Antimicrobial Medical Garb Considered by FDA

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GAITHERSBURG, MD. — Clinical data would be needed to back manufacturers' claims that medical and surgical gowns, gloves, and masks containing antimicrobial agents prevent infections, when these types of products are reviewed for approval, according to a federal advisory panel.

The Food and Drug Administration's General Hospital and Personal Use Devices Advisory Panel met in May to address the scientific and clinical concerns, related to the safety and performance of these devices, that would be raised by the addition of antimicrobial agents. Other than two surgical gowns that became available almost 30 years ago, no such products have been cleared by the FDA, but there may be some interest in developing and marketing these types of products in the United States, according to the agency.

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DR. EDMISTON JR.

Devices incorporating antimicrobial agents that have been cleared by the FDA include intravascular, urinary, and ventricular catheters, which are associated with device-related infections, and wound care products.

The panel agreed that in vitro data would be adequate to allow a manufacturer to claim that personal protective equipment—surgical and isolation gowns, examination gloves, surgical gloves and masks, and N95 respirators—reduces or prevents contamination. But clinical data should also be required to justify any claim that such devices reduce or prevent colonization of bacteria in health care workers or patients, the panel said.

"The onus will be on industry" to provide data for claims regarding clinical benefits attributed to personal protective equipment, said Charles Edmiston Jr., Ph.D., professor of surgery and hospital epidemiologist, at the Medical College of Wisconsin, Milwaukee. For example, he said, a company could claim that the addition of antimicrobial agents to a new surgical gown eliminated contamination by vancomycin-resistant enterococci, methicillin-resistant *Staphylococcus aureus*, or other pathogens from the surface of the gown, if in vitro data were provided to support this indication. But the bar would be raised if, say, a company stated that adding antimicrobial agents to the gown would reduce the risks of nosocomial infections within an ICU patient population. Clinical data would be needed to validate such a statement, he added.

Panelist Dr. James Gordon, of a practice in West Bloomfield, Mich., that specializes in infection care, said that his hospital system would probably not use any of these devices unless they were associated with improved clinical outcomes.

The panel also agreed that the testing of such products would have to include both wet and dry states, which would cover a situation representing contact in body cavities or with blood and body fluids; and should include a variety of clinically relevant organisms. Products would also need to be tested for time periods ranging from a few minutes, which would represent a scenario of a health care worker entering an isolation room, to several hours, which could represent the amount of time such a device is used during a surgical procedure.

Safety concerns for such products could include whether the antimicrobial substance that was impregnated into a product leaches off, whether allergic reactions occur, and whether masks cause problems when worn by health care workers with lung diseases like COPD or emphysema. The safety of pediatric, neonatal, and immunocompromised patients, as well as women of child-bearing age, would also need to be evaluated, the panel said.

Another consideration would be whether inhaling subinhibitory levels of antibiotics through a mask could promote resistance, and whether "intimate contact with the nasopharynges with these masks could possibly create an environment where resistant organisms could develop," Dr. Edmiston said. ■