

Online course
Short introduction to
Pharmaceutical
Marketing

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Why an online course?

- We are expected to be unbiased advisors to our patients
- There are interests and means to bias us
- There is little training in medical school
- Few lecturers
 - who wants to give the same lecture all the time?

What this course?

- Short
 - < 60 min ideally
- Interactive
 - To make it more interesting
 - To give different depths to those who want to know more
 - Repetition of studies as chapter starting point
- Up to date
- To be used once in residency
 - Not another handwashing module

Goal of the course?

- To make us a little better consumers

What the course is not?

- Moralizing
- A list of ethics guidelines and government rules

Why this talk?

- Get Feedback
- Evaluate Interest
- Course as a fixture
 - Integrate into organization???
 - Begin of a series of necessary modules?
- Course as a living organism
 - Interest in collaboration to achieve this

Programming details

- Infrastructure established, servers used for other courses – in house
- No experiments:
 - Language:
 - PHP - server side scripting language (39% of websites)
 - Database:
 - MySQL - allows tracking of participants and analysis of participants responses
 - second most popular sequential database
 - Webserver:
 - Apache (>50% of websites)

Course Structure

1. Presentation of clinical data
2. Advertising
3. Pharmaceutical influence in the lay press
4. Physicians' interaction with pharmaceutical reps
5. Samples
6. Gifts to doctors and "Sunshine Act"

Chapter 1

Presentation of clinical data

Goals:

- Participants will recognize distorting reporting of clinical data

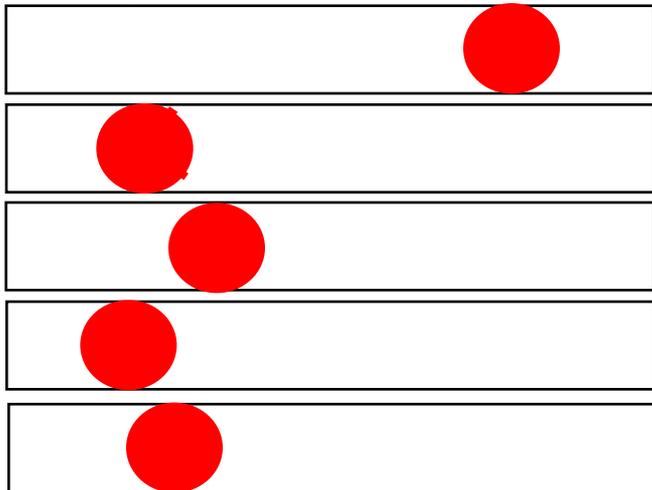
Objectives:

- Participants will be able to recognize different measures of therapeutic effect and their influence on prescribing

Screen shot – sort of

I would definitely **not** prescribe this drug

I would definitely prescribe this drug



Helsinki Heart Study

You are in doubt whether to start drug treatment to reduce serum cholesterol of one of your patients. We will give you five statements derived from five different randomized controlled clinical trials recently published in leading medical journals. On the basis of each statement you should indicate how likely you are to prescribe each drug for your patient. Assume that the dosage is the same for each treatment (one pill twice a day)

During the five-year follow-up :

For drug A a 34% cardiac event reduction was demonstrated;

For drug B an absolute reduction of cardiac events of 1.4% was demonstrated;

For drug C the rate of event –free patients increased from 95.9% to 97.3%;

For drug D 71 needed to be treated in order to avoid one cardiac event:

For drug E a 34% cardiac event reduction was demonstrated along with a 6% relative increase in total mortality

Chapter 2

Advertising

Goals:

- Participants will understand the rules governing pharmaceutical advertising and how you can advertise without ads and reps

Objectives:

- Participants will be able to recognize violations of FDA rules for advertising

This site is intended for healthcare professionals within the United States only.

