Europe's opportunity to open up drug regulation

Reflexión sobre el papel de las agencias reguladoras

Cris: ...si LA EMA lo ha autorizado, ya no hay “nada más que decir”

GOBIERNO DE ESPAÑA

MINISTERIO DE SANIDAD Y POLÍTICA SOCIAL

GENESIS

Sociedad Española de Farmacia Hospitalaria

JUNTA DE ANDALUCIA

Servicio Andaluz de Salud

CONSEJERÍA DE SALUD

HOSPITALES UNIVERSITARIOS

Virgen del Rocío

J. Manuel: conflicto de intereses

Dependencia económica

Secretismo.


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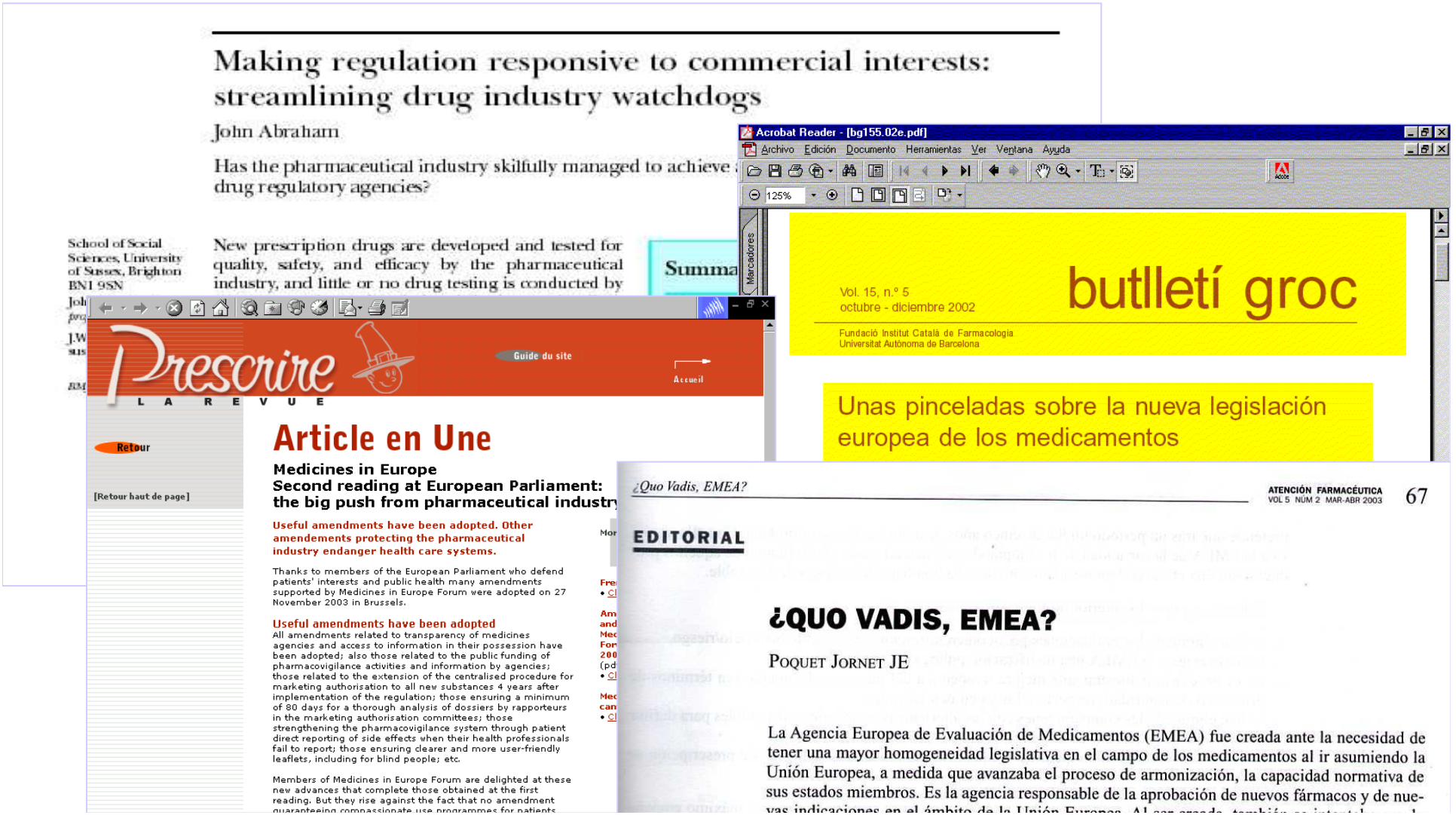
RAISE YOUR HAND IF YOU HAVE ANY FINANCIAL CONFLICTS OF INTEREST IN THIS DECISION...
FDA DRUG DECISION PANEL
CONCEPT-MIKE ADAMS -ART-DAN BERGER- WWW.NATURALNEWS.COM

