

Manejo y selección de información. Criterios generales

Curso de uso racional del medicamento

La Plata, 2 de octubre de 2006

Albert Figueras



El uso racional

Consiste en la prescripción del medicamento adecuado para el paciente que lo necesite, a la dosis adecuada, durante el tiempo apropiado, y proporcionando información sobre su uso al paciente

medicamento adecuado → **SELECCIÓN**



paciente que lo necesite



¿TRATAMIENTO NO FARMACOLÓGICO?

dosis/duración adecuada → **INDIVIDUALIZACIÓN**



información sobre su uso → **REL. MED-PAC. /
SEGUIMIENTO, RAM**



- definición clara y simple
- en la mayoría de los casos, la complejidad clínica es baja
- pocos medicamentos para cada DX

→ ¿CUÁL ES EL PROBLEMA?

la cadena terapéutica

registro

comercialización

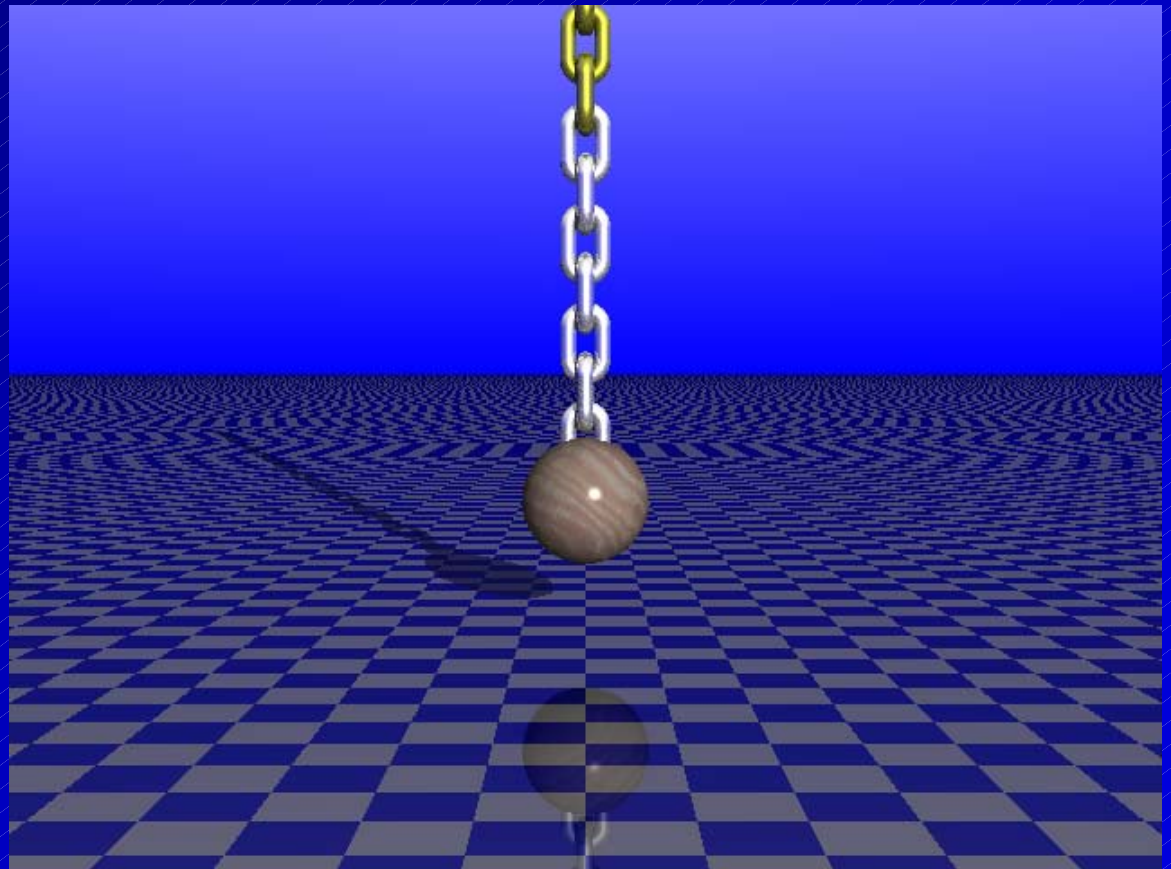
distribución

promoción

prescripción

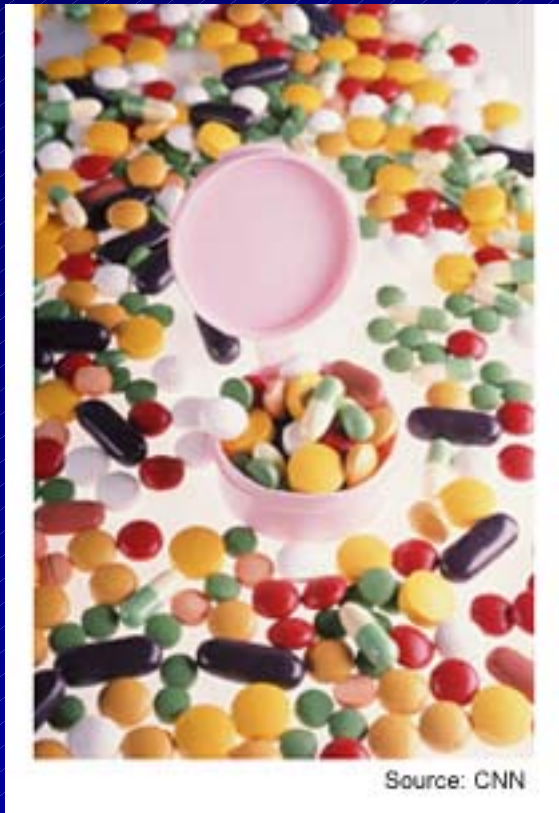
dispensación

utilización



Los problemas del día a día

¿Por qué existe un uso no racional?



1. El nº de medicamentos

- ¿innovaciones?
- ¿todos tienen eficacia?
- etc.



¿Qué aporta de nuevo?
(el problema de la eficacia)



carros y F: otras diferencias

el riesgo asociado al uso de un carro
es similar (Ford = Suzuki)

pero ...

el espectro de RAM asociado a
rofecoxib es diferente al espectro de
RAM asociado a ibuprofeno

(la importancia de la **seguridad**)

carros y F: otras diferencias

la *seguridad* de los carros está bien establecida y los riesgos se conocen pero...

la *seguridad* de los F de reciente comercialización es desconocida

(la importancia de la **farmacovigilancia**)