ZOVIRAX® Ointment Full Prescribing Information | ZOVIRAX® Cream Full Prescribing Information | Important Safety Information | Consumer Site | Contact Us

ZOVIRAX® Ointment

ZOVIRAX® Cream

Patient Materials

Rebate Information

Home

PROVEN EFFECTIVE AT ANY STAGE*
Even When Therapy Is Initiated Late³

	Progression of an untreated herpes lesion	Begin treatment with ZOVIRAX® Cream ^{2,3}	Begin treatment with Valtrex® ⁴
STAGE 1 Prodrome or early ^{4,6}	 Tingling, burning, pain, or itching sensation is present	✓	✓
STAGE 2 Papule or swelling ⁴	 Small red bumps begin to blister	✓	No Data ⁴
STAGE 3 Vesicle or blistering ⁴	 Blisters fill with liquid, forming full-scale cold sore	✓	No Data ⁴
STAGE 4 Ulcer or weeping ⁴	 Blisters rupture	✓	No Data ⁴
STAGE 5 Crust or scabbing ⁴	 The lesion collapses. A yellowish crust forms and falls away	✓	No Data ⁴
STAGE 6 Healing ⁴	 Redness and irritation fade, returning the cold sore virus to a dormant state	✓	No Data ⁴

ZERO IN

WITH

EFFICACY

?

Therapy should be initiated as soon as possible following onset of signs and symptoms.

¹“Early” lesion stage is defined as prodrome or erythema. “Late” stages include papule, vesicle, or ulcer.²

³There are no data on the effectiveness of treatment with Valtrex® initiated after the development of critical signs of a cold sore (eg, papule, vesicle, or ulcer) in the Valtrex® full prescribing information.⁴

⁵Trademarks are the property of their respective owners.



TARGETED. TOPICAL. ANTIVIRAL.

ZOVIRAX® (acyclovir) Cream 5% is indicated for the treatment of recurrent herpes labialis (cold sores) in adults and adolescents (12 years of age and older). ZOVIRAX Cream should be applied 5 times per day for 4 days. Therapy should be initiated as early as possible following onset of signs and symptoms (i.e., during the prodrome or when lesions appear). For adolescents 12 years of age and older, the dosage is the same as in adults.

Important Safety Information

ZOVIRAX® Cream is intended for cutaneous use only and should not be used in the eye or inside the mouth or nose. ZOVIRAX® Cream has a potential for irritation and contact sensitization. In clinical trials, the most common adverse reactions at the site of topical application occurred in less than 1% of patients and included dry lips, desquamation, dryness of skin, cracked lips, burning skin, pruritus, flakiness of skin, and stinging on skin. ZOVIRAX® Cream does not prevent transmission of HSV infections, and its effect has not been established in immunocompromised patients.

ZOVIRAX® Cream is available by prescription only.

Please click [here](#) for full Prescribing Information.

This site is intended for healthcare professionals within the United States only.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

ZOVIRAX® Ointment
 ZOVIRAX® Cream
 Patient Materials

This presentation misleadingly overstates the efficacy of the drug by suggesting that Zovirax is proven effective when initiated during the ulcer or weeping, crust or scabbing, or healing stages (stages 4-6) of a herpes lesion, when this has not been demonstrated by substantial evidence or substantial clinical experience.

PROVEN EFFECTIVE AT ANY STAGE*
 Even When Therapy Is Initiated Late³

	Progression of an untreated herpes lesion	Begin treatment with ZOVIRAX® Cream ^{2,3}	Begin treatment with Valtrex [®]
STAGE 1 Prodrome or early ^{1,4}	 Tingling, burning, pain, or itching sensation is present	✓	✓
STAGE 2 Pule or swelling ⁴	 Small red bumps begin to blister	✓	No Data ¹
STAGE 3 Vesicle or blistering ⁴	 Blisters fill with liquid, forming full-scale cold sore	✓	No Data ¹
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**"Early" lesion stage is defined as prodrome or erythema. "Late" stages include papule, vesicle, or ulcer.
¹There are no data on the effectiveness of treatment with Valtrex[®] initiated after the development of clinical signs of a cold sore (e.g., papule, vesicle, or ulcer) in the Valtrex[®] full prescribing information.
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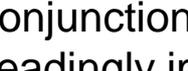
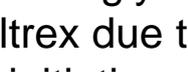
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Even When Therapy Is Initiated Late³

