

ADR reporting and patient safety

**Influencing audiences; social
marketing**

Bruce Hugman

In this session



**Safety
information**



Negotiating skills

**Social
marketing**



Safety information: The big picture

- The provision of drug safety information for prescribers and dispensers that influences their decisions and protects patient safety

The local picture

- What can we do to improve safety information for prescribers?



Question 1

- What are the current methods available for providing health professionals with the latest safety information about medicines for safe, evidence-based prescribing?



FDA MedWatch - March 2013 Safety Labeling Changes includes 53 products with revisions to Prescribing Information - Message (HTML)

Message

Reply Forward
to All

Delete Move to Folder Create Rule Other Actions


Block Sender Not Junk

Categorize Follow Up Mark as Unread

Find Related Select

Send to OneNote

From: FDA MedWatch [fda@service.govdelivery.com]
To: mail@brucehugman.net
Cc:
Subject: FDA MedWatch - March 2013 Safety Labeling Changes includes 53 products with revisions to Prescribing Information

 **The FDA Safety Information and Adverse Event Reporting Program**

The MedWatch March 2013 Safety Labeling Changes posting includes 53 products with safety labeling changes to the following sections: BOXED WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS and PATIENT PACKAGE INSERT.

The "Summary Page" provides a listing of drug names and safety labeling sections revised:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm346535.htm>

The following drugs had modifications to the CONTRAINDICATIONS, WARNINGS and PRECAUTIONS sections:

- Brilinta (ticagrelor)
- Carafate (sucralfate)
- Carafate (sucralfate)
- Wellbutrin (bupropion hydrochloride) and Wellbutrin SR
- Anaprox, Anaprox DS (naproxen sodium tablets)
- Avastin (bevacizumab)
- Clozaril (clozapine)
- Coly-Mycin M Parenteral Solution (colistimethate sodium, USP)
- EC-Naprosyn (naproxen delayed-release tablets)
- Erbix (cetuximab)
- Firmagon (degarelix for injection)
- Geodon (ziprasidone HCl)
- Geodon (ziprasidone mesylate)



Methods and problems

- 'Dear HCP' letters
- Bulletins
- Email alerts
- Electronic prescribing systems
- Labeling changes and warnings
- Detailing
- Training
- Pharmacist advisers
- Journals
- Formularies
- Social media
- Smart phone apps
- More?



Question 2

- What are the *most effective methods* for ensuring health professionals have the latest safety information about medicines for safe, evidence-based prescribing?





Question 3

- What are PV centres doing to ensure the latest safety information influences prescribing?
- How effective is it?
- What can we do to improve safety information for prescribers?



Assessing the effectiveness of communications

- Compare before and after data
 - Prescriptions
 - ADRs
- Examine trends in prescribing
- Examine sales figures
- More?



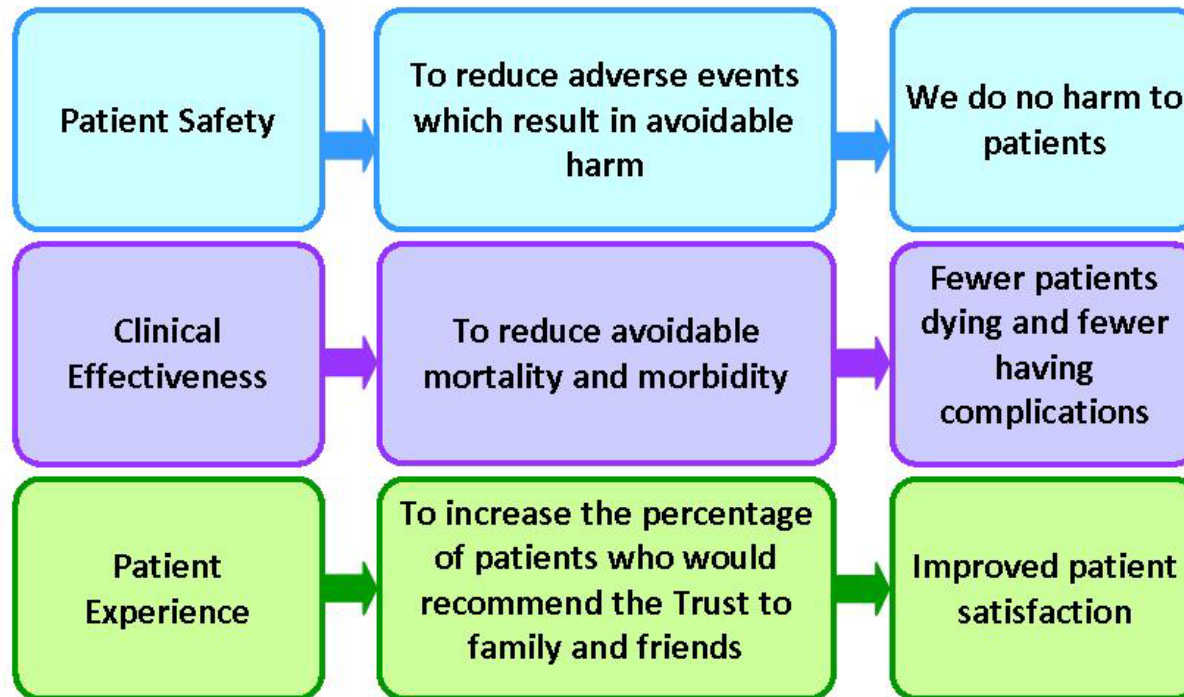
Issues

- Awareness among HCPs about the necessity of keeping up-to-date
- Awareness of the risks of 'blind' or habitual prescribing
- Problems of volume of information (e.g. dozens of US FDA changes in one month)
- How to get relevant information rapidly available at the exact point of need
- How to monitor effectiveness of communications



Identify priorities

Our top three quality and safety related priorities:



Sandwell NHS Trust UK

Safety in Action High 5s

Standard Operating Protocols

- **Managing Concentrated Injectable Medicines**
- **Assuring Medication Accuracy at Transitions in Care**
- **Communication during Patient Care Handovers**
- **Performance of Correct Procedure at Correct Body Site**
- **Improved Hand Hygiene to Prevent Health Care-Associated Infections**



What are your thoughts?



Takeaway lessons

- **The IDEAL**: enforced, updated electronic information at the point of prescribing/dispensing
- Instant electronic information available on demand (PDA, smartphone)
- Brief, critical, headline information through audience-driven channel (print, electronic)
- Motivation of all involved (culture, priorities)
- Critical role of pharmacists





Why negotiation?





I win
You lose

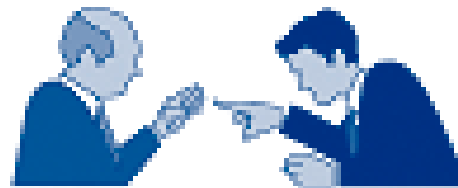
It's a deal!

I win
You win



**Most official,
bureaucratic
communications
fall into this
segment**

I lose
You lose



I lose
You win



What do we mean by negotiating?

