END OF THE LINE

By Daniel L. Prince, PhD

OSHA's Bloodborne Pathogen Rule

Infection control means minimizing the risk of becoming sick due to the exposure of infectious organisms in the healthcare workplace. Since Jarvis from the Centers for Disease Control (CDC) surveyed outbreaks of nosocomial infection, we have come to overly rely on disinfectants rather than practice a comprehensive program of infection control. How we came to this position is partially explained by a convergence of citizenry, regulatory, and marketing forces in response to a desire to be safe from germs. People worry about catching herpes from toilet seats and HIV-1 (AIDS) or human hepatitis B virus (HBV) from blood spills. Thus, the public demands that products used to clean and disinfect provide protection against these perceived risks.

The Environmental Protection Agency (EPA) is responsible for the regulation and registration of liquid chemical germicides used on inanimate environmental surfaces. EPA's policy only permits manufacturers to advertise claims for which there is product-specific, organism-specific proof that the product actually kills the germ intended. This policy works because it prevents guesswork. Published examples (Klein and Deforest, Tsiqaue, Eggers, and Sattar) demonstrate that a compound that kills one germ may not work against a closely related germ. For this reason, the EPA requires specific labeling. A product advertised to inactivate the AIDS virus contains specific language on HIV-1 virus but does not make any mention of HIV-2. The EPA policy has successfully allowed the registration of thousands of disinfectants with product-specific, organism-specific claims. This has allowed the EPA to take precise enforcement actions against companies making exaggerated or false claims.

However, the EPA ran into problems when it departed from its policy in the case of TB claims. This error was not exposed until the Occupational Health and Safety Administration (OSHA) promulgated a rule designed to protect healthcare workers from occupational exposure to bloodborne pathogens (see 29 CFR 1910.1030) in 1991. The EPA may still not appreciate the TB data gap that exists. EPA's error was to rely upon a surrogate organism, *bovis*, instead of the human strain *tuberculosis*. *M. bovis* primarily infects cows. However, agents that kill *M. bovis* cannot be depended upon to kill *M. tuberculosis* because the two organisms have different susceptibilities to liquid chemical germicides. The EPA had no persuasive scientific justification for its *Mycobacterium* surrogate policy. Inexplicably, the EPA and AOAC ignored Ortenzio's 1967 conclusion, which stated: "*Mycobacterium tuberculosis* var. *hominis* H 37 Ra [human tuberculosis] provides a greater challenge to the germicides [tested] than *Mycobacterium bovis* BCG...."

When OSHA published the bloodborne pathogen rule, it required employers to implement a program to minimize infection risks. One element was that the disinfectants used must be registered by the EPA and have specific efficacy claims against two critically important bloodborne pathogens—HIV-1 and human HBV. Because, at that time, there were no products registered against human HBV, OSHA adopted an interim policy that relied on disinfectants with claims against the cow TB surrogate to be also used as a surrogate to human HBV.

OSHA compliance policy was a second-choice policy relying on a surrogate organism without direct scientific support. This concern was recognized by healthcare practitioners. It is better not to rely on surrogates when actual experimental data is available. Thus, when EPA-registered specific primary (chimpanzee-tested) quaternary ammonium disinfectants effective against human HBV became available in 1996 (*i.e.*, Microgen's DISNFX-125™, EPA Registration #61178-1; Public Places®, EPA Registration #61178-2; and PDI Sani-Cloth HB®, EPA Registration #61178-4-9408), OSHA in 1997 revised its policy. Now these agents can officially be used as part of a program designed to comply with the bloodborne pathogen rule. OSHA's policy change was the first step in public policy-making that corrected the improper emphasis on tuberculocidal disinfectants as surface disinfectants.

EPA needs to understand that its surrogate *Mycobacterium* policy was a failure. EPA accepted *M. bovis* as a surrogate for *M. tuberculosis* without statistically controlled, side-by-side, validation testing to show that the organisms were equivalent to each other, and it ignored published data indicating that *M. tuberculosis* was more difficult to kill than the cow surrogate form. Since then, much EPA enforcement time has been spent on tuberculocidal claims that cannot be confirmed by independent testing. EPA should not repeat its mistake by being convinced by competitive interests that, in the case of human HBV, a surrogate once again, without comprehensive dose response, formulation specific, side-by-side testing with human HBV, is a valid substitute for product-specific, human HBV data. Disinfectants that do kill human HBV and HIV-1 (as per EPA) are now commercially available. The goals of FIFRA to promote competition and eliminate monopolies are being fulfilled and importantly the public health welfare is being served by products that have been proven to inactivate the human HBV and HIV-1 viruses.

Now large marketers of competitive products, unwilling or unable to actually test their products against human HBV, want to change the rules in a self-serving way. Their attempts to influence EPA put the entire infection control community at risk because they want EPA to switch from human HBV to yet another surrogate called duck HBV. As in the case of the cow tuberculosis surrogate, this is a bad idea for the following reasons: As published by Tsiquae, duck HBV is easier to kill than human HBV. These two viruses are different viruses. People don't catch DHBV. If we were to rely on DHBV, we would have to admit that our healthcare policies are not supported by direct scientific proof but are based on guesswork.

Who is liable and who is insured from a workman's compensation standpoint if a DHBV claim is wrongly relied upon and human HBV infection arises? We should not put the interest of anti-competitive producers of technical grade activities and inerts ahead of the public's need for reliable disinfectants. The EPA should not knuckle under to lobbying. Let the EPA know what you think regarding their surrogate DHBV policy. Contact Carol Browner, Administrator, US Environmental Protection Agency, 401 M Street SW (W1200), Washington, DC 20046, or E-mail: browner.carol@epamail.epa.gov

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