similar" requirement, which dictated that generic macromolecules could have minor differences in the inactive components, so long as there were no clinically meaningful differences between the "branded" and "generic" versions in terms of safety, purity, and potency. Clinically, the "branded" and "generic" versions were also required to be interchangeable clinically without the aid of a health care provider and with no added safety risk upon switching between the two.

This legislation and similar laws in place across the globe will likely have a major impact on the pharmaceuticals industry. Most of the major pharmaceutical companies have shifted significant resources away from small molecules and into biologics in an attempt to maintain the high profit margins expected from drug companies, but generic companies are also entering the market. In July of 2010, the FDA approved its first generic biologic drug, a biosimilar to Lovenox® (enoxaparin sodium), the blockbuster blood-thinning drug originally brought to market by Sanofi-Aventis. It is likely additional biosimilars will be brought to market as the patent estates created in the biotech revolution come to the end of their enforcement period.

FUTURE DEVELOPMENTS IN DRUG DISCOVERY

The drug discovery process has changed significantly since the first experiments of Paul Ehrlich launched the science at the beginning of the twentieth century. Growth of the field has marched forward with advances in scientific understanding in the areas of biology, pharmacology, chemistry, and computer sciences, and it is likely that this will continue. The pace of innovation will likely quicken over time, as the technological tools currently in place allow for a far more rapid acquisition of scientific data than ever before. Where this will lead, however, is somewhat unpredictable, as the number of unanswered questions in the field of drug discovery is enormous. There is, however, some degree of certainty that the regulatory aspects of drug discovery will continue to grow with the field, although slightly out of phase with the field itself. It is, after all, difficult to create regulatory guidelines for new therapies that have as yet to be discovered.

QUESTIONS

1. Paul Ehrlich is known as the father of modern drug discovery. Between 1872 and 1874 he noted the selective affinity of dyes Trypan red, Trypan blue, and Methylene blue for biological tissues. What hypothesis did he develop based on these observations?
2. What is the significance of the Wistar rat?
3. What are SCID mice, why are they important, and how are they different from nude mice?