- Solving a problem or achieving a goal through collaboration with others who may see the problem differently or have different goals
 - Buyer and seller
 - Provider and consumer
 - Employee and manager
 - Parent and child
 - Patient and HCP
 - PV Centre and HCPs



Procuring drugs or devices

- The purchase of medicines from a pharma company
 - **Pharmacist wants best quality, lowest price, continuity of supply**
 - **Pharma company wants to sell medicines and maximise revenue and profit**
- What are the areas where there is agreement?
 - **Pharmacist wants reliable supply of quality drugs**
 - **Pharma company wants to sell drugs and be preferred supplier over time (maintenance of quality and supply)**
- What is the area of difference?
 - **Pharmacist wants lowest possible price**
 - **Pharma company wants highest possible price**



The settlement zone

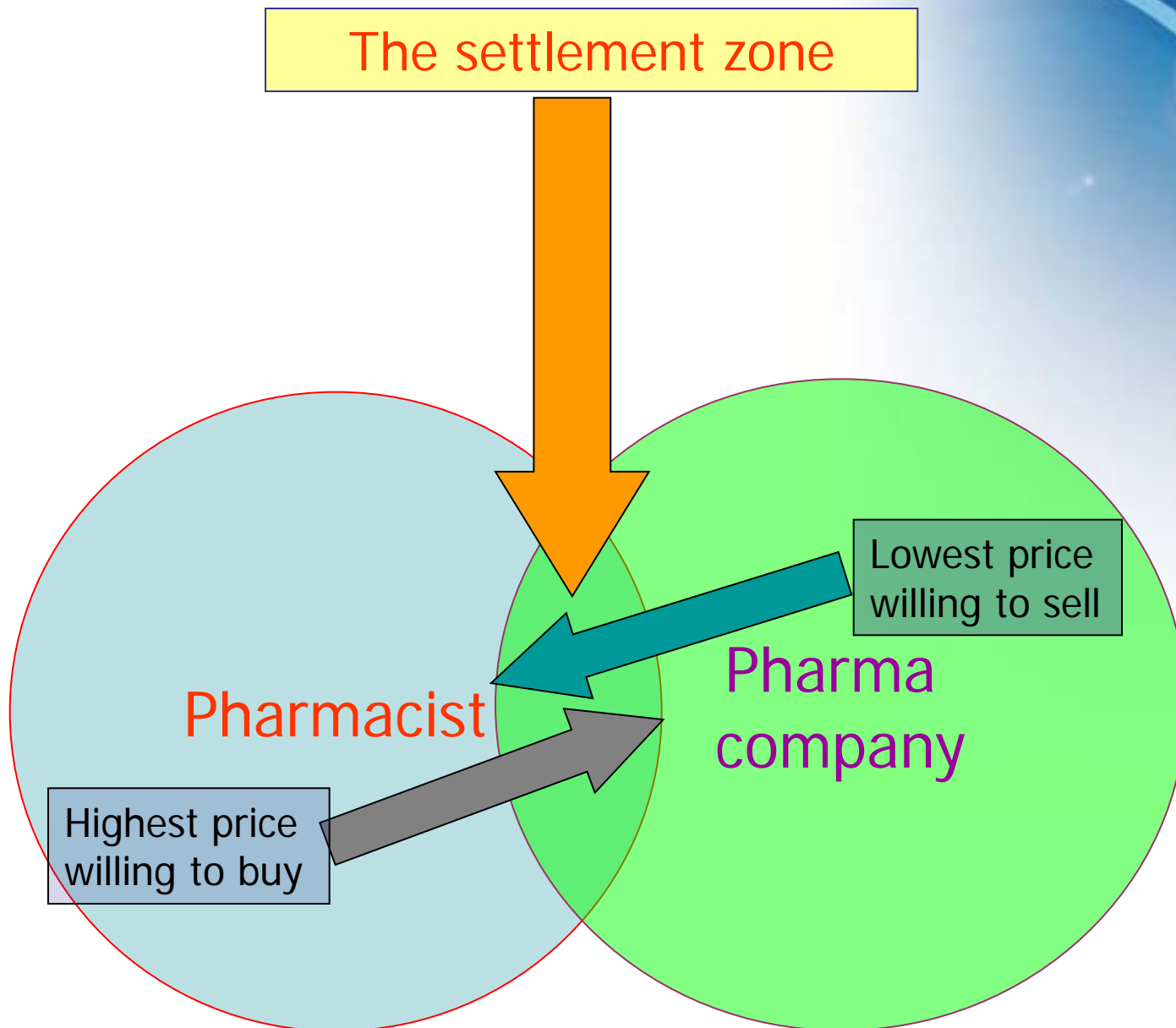
- Pharmacist will have highest price willing to pay; pharma company will have lowest price willing to sell – between these is the settlement zone
- The settlement zone is the area in which the negotiation takes place and an agreement can be reached



The settlement zone

- Pharmacist is willing to pay a maximum of €43,500 for supply of a drug
- Supplier is willing to sell for a minimum of €41,750
- There is room for agreement between €41,750 and €43,500





- This model applies in principle to all negotiations: success in negotiation depends on the skills used in the settlement zone
- There may appear to be no settlement zone early in a negotiation

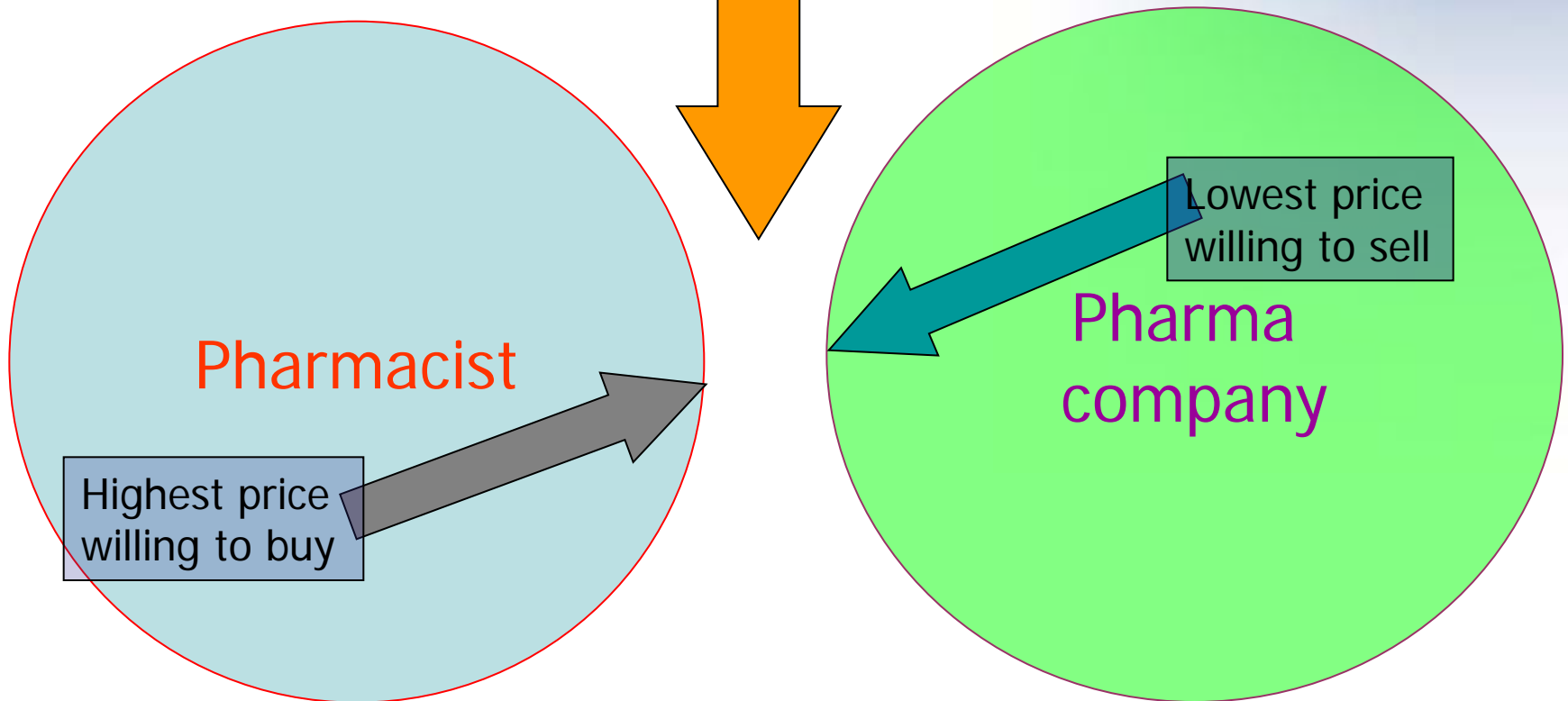


No settlement zone

- Pharmacist is willing to pay a maximum of €13,000 for supply of a drug
- Supplier is willing to sell for a minimum of €15,750
- There is no room for agreement