El debate europeo

Las voces críticas sobre la Agencias reguladora EMEA



Making regulation responsive to commercial interests: streamlining drug industry watchdogs

John Abraham

Has the pharmaceutical industry skilfully managed to achieve
drug regulatory agencies?

School of Social Sciences, University of Sussex, Brighton BN1 9SN

New prescription drugs are developed and tested for quality, safety, and efficacy by the pharmaceutical industry, and little or no drug testing is conducted by

Summa

Acrobat Reader - [bg155.02e.pdf]

Archivo Edición Documento Herramientas Ver Ventana Ayuda

125%

Marcadores

butlletí groc

Vol. 15, n.º 5
octubre - diciembre 2002

Fundació Institut Català de Farmacologia
Universitat Autònoma de Barcelona

Unas pinceladas sobre la nueva legislación europea de los medicamentos

Prescrire

L A R E V U E

Guide du site

Accueil

Retour

[Retour haut de page]

Article en Une

Medicines in Europe
Second reading at European Parliament:
the big push from pharmaceutical industry

Useful amendements have been adopted. Other amendements protecting the pharmaceutical industry endanger health care systems.

Thanks to members of the European Parliament who defend patients' interests and public health many amendments supported by Medicines in Europe Forum were adopted on 27 November 2003 in Brussels.

Useful amendements have been adopted

All amendments related to transparency of medicines agencies and access to information in their possession have been adopted; also those related to the public funding of pharmacovigilance activities and information by agencies; those related to the extension of the centralised procedure for marketing authorisation to all new substances 4 years after implementation of the regulation; those ensuring a minimum of 80 days for a thorough analysis of dossiers by rapporteurs in the marketing authorisation committees; those strengthening the pharmacovigilance system through patient direct reporting of side effects when their health professionals fail to report; those ensuring clearer and more user-friendly leaflets, including for blind people; etc.

Members of Medicines in Europe Forum are delighted at these new advances that complete those obtained at the first reading. But they rise against the fact that no amendment

¿Quo Vadis, EMEA?