Progression of an untreated herpes lesion		Begin treatment with ZOVIRAX® Cream ^{2,3}	Begin treatment with Valtrex ^{®5}
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STAGE 2 Papule or swelling ⁶	 Small red bumps begin to blister	✓	No Data [†]
STAGE 3 Vesicle or blistering ⁶	 Blisters fill with liquid, forming full-scale cold sore	✓	No Data [†]



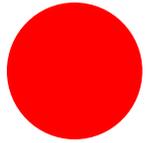
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STAGE 1	 Tingling, burning	✓	✓
STAGE 2	 Pain, itching	✓	No Data [†]
STAGE 3	 Crusting, scabbing	✓	No Data [†]



“This presentation, in conjunction with the effectiveness claim cited above, misleadingly implies that Zovirax is clinically superior to Valtrex due to an extended timeframe of treatment initiation. FDA is not aware of substantial evidence or substantial clinical experience to support the implication that Zovirax is superior to Valtrex, regardless of when treatment is begun. Generally, claims of superiority must be supported by two adequate and well-controlled head-to-head clinical trials comparing effectiveness of Zovirax and the comparator drug, however, none of the references cited in the promotional piece support this misleading presentation.”

And there are references to support the claims:



References: 1. Corey L, Benedetti JK, Critchlow CW, et al. Double-blind controlled trial of topical acyclovir in genital herpes simplex virus infections. *Am J Med.* 1982;73(1A):326-334. 2. Zovirax Cream 5% [prescribing information]. Bridgewater, NJ: CORIA Laboratories; 2009. 3. Spruance SL, Nett R, Marbury T, Wolff R, Johnson J, Spaulding T; for the Acyclovir Cream Study Group. Acyclovir cream for treatment of herpes simplex labialis: results of two randomized, double-blind, vehicle-controlled, multicenter clinical trials. *Antimicrob Agents Chemother.* 2002;46(7):2238-2243. 4. Custom cold sore survey. Princeton, NJ: Multi Sponsor Surveys Inc; December 2009. 5. Valtrex Caplets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; 2008. 6. Barbarash RA. Update on treatments for oral herpes simplex viral infections (cold sores and fever blisters). *Today's Ther Trends.* 2001;19:39-58.



ZOVIRAX is a registered trademark of GlaxoSmithKline.
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“We note that the promotional piece cites the Spruance, et al.³ study, in support of efficacy when treatment with Zovirax is initiated late. This reference details the two pivotal trials for Zovirax, and thus do not constitute substantial evidence for the reasons cited above. In addition, the Barbarash⁶ article is cited in support of beginning treatment with Zovirax at the ulcer or weeping, crust or scabbing, and healing stages (stages 4-6). However, this reference is a review article that discusses herpes simplex viral infections and various treatment options, and does not constitute substantial evidence to support claims of efficacy at any stage.”

It is natural that diseases will only be treated once they have been diagnosed. Thus under-diagnosis of diseases is a serious concern for the pharmaceutical industry. A concerted effort often accompanies the promotion of new drugs, particularly those that treat diseases that are perceived to be underdiagnosed and have FDA approved lucrative treatment. This development of a market is similar to that of other manufacturers that try to stimulate a new need, think of smartphones or toiletries. American women for example started shaving their underarms after an advertising campaign by Wilkinson in the 20s. The clearest example of this strategy in pharmaceutical advertising are the reminder ads which were discussed in the last section, however, some more effective methods are less obvious:

PATIENT ADVOCACY

A global survey from Britain estimated that two-thirds of all patient advocacy groups and health charities now rely on funding from drug companies or device manufacturers. These groups have a legitimate interest in promoting awareness of disease and in improving diagnosis, as well as in increasing the therapeutic options available. They also seem like independent arbiters who are often asked to act as consultants to the FDA – [HYPERLINK TO DISCUSSION OF FDA](#)

SUPPORTING DIAGNOSTIC PROCEDURES

Before the approval of FOSAMAX (alendronate), the first non-hormonal drug to treat osteoporosis, its manufacturer Merck subsidized the distribution of bone density machines needed to ensure that patients could easily get the diagnosis. Similarly, Astra Merck tried to increase the diagnosis of *H. pylori* and licensed a simple bedside test to increase sales of Prilosec (omeprazole).

