Novel antibacterial and protective formulations and their use

Background
Gram-negative bacteria cause serious and severe wound or surgical site infections, bloodstream infections, and respiratory infections. Gram-positive organisms are reported to display highly variable growth and resistance patterns. Some examples of hazards caused by gram-positive bacteria include pneumonia, bacteremia, toxic shock syndrome, and respiratory, skin, and wound infections.

The problem
According to the information published by CDC, gram-negative bacteria show multi-drug resistance, are increasingly resistant to most available antibiotics, and can pass along genetic materials that allow other bacteria to become drug resistant as well. Various Gram-positive bacteria that cause serious healthcare and community-associated infections are resistant to current treatments.

SDSU Solution
The Rohwer Lab is developing compositions and methods for the delivery of non-naturally occurring combinations of microbes such as bacteriophages or prophages using milk/milk fat globules (MFG)/other milk component(s) that the phages adhere to. Phages that are toxic or lysogenic to bacteria of interest / are bactericidal or bacteriostatic are screened, selected, and purified. The phage preparations include pharmaceutically acceptable components. This phage therapy technology has the potential to modify milk phage population and be employed as a competitive agent against pathogens and a prophylactic in the gut.

Value proposition
The innovative mixture of bacteriophages or prophages can treat, inhibit, or prevent infections caused by a multitude of gram-negative or gram-positive bacteria. These can include Methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium* (e.g., *Clostridium difficile*), *Escherichia coli*, *Shigella*, *Salmonella*, *Campylobacter*, *Cholerae*, *Bacillus*, or *Yersinia*. The method can comprise an antibiotic; probiotic bacteria (certain species of *Bacillus*, *Lactobacillus* and *Saccharomyces*), a prebiotic (nondigestible oligosaccharide), a postbiotic, or a synbiotic. The method can be employed in the context of a probiotic, a prebiotic, a postbiotic or a synbiotic for increasing or decreasing various parameters (e.g., effective dose; efficacy of attachment to mucosal surfaces; access to mucosal surfaces; increasing or decreasing chance of an enteral or gastrointestinal pathogenic infection or disease; or resistance to various conditions [temperature, pH, mechanical stress, osmotic stress and/or gastrointestinal enzymes]).

Applications
Treatment, amelioration, and prevention of various infections/disorders - The mixture of bacteriophages or prophages can be incorporated into a food or a feed, a drink (milk, milk product, milk component or milk isolate or a cream), a nutraceutical, a formulation, a pharmaceutical or a pharmaceutical preparation/product form for administration via various routes. The applications include:
- Infant formula or infant dietary supplement
- Veterinary formulation or feed
- Delayed or gradual enteric release composition or formulation

**Stage of Development**
Studies have been completed on the choice of microorganisms, bacteriophages or prophages and formulation components.

**Intellectual Property**
An issued US patent (11,260,089) and a pending US Continuation application (17/541,063).

**Contact information:** San Diego State University

Forest Rohwer, Ph.D.  
Professor, Biology  
Department of Biology

Tommy Martindale  
Director  
Technology Transfer Office  
(619) 594-0791  
tmartindale@sdsu.edu