ATENCIÓN FARMACÉUTICA
VOL 5 NÚM 2 MAR-ABR 2003

67

EDITORIAL

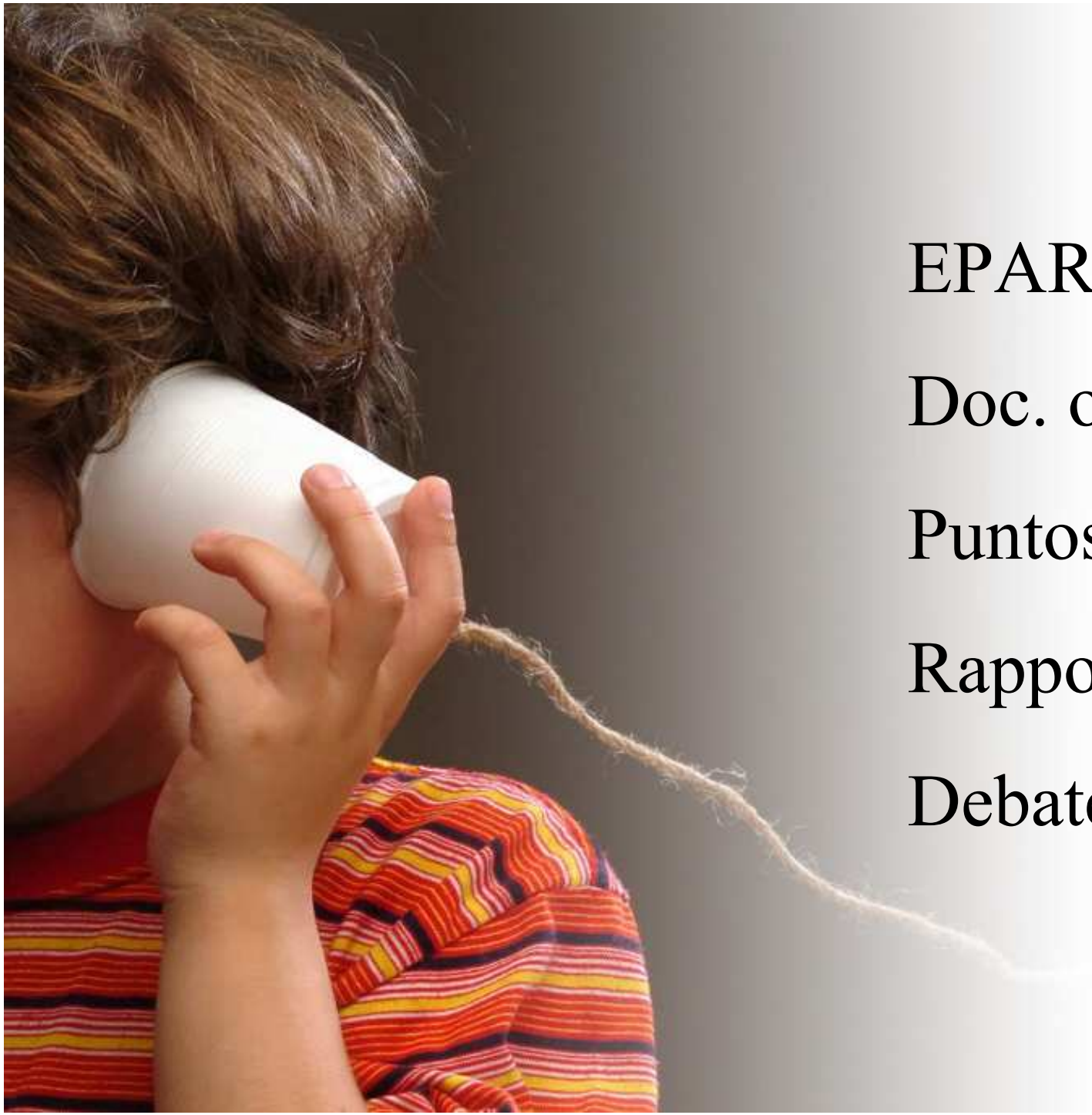
¿QUO VADIS, EMEA?

POQUET JORNET JE

La Agencia Europea de Evaluación de Medicamentos (EMEA) fue creada ante la necesidad de tener una mayor homogeneidad legislativa en el campo de los medicamentos al ir asumiendo la Unión Europea, a medida que avanzaba el proceso de armonización, la capacidad normativa de sus estados miembros. Es la agencia responsable de la aprobación de nuevos fármacos y de nue-

- Creation in 1995
- **400 employees**
- **4.000 experts national agencies**

- Creation in 1938
- **10.000 employees**
- **CDER: 2.500 employees**



EPAR

Doc. original

Puntos Críticos

Rappourteurs

Debate

Any loss of profits could reduce investment in research so in the end it will create a **disadvantage for patients** too, who will have **fewer drugs.**

Victoria: EPAR no contempla alternativas

Natalia y Mª José: Escaso posicionamiento

¿Placebo o tratamiento activo?