EDUCATIONAL EFFORTS

Focusing on physicians directly, educational efforts play a major role in drug promotion. It is not coincidental that the promotional material usually helps to diagnose and treat the diseases in question. An extreme but illustrative example is a questionnaire that was promoted by Bristol-Myers Squibb as part of a funded educational program. It classified about 49% of patients as having a “mental disorder”. A reevaluation of the test concluded that the majority of these patients with “mental disorder” likely had none. In the end the promoted antidepressant was removed from the market due to unacceptable toxicity, which highlights the problem of overtreatment since the toxicity was not related to the disease in question and would have affected healthy patients who were treated, as well as depressed ones.

CME

One of the most widespread marketing and likely very effective marketing tools is CME. It fulfills a need within the medical community for educational material that needs to be expensively vetted and certified. You will find that most freely available CMEs focus on serious diseases that have expensive treatments, like psoriatic arthritis.

ACADEMIC PAPERS

The academic literature is influenced most appropriately by the sponsorship of studies. It should be noted that the publications of large studies are often written by professional medical writers who are either not listed as authors or are somewhere in the middle of the list. Sometimes the authorships are simply given to the head of a department that recruits the most patients for the study but was neither significantly involved in the study conduction, nor its analysis, not indeed in writing the paper. As you will find particularly the premier medical journals often reports large randomized placebo controlled trials that have a placebo arm when other treatments for the disease in question are available.

Chapter 3

Pharmaceutical influence in the lay press

Goals:

- Participants will be able to evaluate lay press medical information for pharmaceutical influence

Objectives:

- Participants will identify typical components of lay press reporting that has been influenced by the pharmaceutical industry

OPEN ACCESS Freely available online

PLOS MEDICINE

Policy Forum

Giving Legs to Restless Legs: A Case Study of How the Media Helps Make People Sick

 Steven Woloshin^{*,} Lisa M. Schwartz^{*,}


This is one of a series of articles on disease mongering in the April 2006 issue

“[Restless legs syndrome] is quite a serious sleep disorder that affects a lot of people.... Their sleep is disturbed and, unless they are really awake, they will not be aware of it” [1].

Life can be hard. Sometimes you feel sad or distracted or anxious. Or maybe you feel a compelling urge to move your legs. But does that mean you are sick? Does it mean you need medication?

Maybe, maybe not. For some people, symptoms are severe enough to be disabling. But for many others with milder problems, these “symptoms”

so normal experiences get labeled as pathologic, and by expanding the definition of disease to include earlier, milder, and presymptomatic forms (e.g., regarding a risk factor such as high cholesterol as a disease in itself).

Discussions about disease mongering usually focus on the role of pharmaceutical companies—how they promote disease and their products through “disease awareness” campaigns and direct-to-consumer drug advertising, and by funding disease advocacy groups. But diseases also get promoted in another way: through the news media. News reports are a major source of health information for people [3]. Unless journalists approach stories about new diseases skeptically and look out for disease mongering by the pharmaceutical industry, pharmaceutical consultants, and advocacy groups, journalists, too,

The Case of Restless Legs Syndrome

To get a sense of how the media works in the context of a major disease promotion effort, we examined news coverage of “restless legs” (see sidebar). In 2003, GlaxoSmithKline launched a campaign to promote awareness about restless legs syndrome, beginning with press releases about presentations at the American Academy of Neurology meeting describing the early trial results of using ropinirole (a drug previously approved for Parkinson disease) for the treatment of restless legs [6,7]. Two months later, GlaxoSmithKline issued a new press release entitled “New survey reveals common yet under recognized disorder—restless legs syndrome—is keeping Americans awake at night”

No sleep for those with restless legs

It has been a long day and you are exhausted. You crawl into bed, longing for sleep, but your limbs have other ideas. Within moments, you experience a burning sensation in your calves, accompanied by an uncontrollable urge to move your legs. Kicking brings relief, but not for long.

If you recognize these symptoms, you may well be among the many people in Britain who suffer from restless legs. The condition sounds like a joke, but its consequences can be devastating. Driven to despair by years of sleepless nights, patients have become suicidal.

