Experiment #2: McCain-Schumer Legislation

In this experiment, your job is to determine the amount of lobbying expenditures to undertake in influencing legislation on rules regarding the introduction of generic drugs. The current law in place, the Hatch-Waxman Act, is thought by some to tilt too strongly toward branded pharmaceuticals. Senators McCain and Schumer have introduced legislation liberalizing the rules for the introduction of generic substitutes for patented drugs. See the attached background document for some details of this legislation. See also the following background site (http://www.cptech.org/ip/health/generic/hw.html).

You will be playing either the role of Pharma, a consortium of branded pharmaceuticals companies, or GPhA, a consortium of generic manufacturers.

Here's the situation: It is estimated that the passage of McCain-Schumer will cost Pharma a net present value of $40 million in lost profits if put into place. These lost profits arise mainly from the anticipation that the act will cut short the period of monopoly profits on most "blockbuster" drugs, which are the main source of profitability for Pharma companies. At the same time, generic profits are estimated to increase (in net present value terms) by $30 million with the passage of the legislation. The gains for these companies are smaller owing to the fact that the introduction of generic substitutes is not nearly as profitable owing to competition with the branded substitute as well as from competition by "pseudogenerics", drugs identical to the branded drug, but introduced with a generic label by Pharma companies.

We will abstract away from the possibility of amendments and the like to McCain-Schumer and suppose that this legislation will either pass or it won't. We will also suppose that once passed (or defeated), the legislative environment will remain unchanged for the foreseeable future. Relative expenditures on lobbying efforts are critical in affecting the probability that the legislation passes. Your job is to determine how much in lobbying expenditures to undertake.

Both sides are extremely secretive in their lobbying activities; therefore, you will not know how much the other side has expended on lobbying at the time you make your decision on how much to spend. We will assume that the probability of passage depends purely on the relative expenditures made by both sides. Specifically, if GPhA expends *$x* and Pharma expends *$y* in lobbying, then the probability of passage is estimated to be $x/(x + y)$.

As usual, in making your lobbying decision, your goal is to maximize the profits of your group. Your profits are determined as follows:

If you do not receive favorable legislation, then your losses are the amount of your lobbying expenditures.

If you receive favorable legislation, then you earn $40 million less lobbying expenditures if Pharma and $30 million less lobbying expenditures if GPhA.

After meeting with others in your group and conferring on the appropriate level of lobbying to undertake, please fill out the attached lobbying authorization form indicating the amount you wish to spend on this activity. You will then be randomly matched with a group representing the other side and your expected profits will be determined.

A variation: Suppose Pharma makes its expenditures first and these are known to GPhA. Replay the lobbying experiment.

Lobbying Authorization Form

Group represented (circle one) Pharma GPhA

Lobbying expenditures authorized (in $ million) _____

Team name::

Group represented (circle one) Pharma GPhA

Lobbying expenditures authorized (in $ million) _____

Team name:

Problem Set 2

Note, for questions 1 and 2, you can either use graphs, excel spreadsheets or calculus to "show" the desired result. Calculus will turn out to be easiest. Here's an application that will do all the calculations for you if you plug in the right stuff to try to optimize: http://www.calc101.com/webMathematica/derivatives.jsp#topdoit

Suppose that the benefits to Pharma are only $30 million and the benefits to GPhA are only $10 million in answering these discussion questions.

1. Suppose that Pharma projects that GPhA will spend $1.875 million on lobbying, show that the best strategy for Pharma is to spend triple this amount, $5.625 million.
2. Suppose that GPhA anticipates that Pharma will spend $5.625 million on lobbying, show that the best strategy for GPhA is to spend $1.875 million.
3. Using the concept of Nash equilibrium, explain how the combination of GPhA spending $1.875mm and Pharma spending $5.625mm constitutes an equilibrium.
4. What are Pharma's and GPhA's expected profits under this equilibrium?
5. Suppose that Pharma makes its expenditures first but keeps these expenditures a secret. How does this affect the analysis?
6. Suppose that Pharma makes its expenditures first and publicizes them. Show that if Pharma spends $10 million or more, the best response of GPhA is to give up immediately and not lobby at all.
7. Show that Pharma prefers to "change the game" by moving first and disclosing its expenditures rather than keeping them secret.

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MCCAIN, SCHUMER UNVEIL NEW GENERIC DRUG LEGISLATION

-Bill Will Encourage Competition in the Pharmaceutical Marketplace By Leveling Playing Field for Generic Drug Makers-

Senators Charles E. Schumer (D-NY) and John McCain (R-AZ) today stood with leaders from the insurance industry and consumer groups to introduce comprehensive bipartisan legislation to help bring lower-cost prescription drugs to the marketplace. The Greater Access to Affordable Pharmaceuticals Act (GAAP) will allow generic drug companies to compete with brand name manufacturers by clearing the major obstacles that delay generic drug approval.

"The 1984 Hatch-Waxman Act was a critical consumer law because it allowed generic drugs to get on the market, but over the years the lawyers have picked the law clean," said Schumer. "Schumer-McCain restores the original purpose of the law. It's not a freebie for generic drug makers – it simply levels the playing field so they can offer consumers a choice at the counter.

"Affordable medicine is a serious economic problem for millions of Americans but it is too often a financially devastating problem for millions of seniors who do not have drug coverage through the Medicare system," said McCain. "Our bill will help all Americans have access to lower priced prescription drugs by creating a stronger and more competitive marketplace."

The 1984 Hatch-Waxman Act was designed to promote the growth of a generic drug industry, but the full potential of the legislation was never realized because of loopholes in the patent laws that allow brand-name drug manufacturers to keep generic competitors out of the marketplace. These abuses have resulted in monopolies for the brand-name manufacturers – and soaring prescription drugs prices.

Under the Schumer-McCain legislation:

The number of patents that a generic drug company must address for FDA approval would be limited to two – the drug substance patent and the method of use patent. This will dramatically streamline the approval process for generic drugs because current law requires generic drug makers to address every relevant brand name patent in the FDA's registry. This list includes patents on formulation, dosage and non-essential features such as size, shape, the types of containers and tablet scoring.

If the first generic drug maker to file and challenge a brand name's patent reaches an agreement with the brand-name manufacturer to stay off the market, that company's 180-day market exclusivity would roll over to the next applicant. This roll-over would also apply if the first generic drug maker fails to go to market once their application is effective or loses in patent-challenge litigation.

Only citizen petitions that present specific and substantial scientific evidence that the approval of a generic drug poses a significant threat to public health and safety would delay that drug's approval.

The discrepancy between the FDA's regulations and statutes on bioequivalence testing methods will be eliminated. The current difference between the regulations and the law dissuades generic drug makers from challenging brand-name companies on drugs that require alternate forms of testing.

Schumer and McCain said that if generic drugs are able to come to market as soon as brand-name patents expire, consumers could save upwards of $71 billion on prescription drugs over the next 10 years. According to industry estimates, by the third year a generic alternative is on the market, consumers save, on average, 60% when they choose the generic over the name brand. For example, instead of purchasing a prescription of Prilosec, a widely-used ulcer medication, for $134.69, a consumer could get a generic alternative for only $52.53. Instead of buying a prescription of Zocor, a popular cholesterol medication, for $115.83, a consumer could buy a generic prescription for only $45.14.
"Over the years, there have been many prescriptions offered to make health care more affordable for working families. Most have broken down over partisan or ideological lines and we have not made much progress," said Schumer. "We are accomplishing these monumental savings not by redrawing ideological battle lines, but by restoring the intent of our patent laws."

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