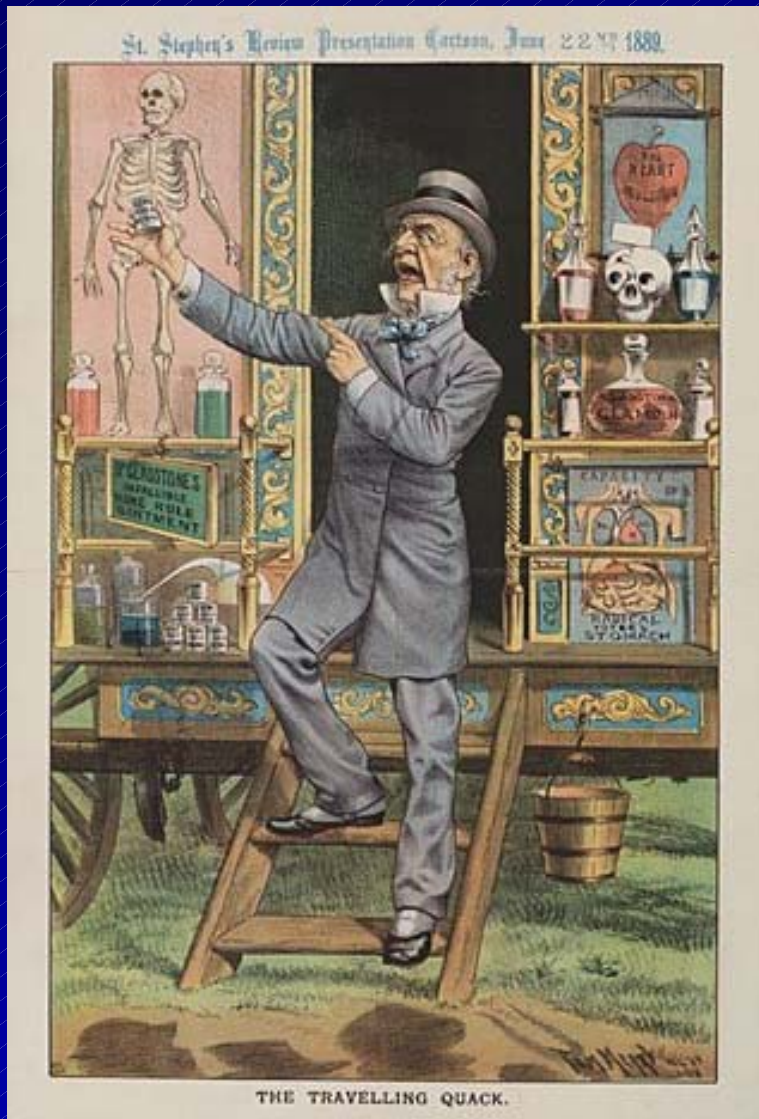


2. La información

“dosis diaria de lectura para mantenerse permanentemente actualizado en el área de conocimiento de cada uno:

19 artículos científicos cada día”

M. Rawlins, NICE, 1999



los representantes
(¿verdaderos Profesores
de terapéutica?)

12 DAYS LEFT 'TIL CHRISTMAS...
Officially Time To Panic!

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<p>AND MANY MORE!</p>		<p>CLICK HERE TO ORDER</p>

el e-mail, los usuarios, etc.



3. El dinero como motor

sobreinformación





Esto no significa que
no sea necesario
escribir más...

(escribir es esencial)

Lo que se requiere es
un buen trabajo
editorial

“trucos” para navegar en el mar de información

- pregunta (objetivos)
- comparador y dosis
- población incluida/excluida y técnicas de “enriquecimiento” (gravedad, comorbilidad)
- duración
- prohibición de algunos tratamientos concomitantes
- variables de medida (*outcomes*) [*surrogate*]
- ...

HARLOT plc: an amalgamation of the world's two oldest professions

David L. Sackett, Andrew D Oxman on behalf of HARLOT plc

Table 1 Stepped care for "me too" drugs or devices and useless screening tests

Step	Bias to be exploited	Strategies for applying this bias (while hiding your intentions and actions)
E—Zee-me-Too Protocols		
1	Selective, non-systematic reviews	Cite just those reports that support your product, proposal, or policy (and slag all your competitors)
2	Substituting placebos for established effective treatment	Invoke fallacious "placebo effects" and "assay-sensitivity" arguments in order to avoid head to head comparisons
3	Unconcealed allocation to ensure better prognoses in "experimental" patients	Provide updatable wall posters for displaying the group to which the next patient will be allocated, see-through allocation envelope systems, etc
4	"Mini-max" manipulation of your competitor's product	Give insufficient ("mini") doses of your competitor's product, accompanied by scary ("max") warnings about its (but not yours) side effects and toxicity
5	Incorporating irrelevant surrogate and composite end points	Concoct an invalid inflation of event rates (especially among control patients)
6	"Shifting the goal posts" for "superiority" and "non-inferiority"	Require trivially better outcomes for "superiority" but massively worse outcomes for "inferiority"

Sobre los resultados

- análisis estadístico realizado por el promotor
- resultados negativos → tendencia a no publicar
- magia estadística (azul puede ser verde... o rosado)
- análisis de subgrupos (y subgrupos de subgrupos)
- presentación parcial...

