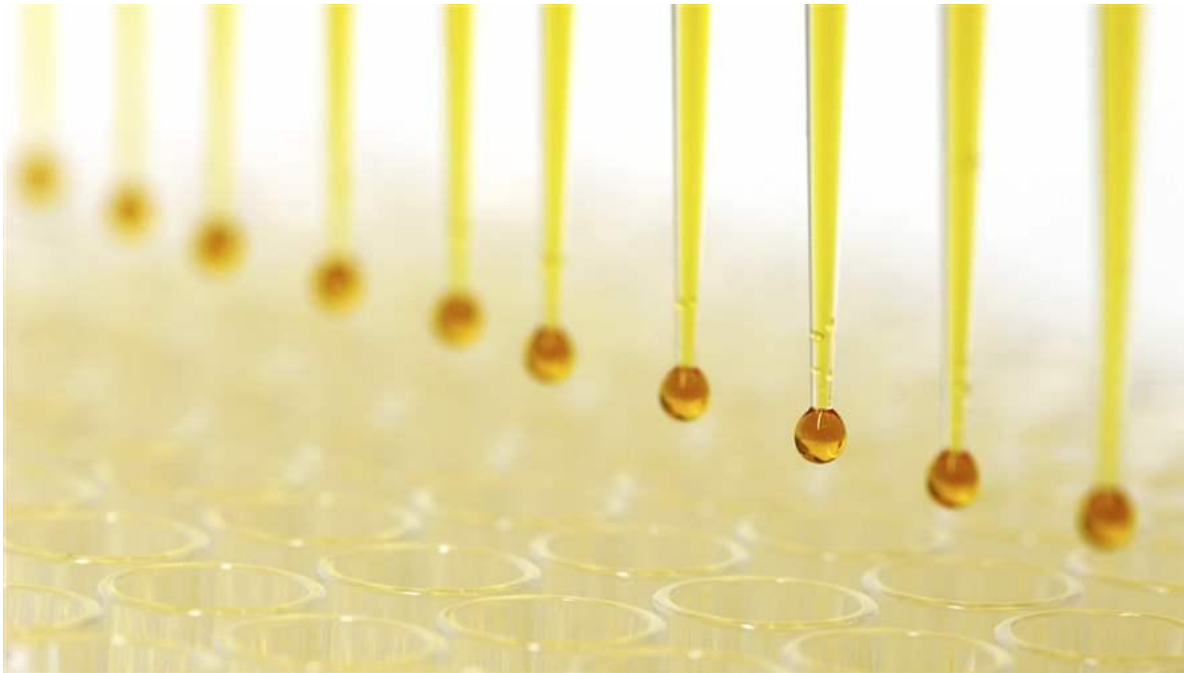


Assessment of Nontraditional Products in Development to Combat Bacterial Infections

Because the conventional antibiotics pipeline remains so thin, finding new approaches is critical

December 20, 2017, [Antibiotic Resistance Project](#)

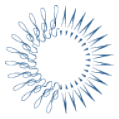


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While antibiotic innovation—finding and designing [new types of antibiotics and improving existing drugs](#)—remains essential to combating antibiotic resistance, “[outside-the-box](#)” approaches to preventing and treating bacterial infections are also needed. Such nontraditional approaches encompass a variety of products, including:

- Well-known medical interventions, such as vaccines and immunotherapies, that have been proved effective in treating other types of disease and may also hold promise for the prevention or treatment of systemic (throughout the body) bacterial infections.
- Entirely new types of therapies that have never been approved for use in human medicine. For example, products that disarm harmful pathogens to neutralize their threat to patients, or products that replace harmful bacteria with “healthy” bacteria to alleviate disease.

Nontraditional products are unlikely to fully substitute or replace antibiotic use but could provide new treatment options for patients through combined use with antibiotics or as a means of preventing an



infection from taking hold. Questions remain regarding how nontraditional products should be tested for safety and efficacy, and how they could be used appropriately in the clinical setting.

To shed light on the development of these types of products and evaluate public policies to spur innovation, The Pew Charitable Trusts assessed nontraditional products for the treatment of systemic bacterial infection in clinical testing. The list, which will be updated regularly, identifies each product and its manufacturer, type of approach, potential targets, and stage in the clinical development process. The list does not include products that are in development but not yet being tested in humans. (See the methodology below for the criteria used to select the nontraditional products.)