I

(Actos cuya publicación es una condición para su aplicabilidad)

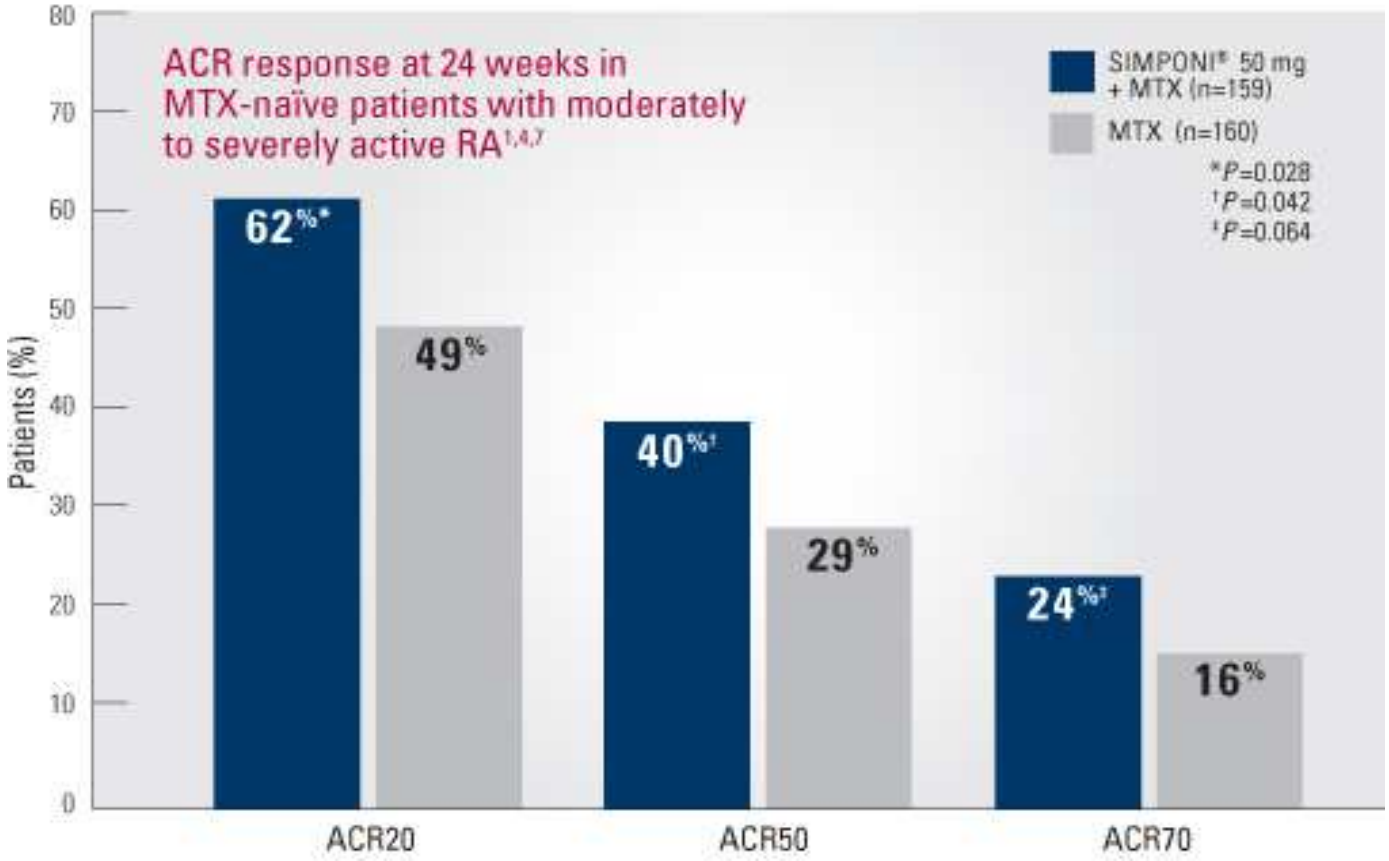
REGLAMENTO (CE) Nº 726/2004 DEL PARLAMENTO EUROPEO Y DEL CONSEJO

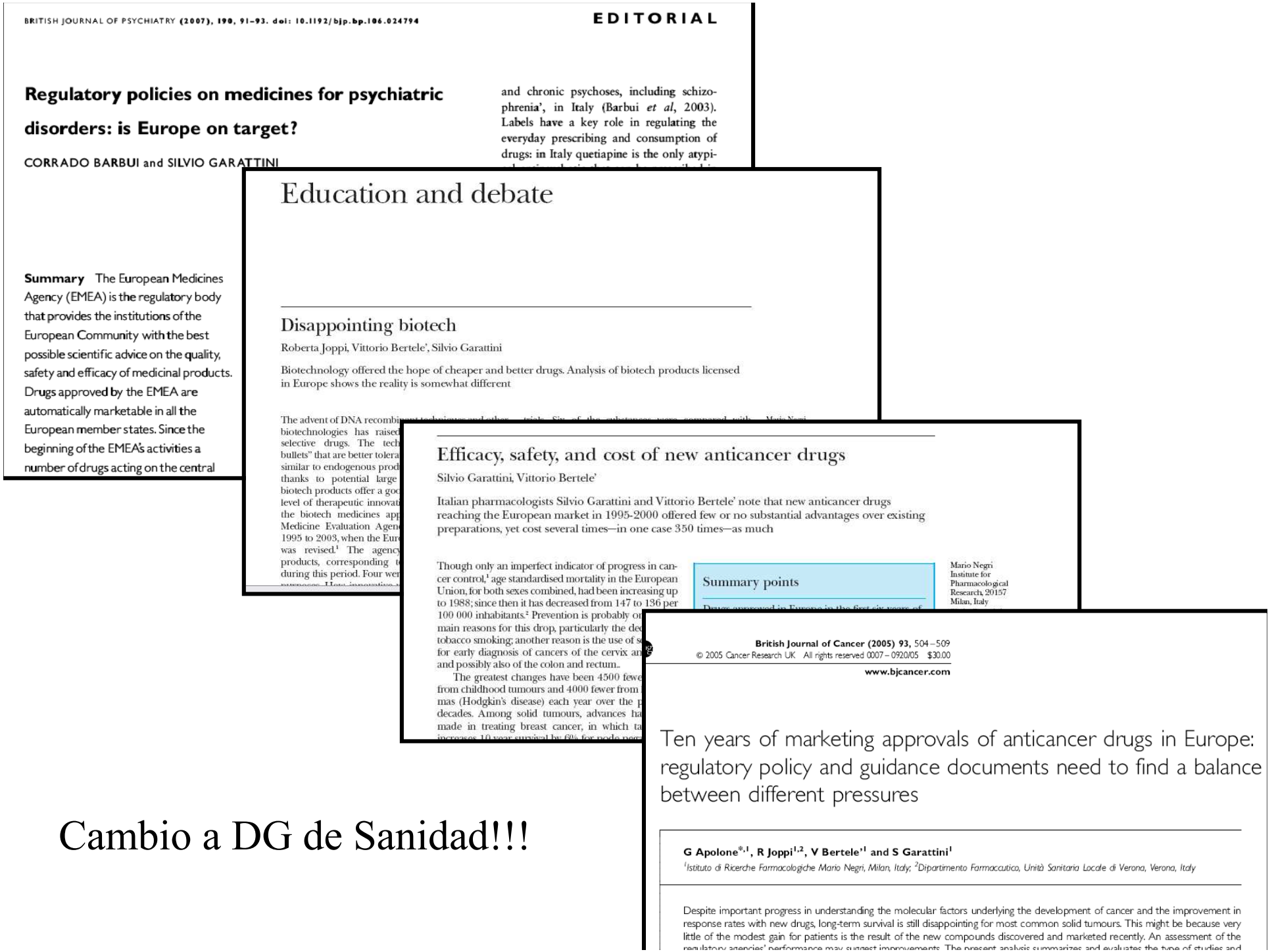
de 31 de marzo de 2004

por el que se establecen procedimientos comunitarios para la autorización y el control de los medicamentos de uso humano y veterinario y por el que se crea la Agencia Europea de Medicamentos