Existen las *guidelines CONSORT*, pero...

Sobre las revistas

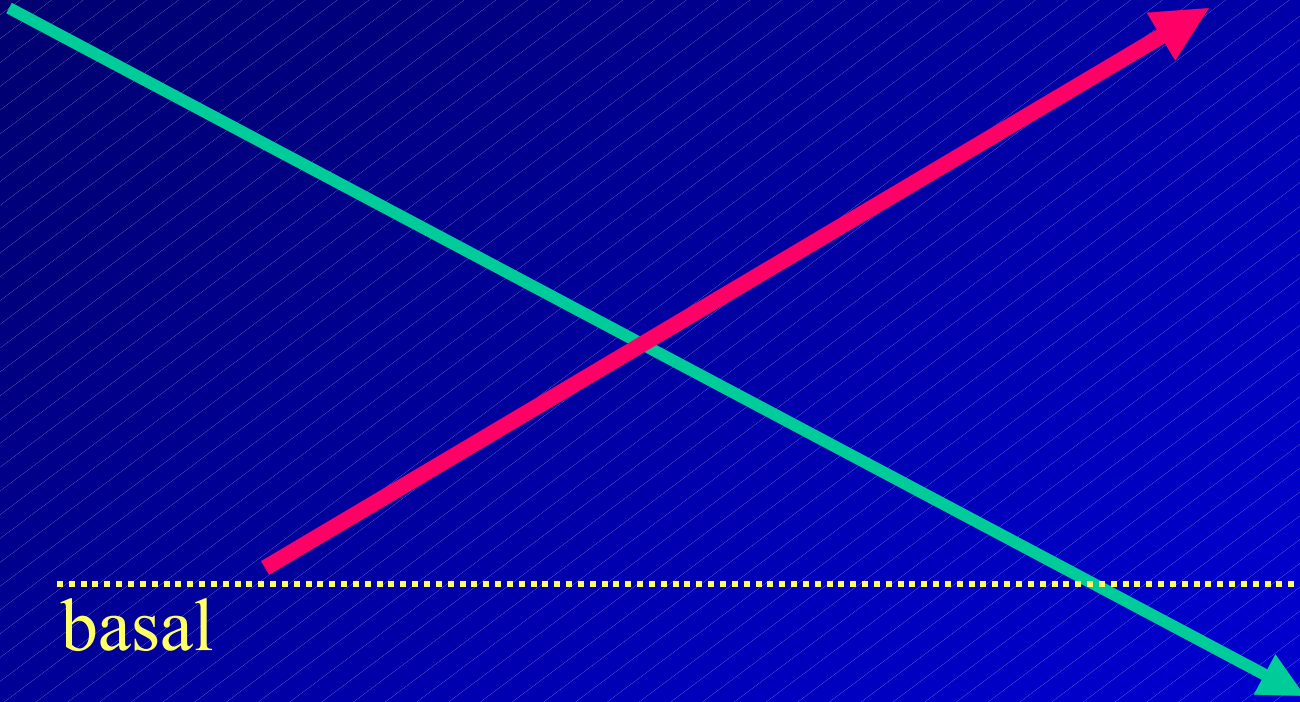
- presiones al comité editorial

Marcia Angell (NEJM)

Richard Smith (BMJ)

