Ethics case considerations:
1. perspective (patient, caregiver, etc.)
2. beneficence
3. nonmaleficence
4. autonomy
5. justice
6. virtue
7. issues of law
8. root cause
9. clinical

Case #1: Direct-to-Consumer Pharmaceutical Ads

Direct-to-consumer (DTC) advertising of prescription drug products really began in the early 1980s, and after some Food and Drug Administration (FDA) second thoughts about these ads being able to provide balanced benefit/risk information, began in earnest in 1985. At that time, the FDA became more comfortable with the ability of “brief summaries” accompanying print advertisements and limited reminder (mention brand but not conditions) or directive (mention conditions but not brand) information broadcast ads to provide sufficient balance. Then in 1997, the FDA further explained that shorter benefit/risk summaries would be acceptable in broadcast advertisements, directing consumers to more complete summaries available elsewhere.

While regulators continue to study the impact of DTC advertising, some have argued that such information provision facilitates consumer-doctor discussions about treatment options. Others have argued that DTC advertising has merely accelerated the costs of prescription drugs, with little or no resulting health benefits. Central to this controversy is the point that an informational imbalance can result in a significant ethical breach, potentially overstating the benefits while understating the risks of some advertised prescription drugs. Is it ethical for the pharmaceutical industry to market directly to consumers in the manner described above?


Case #2: Double-Effect of New Drug

Suppose that researchers at a pharmaceutical company discover a way to produce a drug that treats headaches. The drug costs much more to produce than ibuprofen and aspirin, so marketing it would not be profitable except that the drug would cause a quick and painless death for people who recently have undergone chemotherapy. The company predicts that if it markets the drug as a cure for headaches, a few cancer patients who have undergone chemotherapy and who wish to end their lives quickly and painlessly would realize that they could use the drugs to commit suicide. The company also predicts that news of those people’s deaths would spread to people in similar situations, who also would buy the drug. Therefore, the company predicts that it could earn a profit by marketing the drug. May the company market the drug?


Case #3: Profits vs. Service Quality at Community Pharmacies

John owns and runs community pharmacy in a suburban town of approximately 80,000 people. He has always taken great pride in the time and effort he dedicates to counseling patients and building relationships with the community. In recent years his pharmacy has been particularly busy, forcing John to reduce the time he spends counseling patients in order to fill all of the orders he receives. Increasingly, John is noticing that some patients are not willing to wait to receive service at particularly busy times. He assumes that these patients are choosing to fill their prescriptions at the drive through pharmacy a mile down the road, or from mail-order pharmacies. He is concerned that these patients are not getting adequate
counseling from the other pharmacies. Given that John does not have the profit margin to expand his
business or hire additional pharmacists, he is left with the decision to either fill more prescriptions and
spend less time counseling patients, or spend more time counseling patients and lose patients to pharmacies
that focus much less on counseling. What should John do?

Case #4: Intellectual Property and the Pharmaceutical Industry

Azidothymidine (AZT) is a treatment for AIDS that was developed through research at the National
Cancer Institute and Duke University. GlaxoSmithKline (GSK), however, owns the intellectual property
right of AZT over the specific usage of the compound as an anti-HIV treatment and holds a process patent
that protects the process by which AZT is produced. There have been several challenges to GSK’s patent,
but courts have upheld that GSK is the “sole inventor” and that generic versions of the drug cannot be made
until the patent expires.

GSK has fixed the price of a full treatment of AZT at approximately $2,700. This cost is too great
for many people to be able to afford treatment, particularly in sub-Saharan Africa. In this area, if everyone
eligible to receive AZT treatment did so, the estimated cost would exceed 50% of the GDP of many of
these nations.

The safeguards of patent licensing creates a moral dilemma in this situation, i.e. Can the right to
intellectual property be justified in light of the fact that it places healthcare in developing countries beyond
reach?


Case #5: TV Advert for Restless Leg Syndrome

"I had never heard of RLS before. But after watching the ad, I've of course convinced myself that I exhibit
each one of its vaguely defined symptoms. "Strange sensations"? I get those! A "creepy crawly" feeling?
Now that you've got me thinking about it … yes! @#$!! you, Requip! (And before I get angry mail: I'm
sure there are many bona fide RLS victims. My heart goes out to you and your jittering limbs.)"

Abstracted from Slate 26dec2006 http://www.slate.com/id/2156187

Case #6: Use of Less Costly Alternative Drug Cutting into Company’s Profits

Wall Street Journal 10/12/2007, Jacob Goldstein & Marilyn Chase

“Genentech Inc. said it will stop making its cancer drug Avastin available to certain pharmacies in a
bid to curb its use in treating eye disease—which has cut into sales of the company's high-priced eye drug.
Although regulators haven’t authorized Avastin’s use against eye disease, it is chemically similar to
Lucentis, which was approved last year to treat wet macular degeneration, a leading cause of blindness in
the elderly. Compounding pharmacies, which are licensed to mix and repackage drugs, put Avastin into
syringes that contain a once-monthly dose of the drug for use in the eye and cost about $40. A once-
monthly dose of lucentis costs about $2,000.

…Avastin, which is sold through wholesalers, will continue to be available to hospital pharmacies
and directly to doctors. But it won’t be available to compounding pharmacies as of Nov. 30.”

Is this an ethically sound way for Genentech to preserve its profit margins?