The cause of restless legs, also known as Ekbom syndrome, has not been identified but it may be linked to a lack of dopamine in one of the brain's receptors, which affects the spinal cord reflexes. Post mortems of sufferers carried out at

Penn State College of Medicine confirmed that iron deficiency in the brain also plays a part. It is more common in women and in older

Dr Gary K Miller, an assistant professor Illinois School of Medicine, Chicago, and one of the few American experts on restless leg syndrome syndrome, believes the condition has a huge psychosocial impact. "Chronic sleep deprivation over a period of eight to 10 years - which is how long it takes on average to get a referral to a specialist - can affect cognition, raise anxiety levels and impair daytime functioning."

"We do not know how many accidents at work or on the roads are caused by people with restless legs being unable to sleep. In the worst cases, sleep deprivation and the inability to tolerate certain activities, such as sitting for long periods at a desk, can

lead to job loss, relationship problems and depression."

Some doctors believe the problem is psychosomatic or misdiagnose it as night cramps. Relatively few doctors know about it. This is the most common disorder your doctor has never heard about. Treatment for cramp is useless, and sleeping tablets can actually make restless legs worse.

"Even when restless legs is diagnosed, doctors may dismiss it as trivial and tell patients that they have to put up with it," says Dr Miller. It is, medical specialists say, one of the most common causes of sleep deprivation, affecting up to 10 percent of the population. But it suffers from something of a Rodney Dangerfield complex: It just doesn't get much respect.

"Most patients I see have never had their iron levels measured and less than one per cent of the severe cases

who would benefit from medication actually get it." Indeed, Harriet Johnson who was treated with ropinirole was very happy with the results: "It has been a miracle drug for me and given me back the sound sleep that I need so much."

Walking and stretching, taking a bath, relaxation exercises, massaging the limbs or resting the feet on a cold surface may help. If a blood test reveals low iron levels, taking iron supplements can stop the attacks.

One in four patients is affected severely enough to require prescribed medication, though most do not receive it. Clinical trials have shown that a group of drugs called dopamine agonists, normally prescribed for Parkinson's and not licensed for Ekbom syndrome, reduces the symptoms and improves sleep quality. New drugs are under development.

"A great deal of money is going into research," says Dr Miller, "because there is a huge untapped market."

The text above was enriched, this is the original article

The Telegraph

No sleep for those with restless legs

Ignorance about Ekbom syndrome means that sufferers are not receiving the treatment they need. Barbara Lantin reports

Barbara Lantin

12:01AM GMT 12 Jan 2004



[Comment \(http://www.telegraph.co.uk/health/3304315/No-sleep-for-those-with-restless-legs.html#disqus_thread\)](http://www.telegraph.co.uk/health/3304315/No-sleep-for-those-with-restless-legs.html#disqus_thread)

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The cause of restless legs, also known as Ekbom syndrome, has not been identified but it may be linked to a lack of dopamine in one of the brain's receptors, which affects the spinal cord reflexes. Post mortems of sufferers carried out at Penn State College of Medicine in Chicago confirmed that iron deficiency in the brain also plays a part. It is more common in women and in older people, though it can start at any age. Most sufferers have a family history of the condition.

"As soon as you sit or lie down, you have this irresistible urge to move your legs and this awful tingling feeling in your calves," says Eileen Gill, who has suffered since childhood and founded the Ekbom Support Group. "Some say it is a creepy crawly sensation and others call it 'Elvis legs'. It is a cruel and terrible condition.

"Until I was on medication, I could not sit in a car for more than 20 minutes without getting out and walking around. Going to the theatre or cinema is impossible for many people and nights are horrific. It starts the moment you get into bed and disappears if you stand up again. One man rang me in the middle of the night because he was about to take an overdose. He was not sleeping, could not function properly and had failed to get the job he wanted."

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It is a lay press campaign, so it has to address the reader directly – which most good journal articles do

long-term treatments or a referral to a specialist - can affect cognition, raise anxiety levels and impair daytime functioning."