No settlement zone



Skilled negotiators

- Will create a settlement zone from initial distance and possible failure
- They will establish even a large settlement zone and then narrow it down



Skilled negotiators

- Will use all their communication skills
 - Empathy
 - Reading and using nonverbal behaviour
 - Listening
 - Questioning
 - Proposing
 - ...and more



What do we mean by a successful negotiation?

- An agreement which leaves both sides feeling good, in which neither side feels defeated
- Good negotiations do not end up with a winner and a loser: if one side feels defeated, or humiliated, then there is no future in the relationship
- It is not an unsatisfactory compromise; it is an active, positive result (neither conflict nor compromise model) – meeting the needs of both parties



Influencing





**Siam Square,
Bangkok**



How do you influence someone to do something?

A: There's a great CD sale in Siam Square

B: I'm busy and I haven't any cash

A: They're really cheap; it's one day only

B: How much?

A: All less than ฿200, lots less than ฿50

B: Really? OK. I'll come. Lend me a few baht, will you?



How do you influence someone to do something?

M: Come and have a drink with us

R: No, I'm too busy

M: Oh, come on, we'll miss you

R: I've got an exam tomorrow

M: How much work have you got to do?

R: A couple of hours at least

M: OK, why not join us in a couple of hours?
We'll keep a seat for you.

R: OK. Maybe. See you.

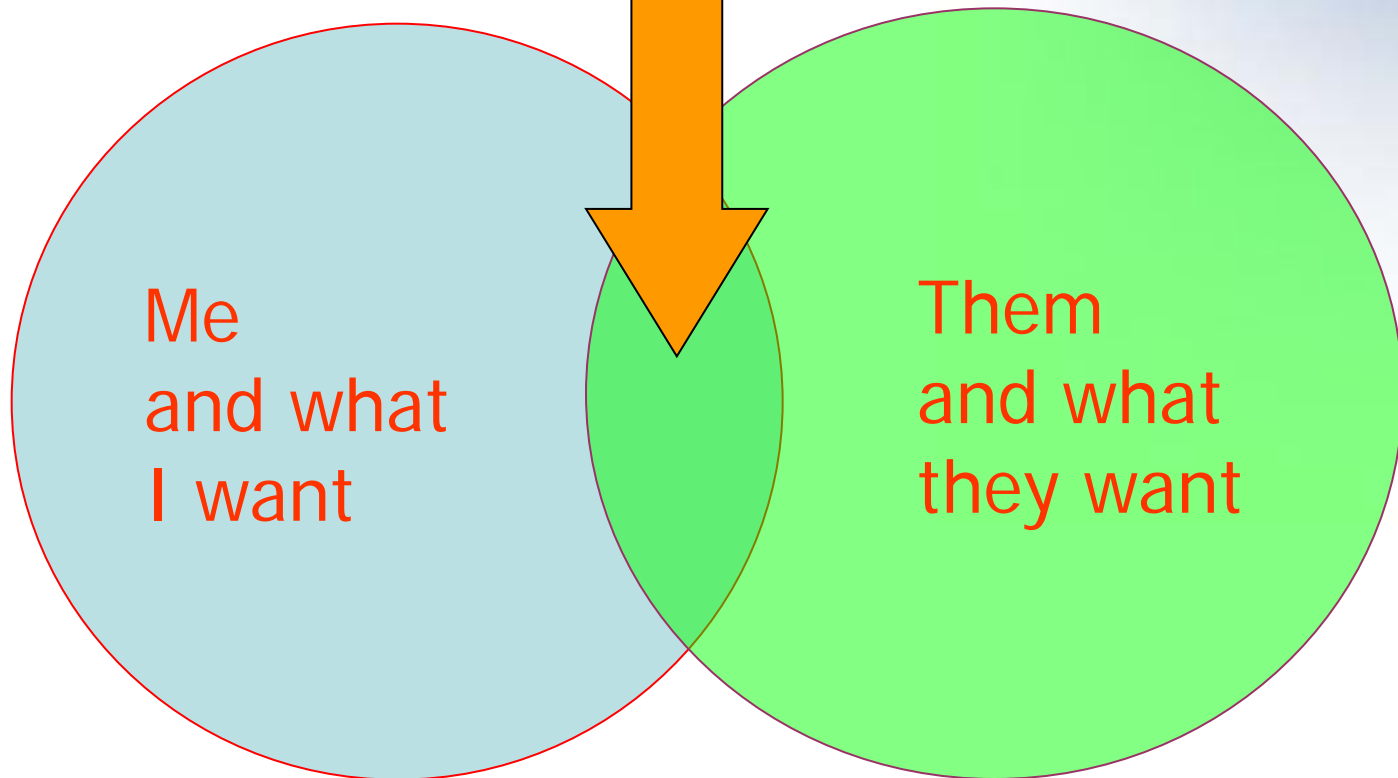


How do you influence someone to do something?

- Make a proposal, suggestion, offer (use empathy)
- Anticipate or deal with resistance (use empathy)
 - Show benefits (for that person)
 - Minimise or negotiate objections
 - Suggest alternatives
- Reward (reinforce) compliance (use empathy)



What we both want
and can agree to



How does this apply to relationships with HCPs?



Bureaucratic or
managerial
enforcement



I win
You lose

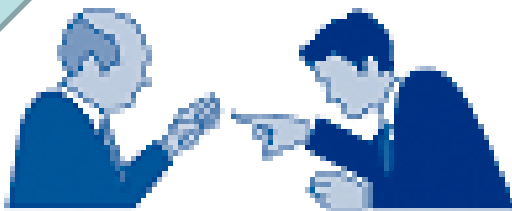
It's a deal!