Findings

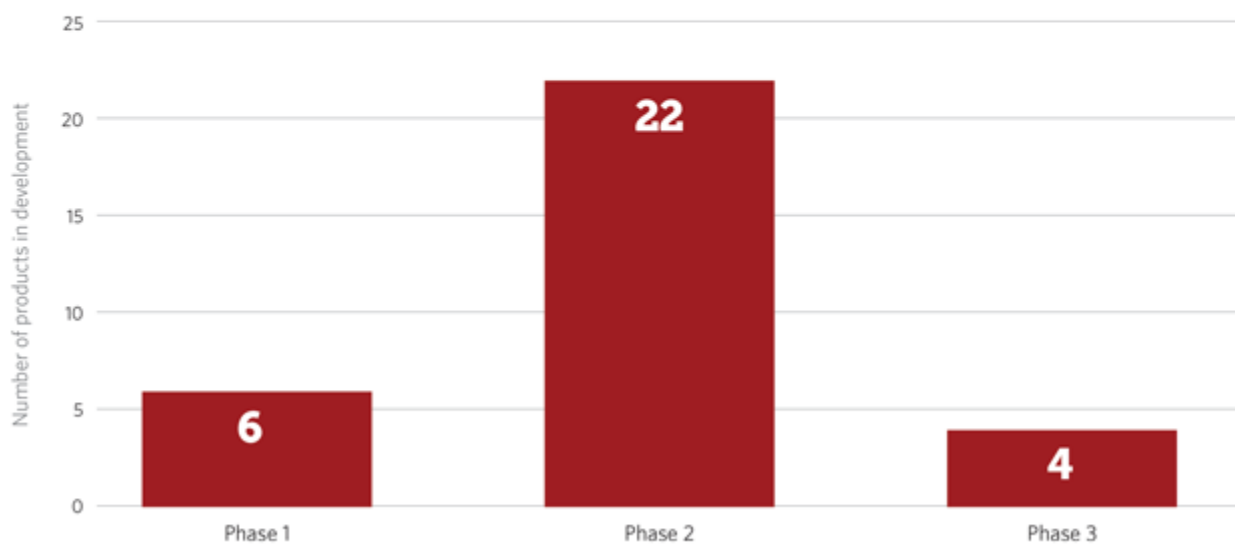
The [current assessment of the pipeline](#) shows that 32 nontraditional products are in clinical development. Unlike many [antibiotics in development](#), most nontraditional products are active against a limited range of pathogens. As of September 2017:

- Of the 32 nontraditional products in development, six were in Phase 1 clinical trials, 22 were in Phase 2 clinical trials, and four were in Phase 3 clinical trials. (See the [glossary of terms](#) for descriptions of each phase.)

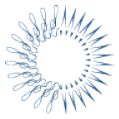
Figure 1

32 Nontraditional Products in Development to Treat or Prevent Bacterial Infections

New approaches to fighting antibiotic-resistant bacteria are essential, but few have reached advanced phases of clinical testing



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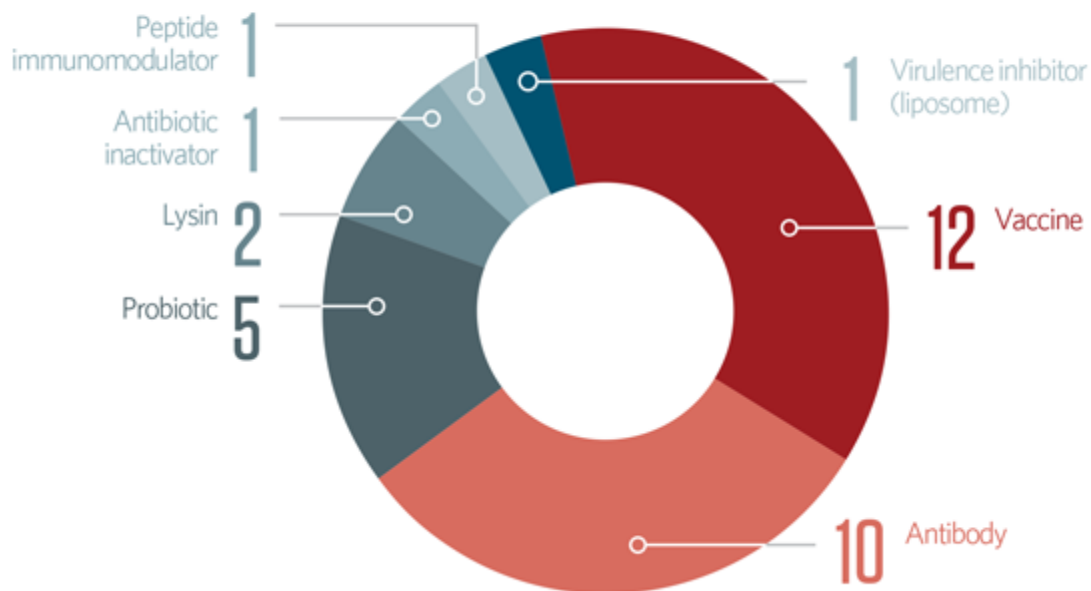


- Over a third of the nontraditional products in development are vaccines, and almost a third are antibodies. The remaining 10 products include lysins, probiotics, and peptide immunomodulators.

Figure 2

Majority of Nontraditional Products in Development are Vaccines and Antibodies

Other products include entirely new types of therapies that have never before been approved for use in human medicine



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- Over half of the nontraditional products in development are for the treatment of *Clostridium difficile* (an organism associated with serious, sometimes life-threatening diarrhea) or *Staphylococcus aureus* (associated with skin and a variety of systemic infections).
- A third of the nontraditional products in development are being pursued by firms in the top 50 pharmaceutical companies by sales revenue. These firms are primarily developing vaccines.

Harnessing the promise of nontraditional products requires focused attention from a broad range of stakeholders, including scientists, clinicians, funders, and regulators to support:

- Targeted research and development to evaluate whether a given nontraditional approach is effective.
- Demonstrated improvement over antibiotic treatment alone.
- Establishment of regulatory guidelines for approval of innovative products.