moved out of the country and forgot to take the medications. Per protocol analysis was also conducted, and this PP analysis mandated further exclusions. For PP analysis, the above five patients were excluded, and an additional six patients were excluded (five were lost to follow-up and one discontinued therapy after one day because of side effects).

Helicobacter is a bacterium that has acquired notoriety for being a cause of stomach ulcers. The standard test for *Helicobacter* infections, which is a breath test, occasionally provides false positive results (60,61,62,63,64). After conducting the breath test, false positives from the breath test generally can be detected by using a bacterial culture test.

d. Excluding subjects who failed to meet inclusion or exclusion criteria – the Weigelt study

In a study of soft tissue infections, Weigelt et al. (65) analyzed efficacy by ITT analysis as well as by modified ITT analysis. The ITT population included all randomized patients who received one or more doses of study medication. But the modified ITT population included only ITT patients who had a culture-confirmed Gram-positive pathogen at baseline. The basis for this modified ITT group was that the inclusion criteria required only that a Gram-positive infection be "presumed," and did not require the availability of actual laboratory data for enrollment in the clinical trial. Of the patients completing the study, the ITT group consisted of 930 patients, while the modified ITT group consisted of 664 patients. By "patients completing the study," what is meant is the number of patients evaluated seven days after drug treatment was completed. This demonstrates that the percentage of patients in failing to have a confirmed Gram-positive bacterial infection was significant and dramatic.

e. Excluding subjects who failed to meet inclusion or exclusion criteria – the Pinchichero study

In a study of bacterial infections treated with antibiotics, Pichichero et al. (66) patients were screened for *Streptococcus pyogenes* by way of a rapid test (immunoassay), where a

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