I win
You win



No common
ground or
shared purpose

I lose
You lose



I lose
You win



Ineffective
communications

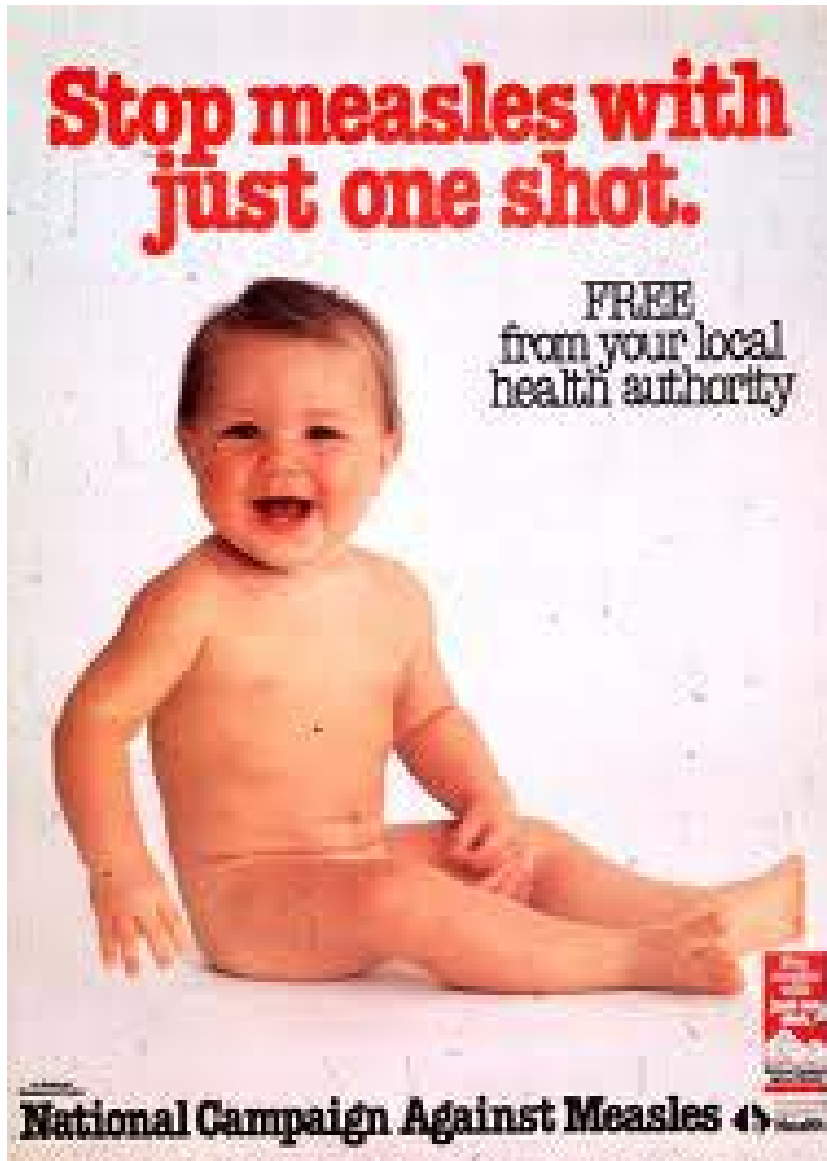


Negotiated arrangements

- What we have in common with HCPs
 - A commitment to the safest possible therapy for patients
- We want HCPs to make use of every piece of evidence and safety information
- They want a quiet life and to carry on as usual
- If we find a maximally effective, acceptable way of communicating information, then...
- They will take notice of it (some of the time)

Is there a settlement zone?





Social marketing

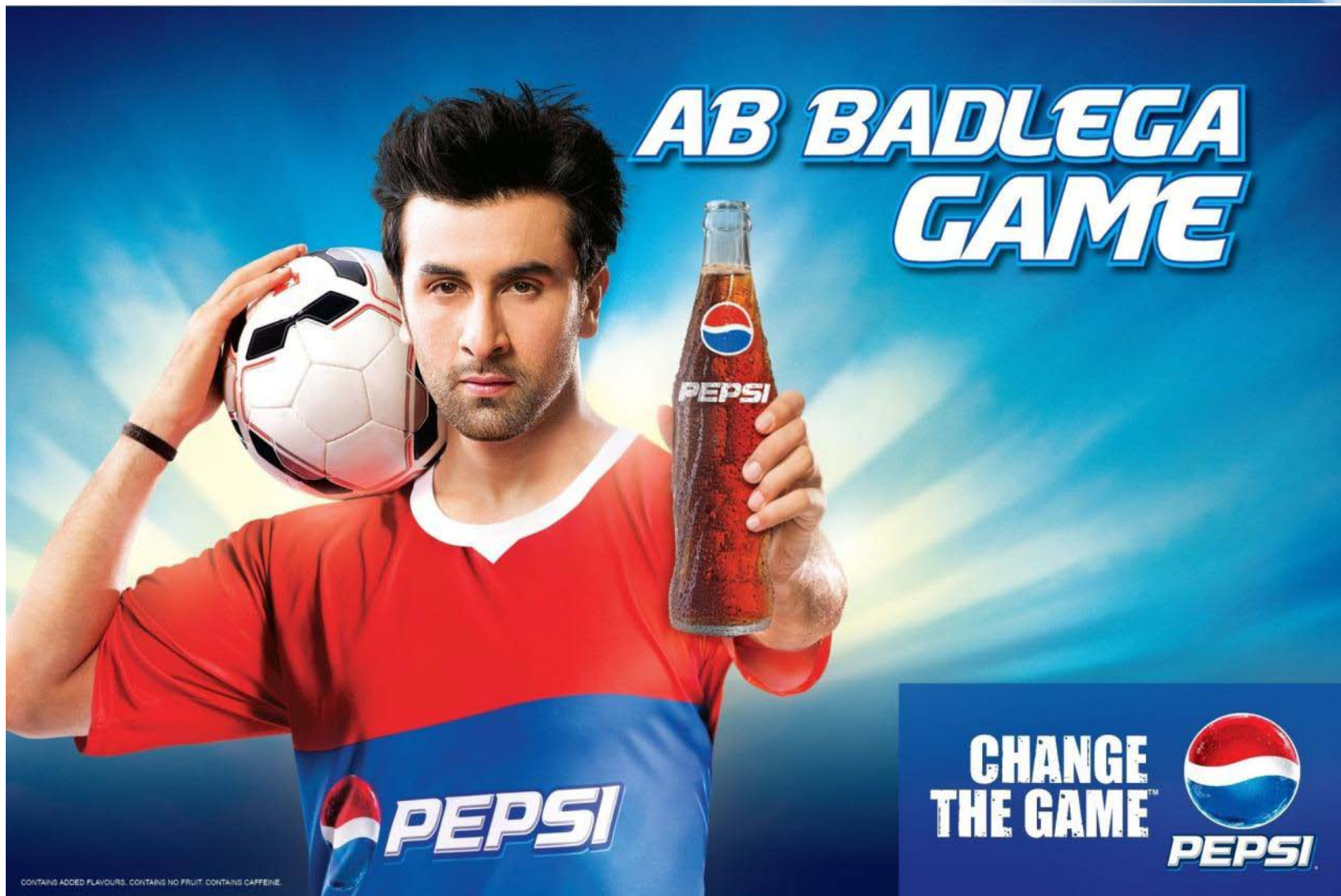


What is social marketing?