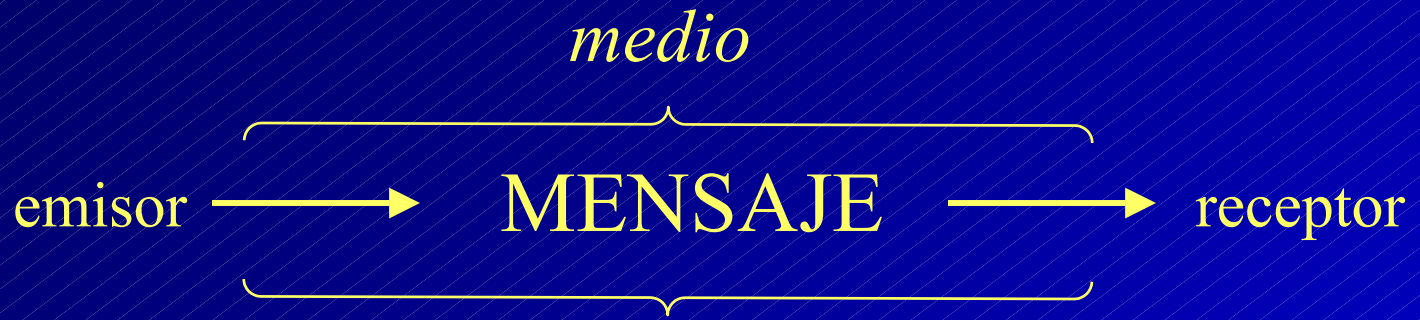
Richard Horton (The Lancet)