(13) En interés de la salud pública, las decisiones de conceder una autorización en el marco del procedimiento centralizado deben adoptarse a partir de criterios científicos objetivos sobre la calidad, la seguridad y la eficacia del medicamento de que se trate, excluyendo cualquier consideración económica o de otro tipo. No obstante, debe darse a los Estados miembros la posibilidad, con carácter excepcional, de prohibir la utilización en su territorio de medicamentos de uso humano que atenten contra los principios de orden público o de moralidad pública, definidos objetivamente. Además, un medicamento vete-

GO-BEFORE™ ACR response at 24 weeks[1,4,7]





BRITISH JOURNAL OF PSYCHIATRY (2007), 190, 91–93. doi: 10.1192/bjp.bp.106.024794

EDITORIAL

Regulatory policies on medicines for psychiatric disorders: is Europe on target?

CORRADO BARBUI and SILVIO GARATTINI

Summary The European Medicines Agency (EMEA) is the regulatory body that provides the institutions of the European Community with the best possible scientific advice on the quality, safety and efficacy of medicinal products. Drugs approved by the EMEA are automatically marketable in all the European member states. Since the beginning of the EMEA's activities a number of drugs acting on the central

and chronic psychoses, including schizophrenia', in Italy (Barbui *et al*, 2003). Labels have a key role in regulating the everyday prescribing and consumption of drugs: in Italy quetiapine is the only atypi-

Education and debate

Disappointing biotech

Roberta Joppi, Vittorio Bertele', Silvio Garattini

Biotechnology offered the hope of cheaper and better drugs. Analysis of biotech products licensed in Europe shows the reality is somewhat different

The advent of DNA recombi
biotechnologies has raised
selective drugs. The tech
bullets" that are better tolera
similar to endogenous prod
thanks to potential large
biotech products offer a goo
level of therapeutic innovat
the biotech medicines app
Medicine Evaluation Agen
1995 to 2003, when the Eur
was revised.[1] The agency
products, corresponding t
during this period. Four wer

Efficacy, safety, and cost of new anticancer drugs

Silvio Garattini, Vittorio Bertele'

Italian pharmacologists Silvio Garattini and Vittorio Bertele' note that new anticancer drugs reaching the European market in 1995-2000 offered few or no substantial advantages over existing preparations, yet cost several times—in one case 350 times—as much

Though only an imperfect indicator of progress in cancer control,[1] age standardised mortality in the European Union, for both sexes combined, had been increasing up to 1988; since then it has decreased from 147 to 136 per 100 000 inhabitants.[2] Prevention is probably o
main reasons for this drop, particularly the de
tobacco smoking; another reason is the use of s
for early diagnosis of cancers of the cervix an
and possibly also of the colon and rectum..

The greatest changes have been 4500 fewe
from childhood tumours and 4000 fewer from
mas (Hodgkin's disease) each year over the p
decades. Among solid tumours, advances ha
made in treating breast cancer, in which ta
increases 10 year survival by 6% for node pos

Summary points

Mario Negri
Institute for
Pharmacological
Research, 20157
Milan, Italy

British Journal of Cancer (2005) 93, 504–509
© 2005 Cancer Research UK All rights reserved 0007–0920/05 $30.00
www.bjcancer.com

Ten years of marketing approvals of anticancer drugs in Europe: regulatory policy and guidance documents need to find a balance between different pressures

G Apolone*,[1], R Joppi[1,2], V Bertele'[1] and S Garattini[1]

[1]Istituto di Ricerche Farmacologiche Mario Negri, Milan, Italy; [2]Dipartimento Farmaceutico, Unità Sanitaria Locale di Verona, Verona, Italy

Despite important progress in understanding the molecular factors underlying the development of cancer and the improvement in response rates with new drugs, long-term survival is still disappointing for most common solid tumours. This might be because very little of the modest gain for patients is the result of the new compounds discovered and marketed recently. An assessment of the regulatory agencies' performance may suggest improvements. The present analysis summarizes and evaluates the type of studies and

Cambio a DG de Sanidad!!!