- **Social marketing** is the systematic application of marketing, along with other concepts and techniques, to achieve specific **behavioral goals** for a **social good**.
 - Wikipedia





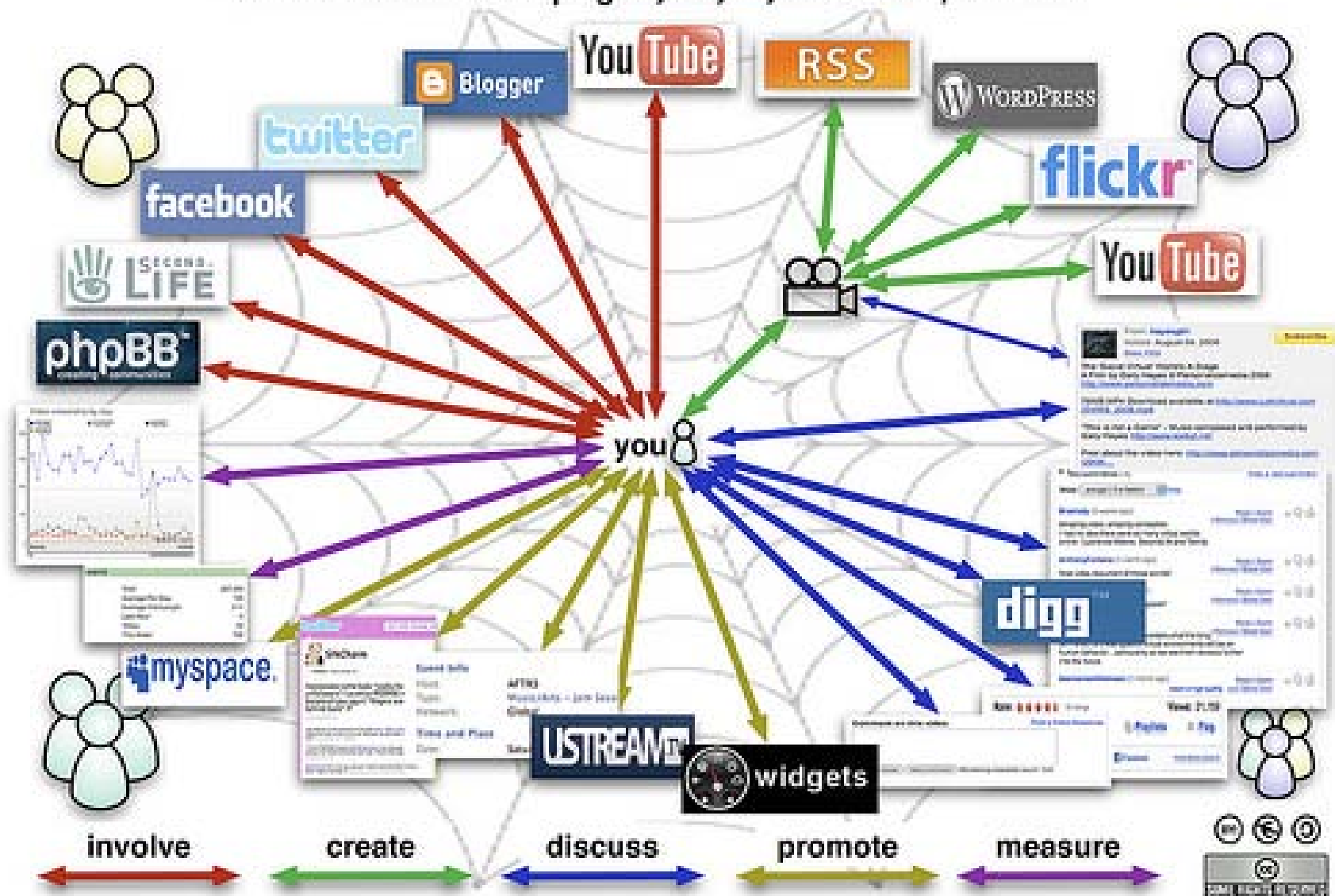








The Social Media Campaign by Gary Hayes & Laurel Papworth 2008



Fight ^{the} Flu



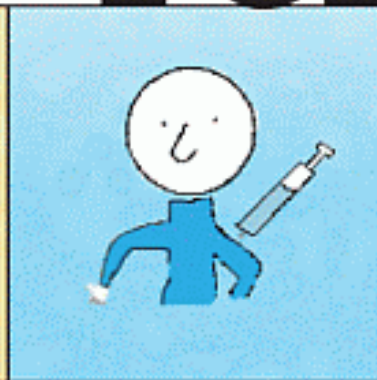
**Cover
your
cough!**



**Wash
your
hands.**



**Stay home
when sick.**



**Get
vaccinated.**

New 2010-11 vaccine protects against both seasonal and H1N1 flu!