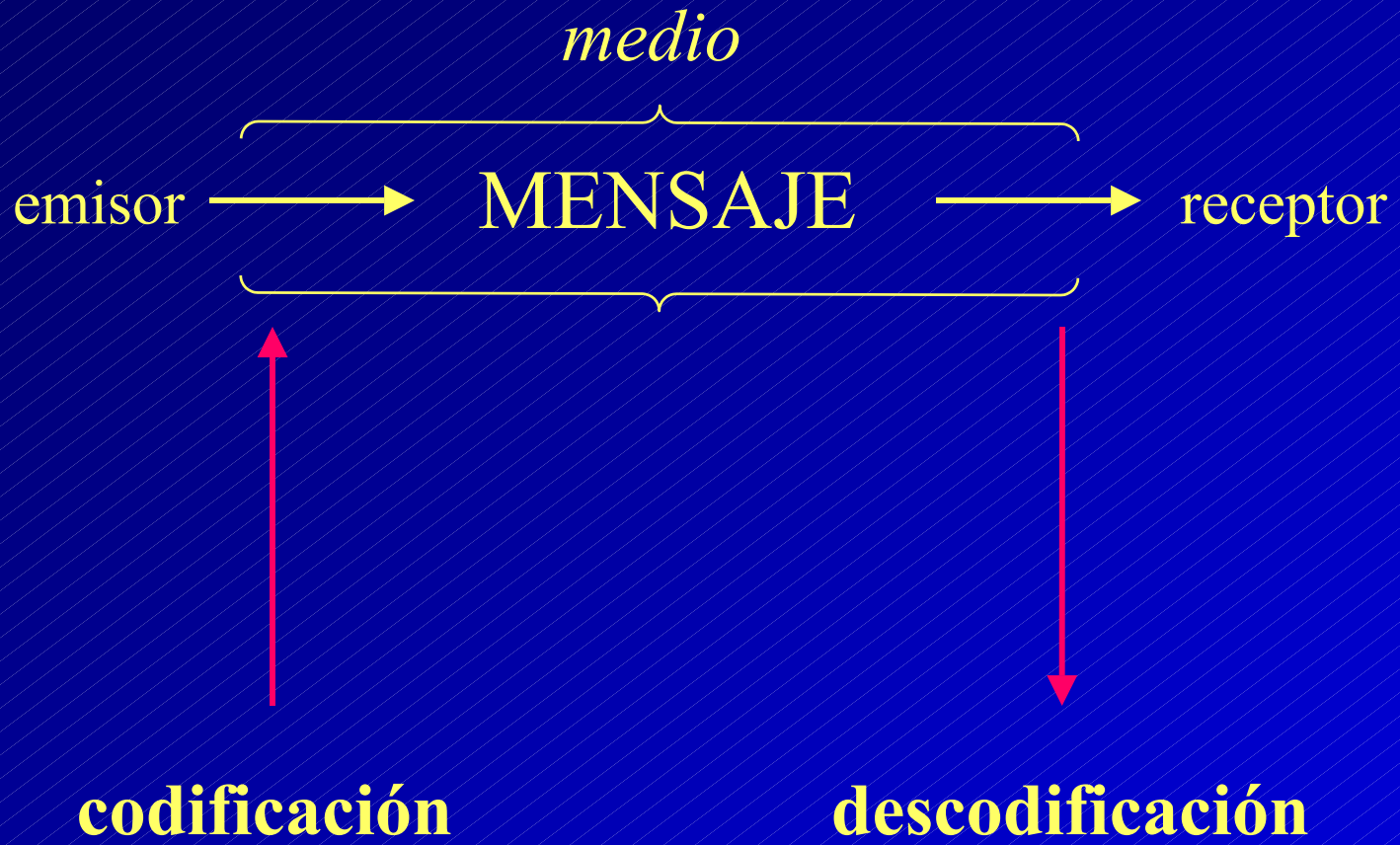
ansiedad, presiones

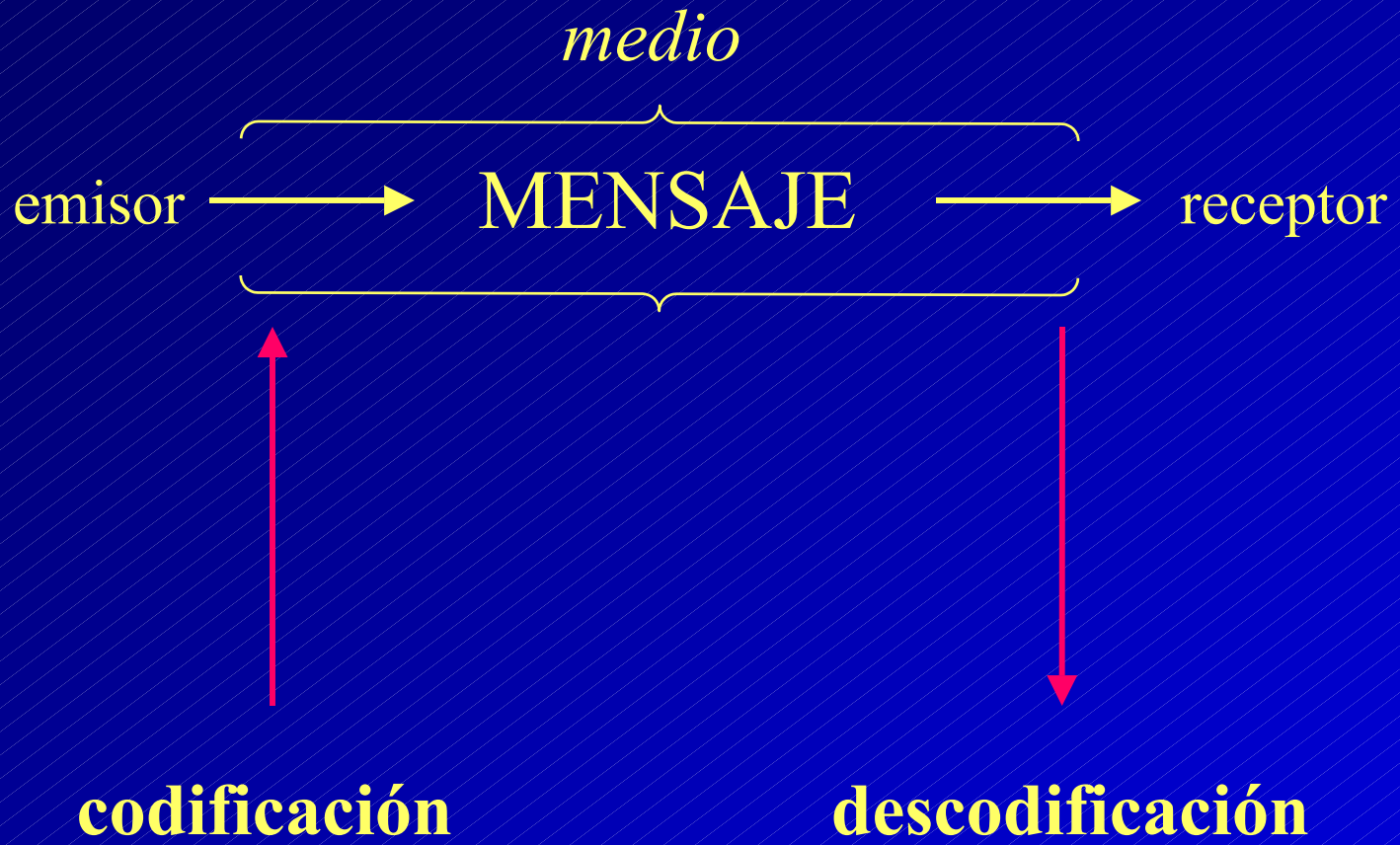


basal

nº de moléculas en
la pipeline







x n mensajes

La descodificación puede verse afectada por:

- interferencias (colegas)
- descodificación parcial (*abstracts*)
- suposiciones (no se detalla, pero...)
- confusiones (exceso de información)

La era de los eufemismos

“tendencia” \equiv “significación estadística”

$p < 0, \dots$ / OR, etc. \equiv estadísticamente bien hecho

“ensayo clínico...” \rightarrow “conclusivo”

“investigador” \equiv “colector de datos y agente de ventas”

“seguridad” \equiv “toxicidad y efectos indeseados”

además de lo anterior:

cualquier mensaje repetido muchas veces se confunde como una verdad

del *primum non nocere*

al

primum beneficiare

Hoy se comercializa por angustia, compulsivamente

Se está perdiendo la credibilidad

“Todo” es tanto, que significa “nada”

¿Estamos caminando hacia el colapso? (del sistema,