In All Fairness

A New FDA?

With a Commissioner now in place, hope is rising that Americans will finally get the kind of FDA we deserve. That will only happen, however, with bold, decisive leadership. The FDA he inherits can't keep pace with unprecedented advances in medical technology. The Commissioner not only must modernize a thoroughly outdated agency, he must confront a bureaucratic culture which encourages FDA to constantly insert itself in the middle of the doctor-patient relationship.

With the number of breakthrough medical therapies released this year nearing an all-time low, FDA's first priority should be overhauling its overcautious and inflexible review process. Make no mistake, unnecessary approval delays have human costs. Rigid procedures, endless data requests, and the pursuit of absolutely risk-free products keep new treatments bottled up at FDA while radically ill patients wait, suffer, and often die. Shouldn't our government put medicines, once they've been judged safe, into the hands of doctors and allow them and their patients, not FDA, to make choices?

675 Lobbyists vs 435 congresistas USA

Retos para el sistema sanitario

- Comparar el nuevo medicamento con los existentes. Definir su papel en terapéutica.
- Valorar las aportaciones del nuevo medicamento en términos de beneficio clínico
- Valorar la relación coste-efectividad e impacto presupuestario.
- Identificar subgrupos de pacientes que obtengan mejor relación coste-efectividad

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

JUNE 3, 2010

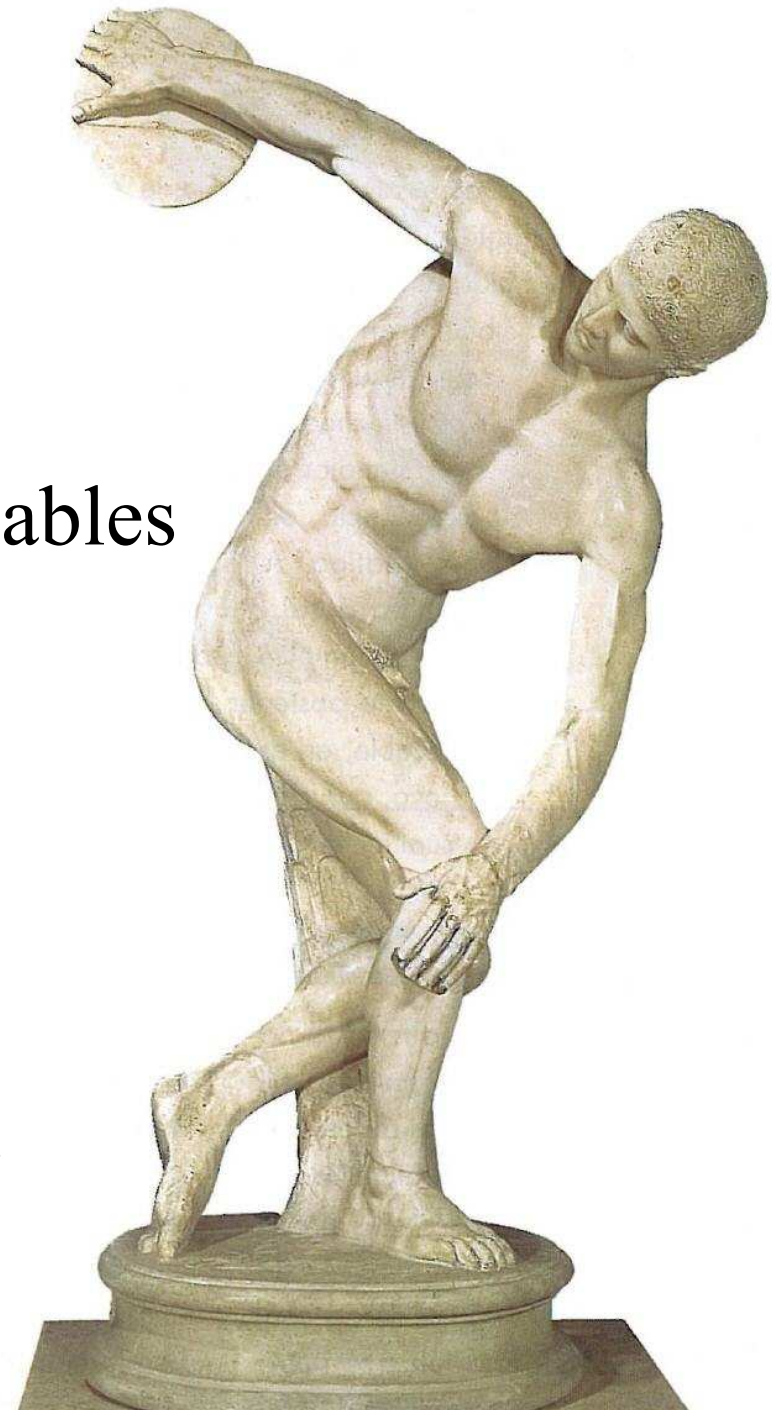
Incentives for Drug Development — The Curious Case of Colchicine