Your city or county
public health department

Find a Flu Shot Clinic near you at
www.mdhflu.com

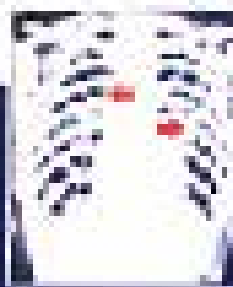


Fight the Flu 10/10





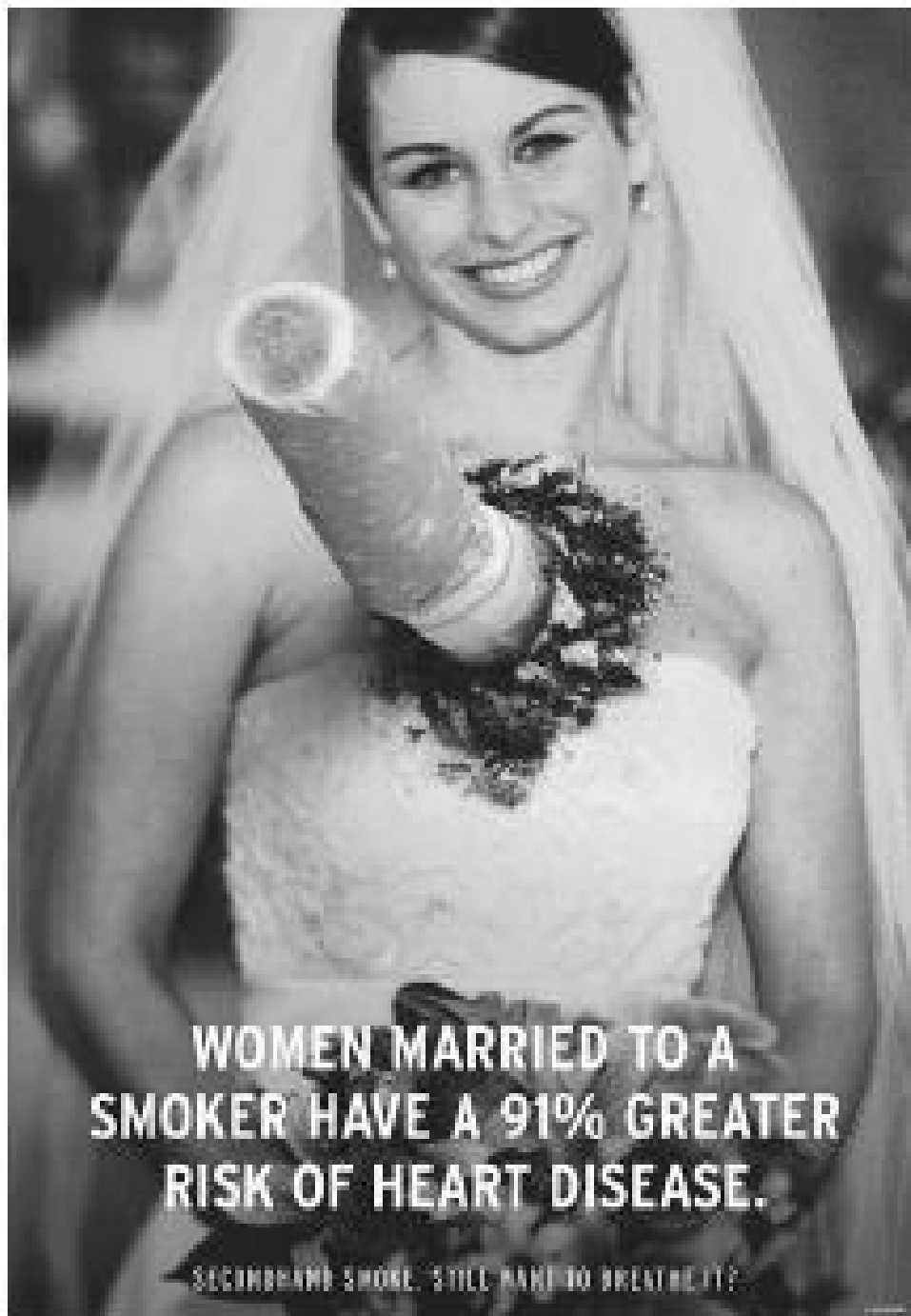
"Healthy Lookers" can hide
TUBERCULOSIS



the X-RAY will show it
before *you* know it

Christmas Seals Fight Tuberculosis

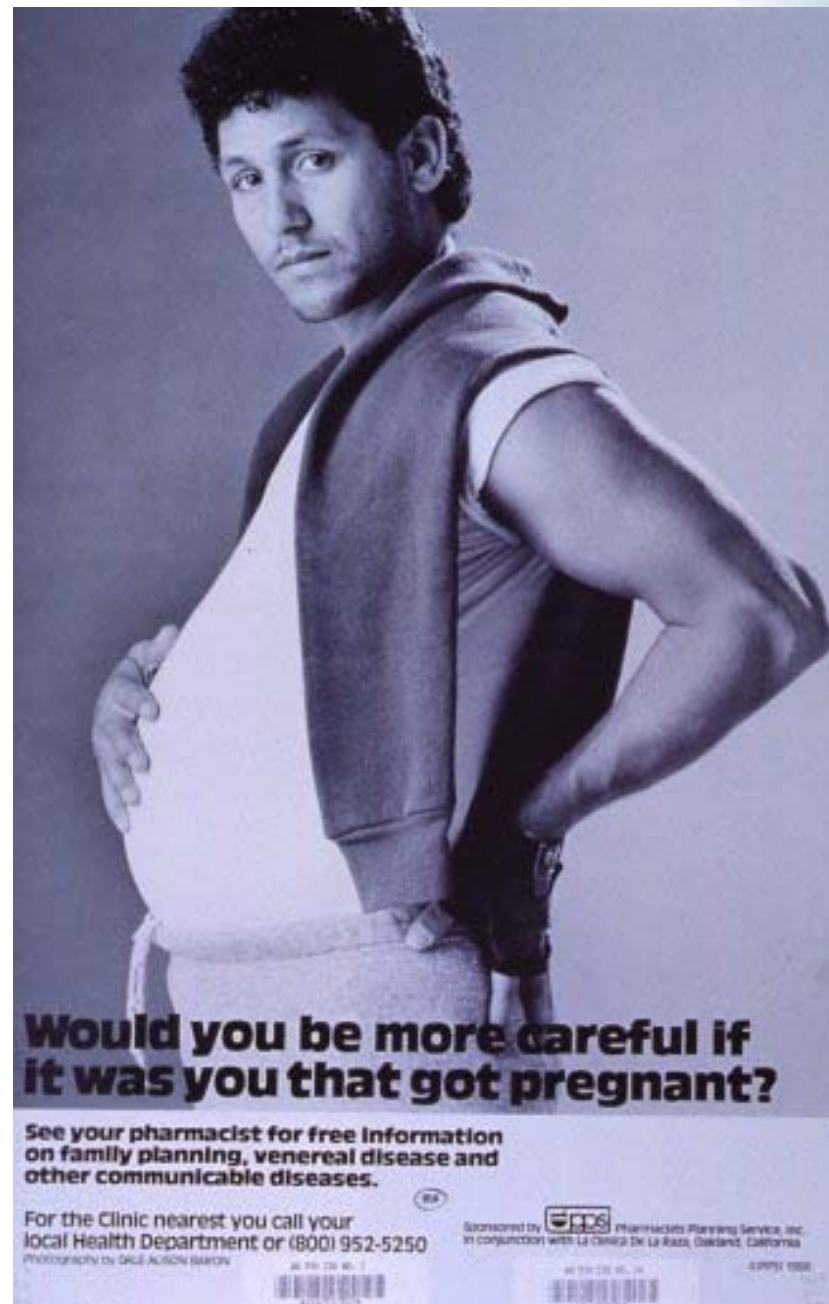




Variable responses

- Danger control
 - A response that takes action to avoid the danger or threat
- Fear control
 - A response that controls or denies the fear of the threat or risk, but takes no action ('It won't happen to me')






**Would you be more careful if
it was you that got pregnant?**

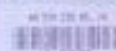
**See your pharmacist for free information
on family planning, venereal disease and
other communicable diseases.**

For the Clinic nearest you call your
local Health Department or (800) 952-5250

Photography by DACE ALISON BARON

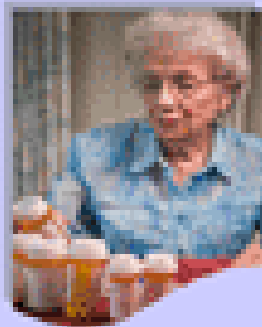


Sponsored by  **Pharmacist Planning Service, Inc.**
in conjunction with La Clínica De La Raza, Oakland, California



4/8/87 1000





Medication Safety and YOU!

KEEP TRACK OF ALL YOUR MEDICATIONS
USE A PERSONAL MEDICATION RECORD (PMR)

- List the names of ALL your medications (prescription and over-the-counter medications, vitamins, and herbal/supplementary supplements)
- Include how and when to take each medication
- Include the reason why you take each medication
- Record important information about your medical history and allergies
- Use the checklist of questions to ask when prescribed a new drug

Ask your doctor or pharmacist to help you fill out or review your PMR

Using a PMR:

- Always update your PMR when there's a change in your medications
- Carry a copy with you at all times
- Keep a copy at home
- Give a copy to a loved one
- Bring a copy to all your doctor appointments, the pharmacy, and the emergency room or hospital

*Ask your Doctor or Pharmacist
or visit <http://www.njdss.org> for a Personal Medication Record*



The New Jersey Drug Safety Initiative (NJDSI) is a quality improvement project conducted by Healthcare Quality Strategies, Inc. (HQSI), the federally designated quality improvement organization (QIO) for New Jersey. It is a patient-centered, community-based project designed to improve medication safety for Medicaid recipients in New Jersey.



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認識結核病

結核菌由飛沫傳染



給嬰兒接種卡介苗，
以減低患上結核病的機
會。十五歲以下的兒童如
從未接種卡介苗，亦建
議接種此疫苗。



病者應接受全監督
短期（六個月）藥物
治療，可迅速減少傳
染性，更可徹底
痊癒。

打噴嚏及咳嗽時應
用紙巾或手帕掩蓋口鼻，
如有痰涎，應吐在廁所內，
或用紙巾包好，丟進垃圾
箱。



如有以下病徵，應接
受檢查：持續咳嗽、痰中
帶血、食慾不振、持續發燒
或發熱、夜間出汗、體重
減輕、胸痛、氣喘。



衛生署

結核病電話熱線：2572 6024

結核病網站：http://www.info.gov.hk/tb_chest

三月廿四防癆日 齊來認識肺結核

TB and chest service department







STOP!


PAY ATTENTION!

REMEMBER!


ACT!