"We do not know how many accidents at work or on the roads are caused by people with restless legs being unable to sleep. In the worst cases, sleep deprivation and the inability to tolerate certain activities, such as sitting for long periods at a desk, can

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Some doctors believe the problem is psychosomatic or misdiagnose it as night cramps. Relatively few doctors know about it. This is the most common disorder your doctor has never

heard of. Treatment for cramp and sleeping tablets can make restless legs worse. When restless legs is diagnosed, doctors may dismiss it and tell patients that they have to put up with it," says Dr Miller. It is, medical specialists say, one of the most common causes of sleep deprivation, affecting up to 10 percent of the population. But it suffers from something of a Rodney Dangerfield complex: It just doesn't get much respect.

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One in four patients is affected severely enough to require prescribed medication, though most do not receive it. Clinical trials have shown that a group of drugs called dopamine agonists, normally prescribed for Parkinson's and not licensed for Ekbom syndrome, reduces the symptoms and improves sleep quality. New drugs are under development.

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Dr Gary K Miller, an assistant professor Illinois School of Medicine, Chicago, and one of the few American experts on restless leg syndrome syndrome, believes the condition has a huge psychosocial impact. "Chronic sleep deprivation over a period of

Uncommon, but stresses lethal consequence and seriousness of the disease

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less than one per
severe cases

It is very common for newspaper articles to mention the underdiagnosis of the disease that they are covering – in the survey that is the basis of this section 50% of the articles mentioned underdiagnosis. However as we see below the prevalence of the disease in these articles is often overstated based on a simplified and exaggerating diagnostic approach. In this case the number was based on a survey using one diagnostic criteria and not the combination of multiple diagnostic criteria which defines the disease.

Thus it is all the more worrying that in a quarter of the articles surveyed, the authors encouraged self-diagnosis. The combination of information about effective treatment – sold by Glaxo Smith Kline – and self diagnosis in a fairly obscure disease lends itself to the chance of overtreatment, which is exactly the point of disease promotion. In 20% of the articles referred the readers to the “non-profit” Restless Legs Foundation which is heavily subsidized by Glaxo Smith Kline, however, the Restless Legs Foundation has the 5 diagnostic criteria prominent published on its website which may reign in self diagnosis.

"A great deal of money is going into research," says Dr Miller, "because there is a huge untapped market."

Chapter 4

Pharmaceutical Reps

Goals:

- Participants will understand techniques used by pharmaceutical reps to interact with physicians

Objectives:

- Participants will recognize behavior patterns of reps that tailor to different physician personality types

How would a rep most effectively address you?

Good sales people work on an intuitive level to make sure that they can offer what you need.

Not all reps are natural sales people and some may cling to this schematic representation of four broad physician types in order to assure that they can cater to your individual needs. You will find them on the next page.

Try to check out the type that you think fit best and follow the hyperlink see what the rep will do for you. Think of colleagues and what types they are and follow these hyperlinks. They may explain what you see in your department – if they still allow reps.

Independent

- Do not value Rep interactions
- Try to rely on independent evidence-based medicine materials
- May ask rep for targeted data and primary peer reviewed publications

Transactional

- Contact reps for samples
- Are cost conscious
- Receptive to patient preferences
- Slow to adopt new medications

Knowledge Seekers

- Generally interested in pharmaceutical supported educational programs
- Do not want rep talks
- Do not want samples

Relationship Seekers

- Value samples
- Value Rep interactions and pharmaceutical education
- Early adopters of new medicine

Independent

What does the rep do?

- Try to build relationship with you and your office by including everyone in all invitations to speaker programs
- Try to become a **resource** rep by making you aware of all new clinical trials and details rather than a **sales** rep only

What can you do?

- Develop standards for interactions with pharm reps
- Try to make yourself familiar with the freely available sources of EBM that are on the internet. Use medline, and best buy drugs which is published by consumerreports.org but remains free. If you are willing to invest journal watch can keep you up to date and the medical letters will give you unbiased, often scathing reviews of new drugs

Independent

- Do not value Rep interactions
- Try to rely on independent evidence-based medicine materials
- May ask rep for targeted data and primary peer reviewed publications

Transactional

- Contact reps for samples
- Are cost conscious
- Receptive to patient preferences
- Slow to adopt new medications

Knowledge Seekers

- Generally interested in pharmaceutical supported educational programs
- Do not want rep talks
- Do not want samples