del usuario... de las empresas)

Una solución:

seleccionar

filtrar

leer

investigar

... sin ansiedad y con convicción

Prescribir siguiendo los principios del uso racional

Enseñar y diseminar el hábito de la prescripción
racional

Volver (y revalorizar) la inteligencia clínica

de la *medicina basada en pruebas*
a la
medicina basada en la inteligencia

First, I ask whether the patient needs any NSAID on a chronic basis

vascular risk. However, even in low doses, aspirin can cause macroscopic ulcerations, and a COX-2 selective NSAID can potentially (based on animal studies) slow the healing of these ulcerations and perhaps permit them to evolve into a true ulcer or bleed. The CLASS study suggests that some of the gastrointestinal-protective benefits of a COX-2 selective drug may be lost when given with low-dose aspirin. But I believe this combina-

■ REFERENCES

1. **Mukherjee D, Nissen SE, Topol EJ.** Risk of cardiovascular events associated with selective COX-2 inhibitors. *JAMA* 2001; 286:954-959.
2. **Lipani J.** COX-2 inhibitors and cardiovascular risk. The data are inconclusive, and these drugs are needed. *Cleve Clin J Med* 2001; 68:961-962.
3. **Mukherjee D, Nissen SE, Topol EJ.** COX-2 inhibitors and cardiovascular risk. We defend our data and suggest caution. *Cleve Clin J Med* 2001; 68:963-964.
4. **Bombardier C, Laine L, Reicin A, et al.** Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis. *N Engl J Med* 2000; 343:1520-1528.
5. **Silverstein FE, Faich G, Goldstein JL, et al.** Gastrointestinal toxicity with celecoxib vs nonsteroidal anti-inflammatory drugs for osteoarthritis and rheumatoid arthritis. The

I also consider other effective measures for limiting cardiovascular disease, such as maximized lipid control, maximized blood pressure control, and angiotensin-converting enzyme inhibitors and beta-blockers following myocardial infarction. These measures are underutilized.

