Pharmaceutical quality is an area where Hatch-Waxman Amendments have had a favorable impact on the development of both brand and generic products.
The notion and availability of generics has brought about a public interest in and public discourse of pharmaceutical product quality. Questions include:

• Who, where, and how is medication made?
• What non-drug ingredients go into the medication and what is their impact?
• What quality control tests are used and what do they assure?
• What is the bioequivalence standard and is it good?
• Is it the same product made last month?
• Is the drug a narrow therapeutic index drug?
Common Excipients with No Impact on Bioequivalence

- Sodium Lauryl Sulfate
- Corn Starch
- Sodium Starch Glycolate
- Colloidal Silicon Dioxide
- Dibasic Calcium Phosphate
- Crospovidone
- Lactose
- Povidone
- Stearic Acid
- Pregelatinized Starch
- Croscarmellose Sodium
- Magnesium Stearate

Average profiles

Cmax 90% CI: (98.8%, 104.5%) with mean ratio = 101.6%
AUC 90% CI: (97.2%, 101.6%) with mean ratio = 99.4%
Cmin 90% CI: (93.4%, 101.0%) with mean ratio = 97.1%

Summary

• Hatch-Waxman Amendments have had a favorable impact on the development of both brand and generic products through public interest in and public discourse of pharmaceutical product quality.