed below are to serve as alerting information to physicians Anaphylaxis; erythema multiforme including Stevens Johnson syndrome, angioedema, arthritis; tachycardia/palpitations; bronchospasm including asthma like symptoms abnormal liver function tests, migraine; syncope; paresis; neuropathy including hypoesthesia, paresthesia, Guillain Barré syndrome and Bell's palsy, transverse myelitis; thrombocytopenia; eczema. purpura; herpes zoster vertigo; conjunctivitis; keratitis; visual disturbances

Potential Adverse *Experiences* In addition, certain other adverse experiences not observed with 'Engerix B' have been reported with Heptavax B* † and/or Recombivax HB® ‡ Those listed below are lo serve as alerting information lo physicians Optic neuritis

HOW SUPPLIED: 20 mcg/mL in Single-Dose Vials in packages of 1, 10 and 25 vials

NDC 0007-3860-01 (package 011)
NDC 0007 3860-11 (package of 10)
NDC 0007 3860 16 (package of 25)

10 mcg/0 5 mL in Single Oose Vials in packages of 1 vial

NDC 0007 3859 01 (package of 1)

† plasma-dewed. Hepatitis B Vaccine, MSD
‡ yeast derived, Hepatitis B Vaccine, MSD

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Date of issuance Aug. 1989

BRS—EB L6 EB901A

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1. Poovorawan Y, Sanpavat s, Pongpunlert W, et al: Protective efficacy of a recombinant DNA hepatitis B vaccine in neonates of HBe antigen-positive mothers. *JAMA* 1989; 261(22):3278-3281. 2. Based on published prices, August 1989.

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washer/decontaminators have a cleaning and a disinfection cycle. The user should decide what process or processes they want.

Let me address what appears to be your number one point and the one in which we differ. You believe that decontamination consists of cleaning and the application of an effective biocidal process. I hold to a more basic viewpoint that decontamination is simply physically removing the organisms.[1] When the microbes in the organic material have been physically removed, preferably by some washing mechanism, the microbes do not have to be disinfected because they are not there anymore; they went straight down the drain in the washing process.

You and I have had a professional difference of the definition of decontamination for years. We see the process from different perspectives. This seems logical because there is no scientific evidence to support either view.[2] At this point in time each person has to base his or her judgement on common sense.

Sue Crow, MSN, RN, CIC
Shreveport, Louisiana

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Prophylaxis for Caesarean Section: Where to Turn

To the Editor:

Cefotetan has often been recommended as prophylactic agent for women undergoing caesarean section[1] or vaginal[2] or abdominal[3] hysterectomy, and for therapy in established gynecologic infections.[4] For the last three years, cefotetan has been used in our hospital (a busy county hospital where approximately 50 caesarean sections per month are done) as the antibiotic of choice for prophylaxis in caesarean section. Recently, during a five-week period between May and June 1989, we experienced a series of seven infections among women undergoing caesarean section for term or post-term pregnancies, giving us a monthly infection rate of approximately 13%. All procedures were done urgently in the labor and delivery area of the hospital following skin prep with chlorhexidine gluconate. One patient received 2 grams of intravenously cefotetan two hours preoperatively, and four received initial doses of 1 to 2 grams of intravenously cefotetan intraoperatively. In two of the seven cases, the dosage of cefotetan prophylaxis used could not be documented. All seven patients developed clinically obvious postoperative wound infections within one week of surgery; three were also diagnosed as having chorioamnionitis or metritis.

Two patients, one with chorioamnionitis and one with metritis, received cefotetan as therapy postoperatively in spite of the fact that it had apparently failed as prophylaxis. The first patient received cefotetan plus a gentamicin-based regimen and recovered. The second received cefotetan alone for three days and was then switched to a gentamicin-based regimen ("triple" antibiotics) when she failed to respond.

All infections resolved without sequelae. The epidemic appeared to subside after substitution of cefoxitin as antimicrobial prophylaxis.

Unfortunately, bacterial cultures of infected sites were done in only three patients, and sensitivity testing to cefotetan was not done at all by the hospital microbiology laboratory. Factors other than microbial resistance to cefotetan, therefore, may have contributed to this outbreak. Still, cefotetan was a common factor in all these cases, and we feel that vigilance may be in order in hospital settings where cefotetan has been used intensively for prophylaxis in a specific group of patients. The possibility of nosocomial infection caused by resistant organisms should be kept in mind.

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Vickie S. Williams, DO
Texas Tech University

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