I applaud the willingness of Drs. Lipani, Mukherjee, Nissen, and Topol to put in print their thoughts on this thorny issue. ■

CLASS study: a randomized controlled trial. *JAMA* 2000; 284:1247-1255.

6. **Food and Drug Administration.** Cardiovascular safety review. Rockville, Md: Food and Drug Administration; 2001. Available at: http://www.fda.gov/ohrms/dockets/ad/01/briefing/3677b2_06_cardio.pdf.
7. **Steering Committee of the Physicians' Research Study Group.** Final report on the aspirin component of the ongoing Physicians Health Study. *N Engl J Med* 1989; 321:129-135.
8. **Mandell BF.** And then there were two: the cyclooxygenase story. Can the expectations be fulfilled. *J Clin Rheumatol* 1996; 2:173-175.

ADDRESS: Brian F. Mandell, MD, PhD, FACR, Cleveland Clinic Journal of Medicine, NA32, The Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, OH 44195; e-mail ccm@cdf.org.



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Stronger sanctions needed against companies that suppress data

Bob Roehr *Washington, DC*

"Suppression of science is not an anomaly but is typical of, and produced by, the current economic, political, and social situation, and that is—money talks. It is the system; it is not just a few bad apples," Dr David Egilman, a professor of medicine at Brown University, Providence, Rhode Island, told a conference this week.

Although money was important, there were also other forces at work, he said. "It is broader than money, it's ideology and power. Ideology is a much larger bias than money—much harder to ferret out and think through," he added.

His words found a ready audience among those attending the one day conference *Conflicted Science: Corporate and Political Influence on Science-based Policymaking*, held in Washington, DC, this week. It was sponsored by the Center for

Science in the Public Interest, a US consumer advocacy organisation for health and nutrition.

Dr Egilman said ethical companies could not compete with the unethical ones because "the penalties for getting caught never approach the cost advantages of increased profit, and there rarely are criminal penalties."

He believes that part of the reform package must be to press criminal charges against industry leaders who suppress data that results in death. "And even if they get off, a trial or two will really clean the act up."

Dr Arnold Relman, emeritus editor of the *New England Journal of Medicine*, lamented that the dominant role that academic research institutions played in conducting clinical trials, as recently as the 1970s, had "largely been coopted by the pharmaceutical industry."

"The rhetoric from the acad-

emy [academic community] claims that their collaboration with the industry really serves the public interest because it favours the rapid transfer of basic science into the marketplace. But they do not acknowledge that scientific collaboration does not have to include financial arrangements that compromise the integrity and independence [of those institutions]," he said.

Keynote speaker Brian Baird, a Democratic Congressman from Washington state, criticised the Bush administration and Republican leadership in Congress, charging that they are conducting a "full assault on scientific integrity that is a danger not only to the enterprise of science, but ultimately to the value of inquiry, debate, and decision making that underlie the democratic process."

Mr Baird, who was first elected in 1999, is also a licensed clinical psychologist and former academic researcher. He chastised the scientific community as well, saying that its response had been "pathetic, self serving and by and large craven."

Far too often researchers using government appropriations do not stop to think that it is someone else's hard earned money. Too often that research is "esoteric, largely unmeasurable, with no clear benefits to society, yet concludes with the obligatory sentence, 'further research is necessary.'" He challenged the audience to seriously examine their own actions.

"The scientific community has been politically asleep for too long," he said. He urged them to defend the integrity of the scientific process and also to get involved in politics at the grassroots level.

Although critics of "checkbook science" were well represented at the conference, fewer participants offered detailed remedies.

One common theme at the conference was the need for greater transparency of information in everything from the financial interests of investigators and funding sources, to a registry of all clinical trials, to comparative rather than placebo controlled trials, to publication of negative data. □