Relationship Seekers

- Value samples
- Value Rep interactions and pharmaceutical education
- Early adopters of new medicine

Chapter 5

Samples

Goals:

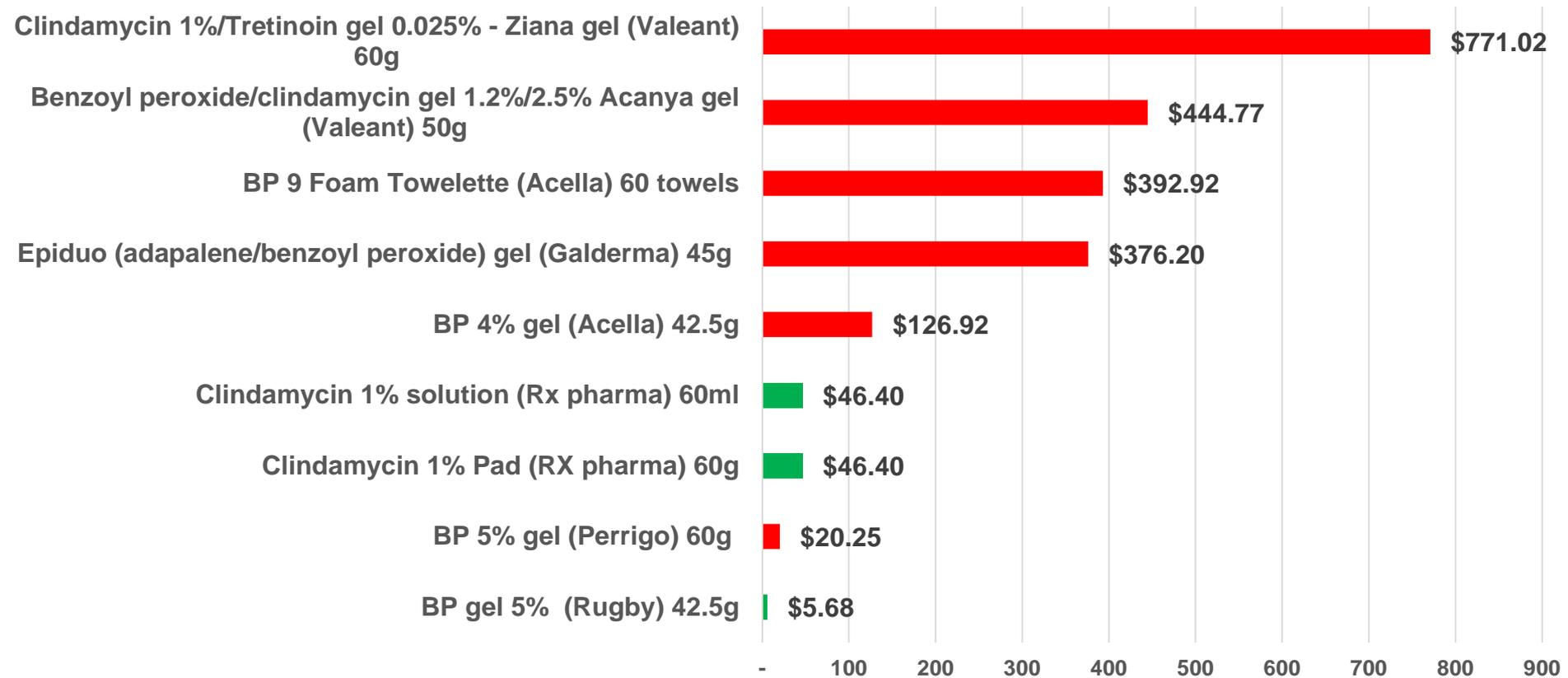
- Students will recognize the downsides of using samples in their clinics

Objectives:

- Students will be able to critique sample use and its consequences for cost effective treatment

Who will give you samples?

