

## Overview:

Bacteriophage therapy, or phage therapy, is a treatment for bacterial infections distinct from antibiotics. It is increasingly important as antibiotic resistance becomes a growing problem, killing around 50,000 Americans each year. It relies on bacteriophages (phages), or viruses that kill only a narrow range of bacteria but are harmless to others and to humans. Phage therapy is not widely used because the current regulatory regime requires expensive drug approvals for each individual phage, but the combinations of phages used require continual updating to prevent resistance from developing. Complicating efforts to finance this development, phages are not eligible for patent protection as they are naturally occurring. A regulatory regime specific to phage therapy is needed if it is to become a viable treatment.

## Intellectual Property Rights:

1. Patent protection is not available, but market exclusivity for a limited time is feasible.
2. Plant Variety Protection, overseen by the USDA's Agricultural Marketing Service, provides 20 years of market exclusivity for new, distinct, uniform, and stable varieties of plants. Protection is granted to about 400 new plant varieties each year.
3. A similar approach for phages, including those newly discovered as opposed to invented, provides a needed incentive for pharmaceutical companies to invest in phage therapy research.

## Regulatory Approval:

1. As is the case for the current influenza vaccine, de novo regulatory approval for each new phage should not be required. This will make phage therapies evolutionary stable by allowing continual updating with phages not presently in use.
2. Regulation should center on safety as opposed to efficacy. Basic purity and manufacturing standards should grant "safe harbor" to manufacturers of phage therapies.

## Information Repositories:

1. To prevent bacteria from developing resistance, new phages must be discovered and known phages must be rotated in and out of use.
2. Repositories of information about use and efficacy are needed and may be run privately or by the government.
3. Reporting the use of a phage therapy treatment should be mandatory and should include the target bacteria and outcome. Only when such knowledge is available can informed decisions about treatments be made.

4. Provided doctors have the necessary information about use and efficacy, they should make treatment decisions without oversight from the information repository.