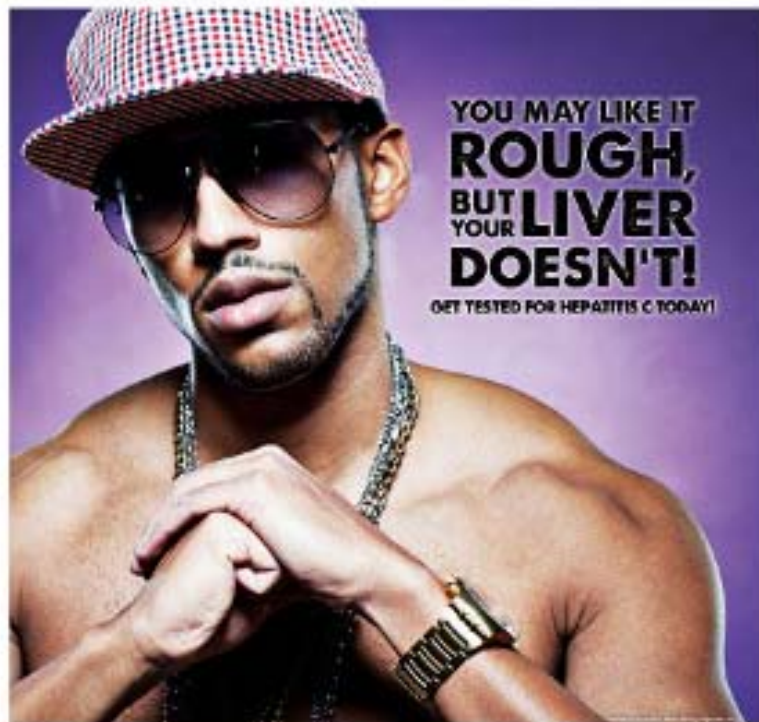
	<p>Hepatitis C is a liver disease caused by infection with hepatitis C virus (HCV). An estimated 2.7 million Americans are infected with HCV; most are younger than 60 years old.</p> <p>Most persons infected with HCV do not know it because they do not have any symptoms.</p> <p>Hepatitis C can cause long-lasting liver damage, even liver cancer.</p>
	<p>You should be tested for hepatitis C if you:</p> <ul style="list-style-type: none"> • Received a blood transfusion, or organ transplant before July 1992 • Ever injected illegal drugs not ordered by a doctor (even many years ago)
	<p>Hepatitis C can be a serious disease, but treatments are available.</p> <p>A blood test can help you learn if you have hepatitis C.</p> <div data-bbox="888 1071 1294 1199">  </div>



1-888-4HEP-CDC (1-888-443-7232) www.cdc.gov/hepatitis







ARE YOU AT RISK FOR HEPATITIS C?

Gay and bisexual men are at increased risk for Hepatitis C if they are involved in high-risk behaviors, such as:

- Sharing needles or other injection drug equipment (even if just once)
- Having unprotected rough sex (including fisting without gloves)
- Having sex with multiple partners
- Previously been diagnosed with a sexually transmitted disease or HIV infection

THERE IS NO VACCINE FOR HEPATITIS C. EARLY DIAGNOSIS AND TREATMENT IS KEY!

At Harlem United we offer free, convenient, and confidential testing for Hepatitis C and HIV. We also provide syringe exchange, medical and social service referrals, and safe injection/disposal information. No appointment is necessary.



Harlem United Testing Services
280 Essex Avenue
Lower Level
New York, NY 10027
Phone: (212) 269-3278

FREE TESTING SERVICES ARE OFFERED:
MONDAY-FRIDAY 10:00 A.M.-4:00 P.M.
1-877-TEST-125
WWW.HARLEMUUNITED.ORG

*For testing information, contact the above phone number.



**WHICH ONE
DESERVES
TO DIE?**

HepatitisB.org

1 in 10 Asian Americans is infected with hepatitis B, the leading cause of liver cancer. But hepatitis B can be treated, even prevented. Get the simple blood test. Stop liver cancer by stopping hepatitis B.

IT'S A HERO. SEE A DOCTOR WHO TESTS FOR HEP B.





Be safe. Be sure. Read the label.

Check your name.

**ABC
Pharmacy**

SMITH, JOHN
123 MAIN STREET
SPRINGFIELD, US 01234

Rx. 587123

PRESCRIBER:
DR. PETER JONES

**TAKE 1 TABLET BY MOUTH
EVERY DAY**

**Check any
warnings.**

DIGITALIS 0.25 MG TABLET

Qty: 30 TABLETS

Date Filled: 01/12 Discard After: 07/12

CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PATIENT FOR WHOM IT WAS PRESCRIBED.

**Check the
directions.**

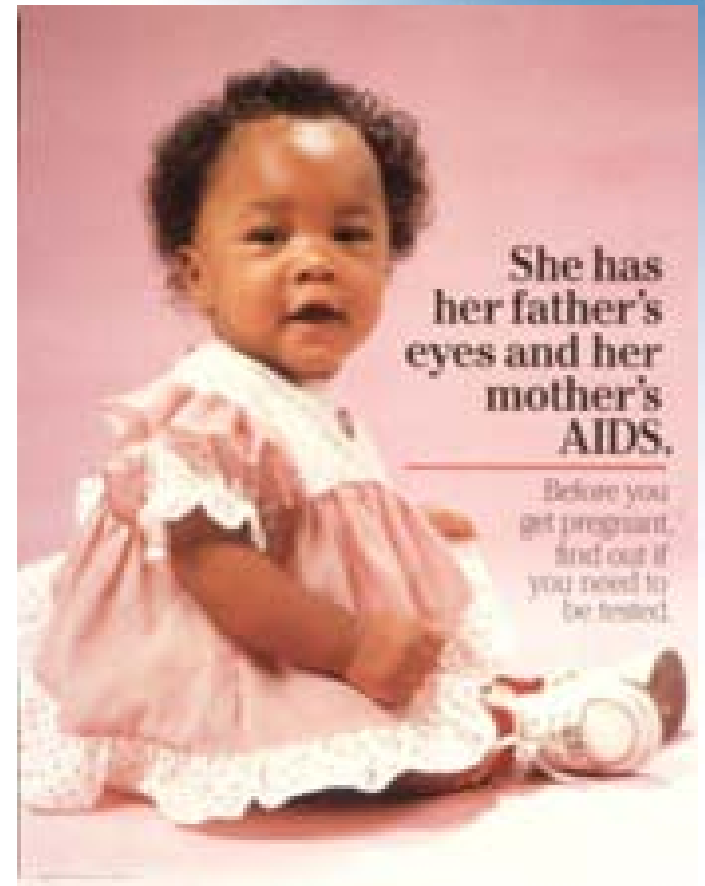
TAKE OR USE THIS EXACTLY AS
DIRECTED. DO NOT SKIP DOSES
OR DISCONTINUE.

