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Pharmaceuticals and the Economics of Innovation

Comprehension Questions

Indicate whether the statement is true or false, and justify your answer. Be sure to cite evidence from the chapter and state any additional assumptions you may need.

1. In the U.S., drug companies receive a patent of 100 years for each drug they develop. This allows them a prolonged legal monopoly on the sale of that drug.

   FALSE. Drug companies receive a patent of 17 years for each new drug that is deemed an original innovation. This does allow a prolonged legal monopoly.

2. Phase III clinical trials are a minor part of the drug development process in the United States.

   FALSE. Phase III trials, which feature many human subjects, can take years and cost tens of millions of dollars. This is the phase where the drug company generates the data it hopes to use to get its drug approved by regulatory agencies like the FDA.

3. If a government wishes to maximize the rate of pharmaceutical innovation, it should offer non-expiring patents to drug companies.

   FALSE. Horowitz and Lai (1996) and Gallini (2002) argue that very strong

patent protections can actually decrease the overall level of innovation by discouraging established drug companies to make new products and deterring subsequent innovation by other companies.

4. Price controls decrease the innovation rate for drugs but make existing drugs more affordable.

   TRUE. This is the major tradeoff to consider when deciding whether to institute price controls.

5. The U.S. government has harnessed the power of induced innovation to create cures for orphan diseases.

   TRUE. When the U.S. government passed the Orphan Drug Act in 1983, innovation in that sector increased rapidly. This is an example of induced innovation because drug companies responded to tax incentives.

6. Most economists think that innovation is *not* random, and that pharmaceutical companies can steer their research toward profit opportunities.

   TRUE. This is the basis for induced innovation. Acemoglu and Linn (2004) and Finkelstein (2004) find amply evidence of induced innovation in American pharmaceutical markets.

7. After passage of the Kefauver-Harris Amendment in 1962, the number of new chemical entities introduced into the U.S. market by pharmaceutical companies dropped substantially.

   TRUE. This is the evidence found by Peltzman (1973). After the amendment, it became much more expensive to bring drugs to market because companies had to demonstrate their offers were both safe and effective.

8. The Food and Drug Administration (FDA) decides whether to approve a drug for use in the U.S. based in part on whether each drug is cost-effective in the treatment of some disease.

   FALSE. The FDA does not consider cost-effectiveness; drugs must be shown to be safe and effective at treating a certain condition.

9. Phase II drug trials are conducted on animals, while Phase III drug trials are conducted on healthy volunteers. Both are required for FDA approval.

   FALSE. Animal testing typically happens before Phase I trials, which feature healthy volunteers.

10. The approval of Vioxx, a painkiller that was taken off the market in 2004 because it was implicated in several cardiac arrests, is an example of Type I error by the Food and Drug Administration.

    TRUE. The approval of Vioxx is an example of an undesirable drug being approved.