Selected price range of Acne topicals



Chapter 6

Gifts, stipends, dinners and the sunshine act

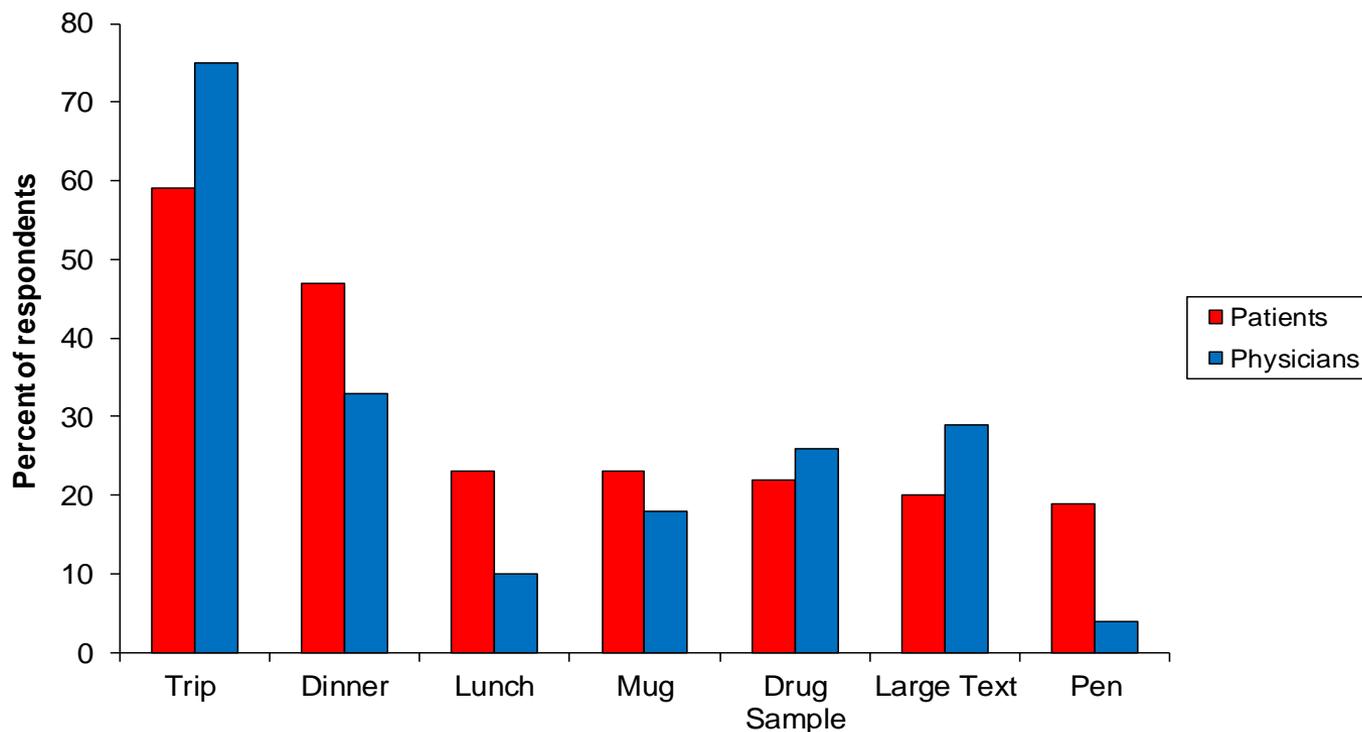
Goals:

- Students will understand the psychological effects of gifts on physicians and the new transparency rules that govern physician pharmaceutical exchanges

Objectives:

- Students will be able to assess the effect of presents or stipends by pharmaceutical companies on their behavior and the perception of themselves on patients and peers

Percent of respondents who agreed the following gifts were inappropriate



Gibbons RV, et al. *J Gen Intern Med.* 1998;13(3):151-154.

Sunshine act

Showing Results for: [All]

Show Entries 10 ▾

Affirm Record

Dispute Record

Withdraw Dispute

Select	Entity Making Payment	Record ID	Dispute ID	Payment Category	Form Of Payment or Transfer of Value	Nature Of Payment or Transfer of Value	Date of Payment	Amount(\$)	Delay in Publication of Research Payment Indicator	Last Modified Date	Current Record Standing
<input type="checkbox"/>	Janssen Pharmaceutical Inc	23823434		General Payments	In-kind items and services	Education	2013-10-15	\$69.95	No	2014-06-27	Attested

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Thanks

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