**POISON
Help**
1-800-222-1222

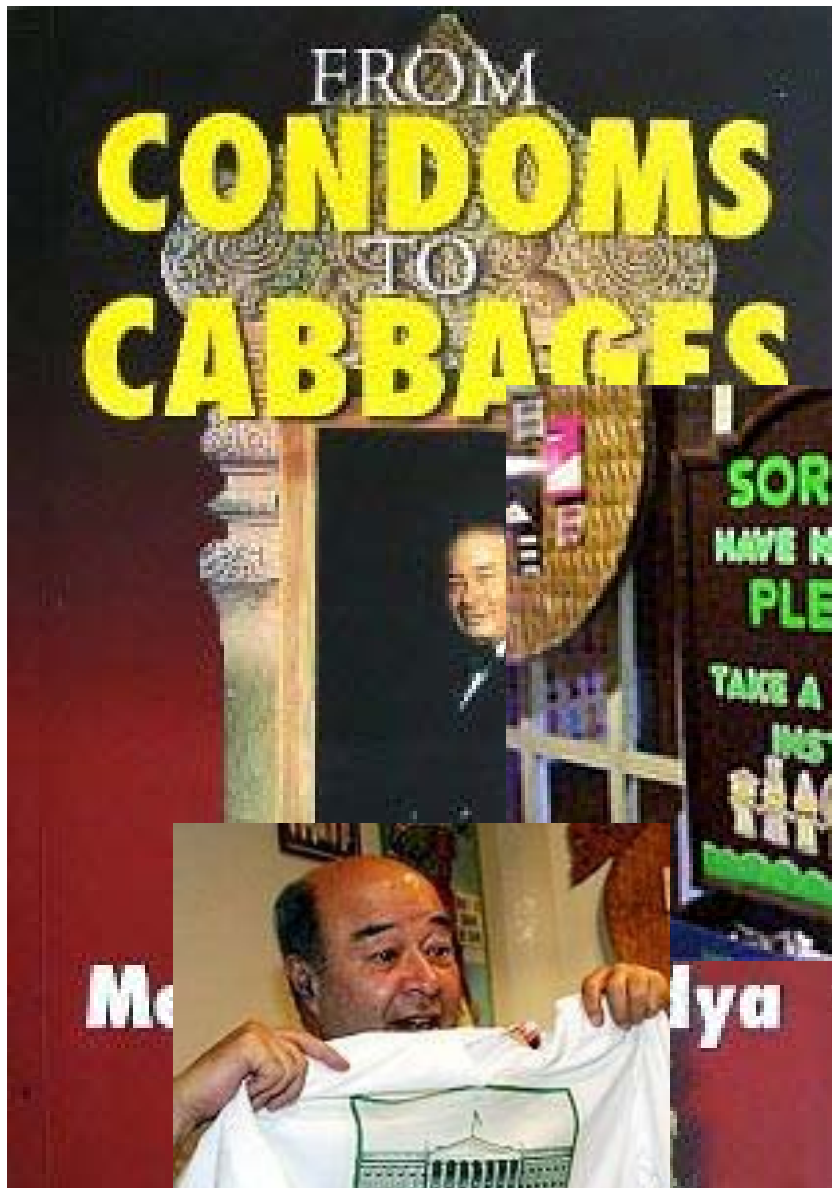
**Did you take the wrong
medicine? Did you take
too much? Call your
Poison Center. Expert
advice is available 24/7.**

For poison prevention tips, visit www.1-800-222-1222.info

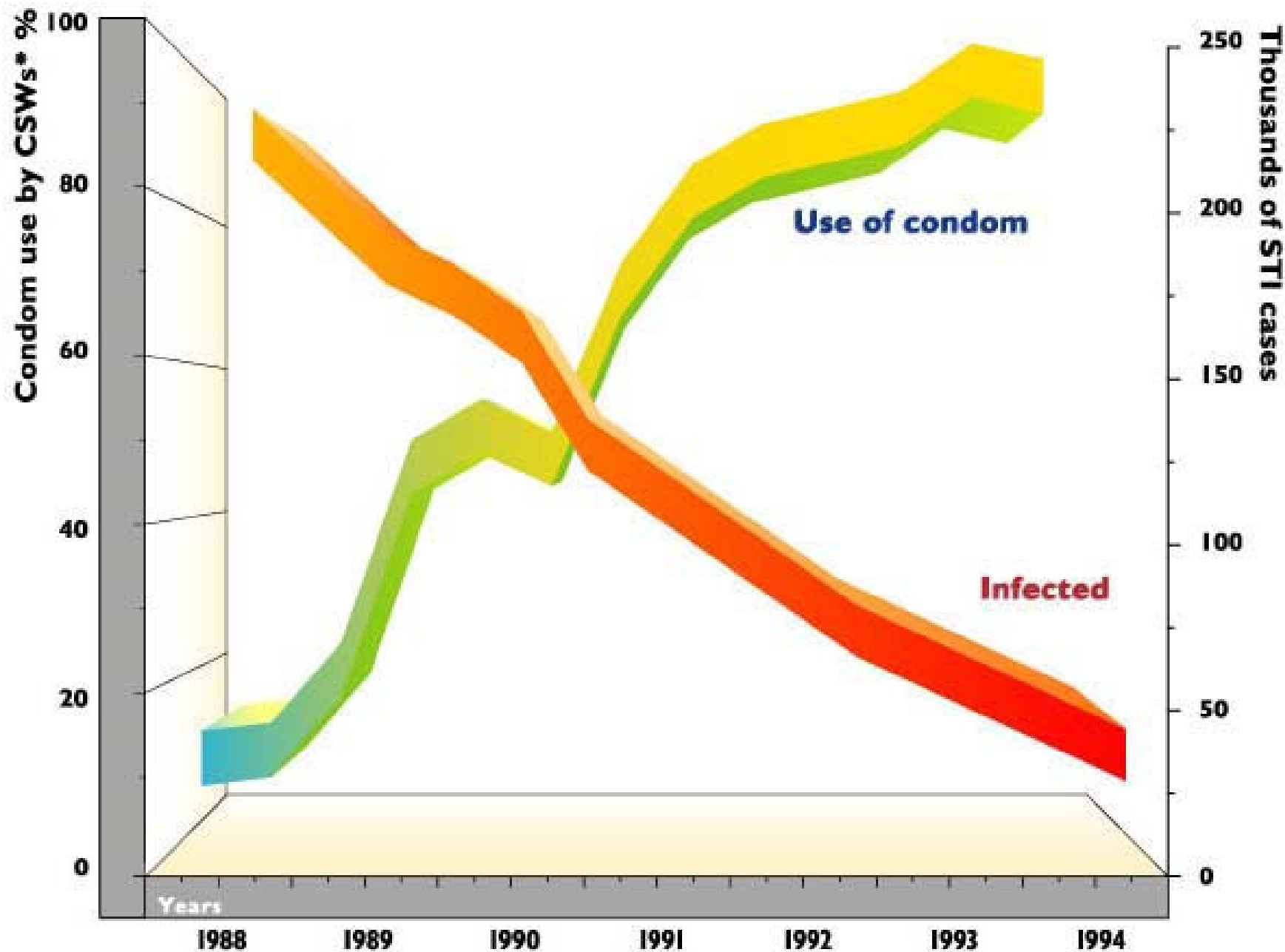












*STI: Sexually Transmitted Infections, *CSW: Commercial Sex Workers

Source: Rojanapithayakom and Hanenberg, 1996

Thailand's talent...for a time

- Humour
- Making private, embarrassing things public and amusing
- Reaching out to targeted individuals and communities
- Making public health fun
- Changing behaviour (condom use/lower infection rate)
- Then...
 - *Giving up*



In Thailand

- After peaking at 143,000 in 1991, the annual number of new cases of HIV infection fell to 19,000 in 2003. That still leaves 604,000 Thais living with HIV or AIDS
- "We have become complacent," says Mechai Viravaidya, (a.k.a. Mr. Condom) [TIME Asia, 12.07.04]
- Removing condom machines from schools [2011]





Influencing people: summary of major issues

- Know your audience
- Devise a creative, engaging campaign
- Make a proposal or offer
- Make the benefits clear
- Negotiate objections or problems
- Offer alternatives
- Reward agreement



Social marketing and public health campaigns: summary of major issues

- Know your audience; research, consult
- Describe the threat/risk vividly
- Make the appeal strongly, stressing benefits
- Make it clear what people should do
- Be creative and original
- Use multiple methods
- Repeat the message
- Research the results



Takeaway messages?

- Safety information for HCPs
- Negotiating
- Social marketing





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