Clara: sorpresa FDA.

Ana: ridículo...bucodispersables

Conchi: picaresca.

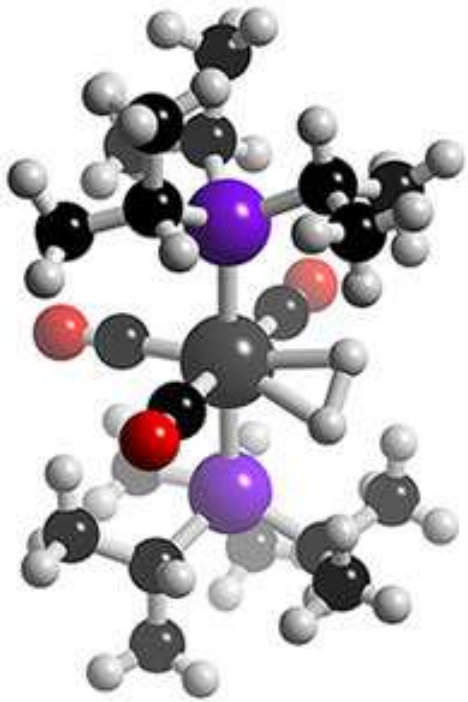
María: víctima del sistema.



Incentivar la innovación terapéutica.

Nuevas indicaciones no premiadas (no estandarizar).

Manuela: revisión de precio, nuevas indicaciones.



INDICATIONS AND USAGE

GLEEVEC is indicated for the treatment of patients with chronic myeloid leukemia (CML) in blas crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy.

----------INDICATIONS AND USAGE----------

Gleevec is a kinase inhibitor indicated for the treatment of:

- Newly diagnosed adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
- Patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy (1.2)
- Pediatric patients with Ph+ CML in chronic phase who are newly diagnosed or whose disease has recurred after stem cell transplant or who are resistant to interferon-alpha therapy. There are no controlled trials in pediatric patients demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival (1.3)
- Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (1.4)
- Adult patients with myelodysplastic/ myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements (1.5)
- Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown (1.6)
- Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRα fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRα fusion kinase negative or unknown (1.7)
- Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP) (1.8)
- Patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST). (1.9)
- Adjuvant treatment of adult patients following resection of Kit (CD117) positive GIST (1.10)

Fármacos sin interés comercial: EECC independientes.

Vitamina D

Levofloxacino

EPO + Fe

Colistina

SSH

caiber

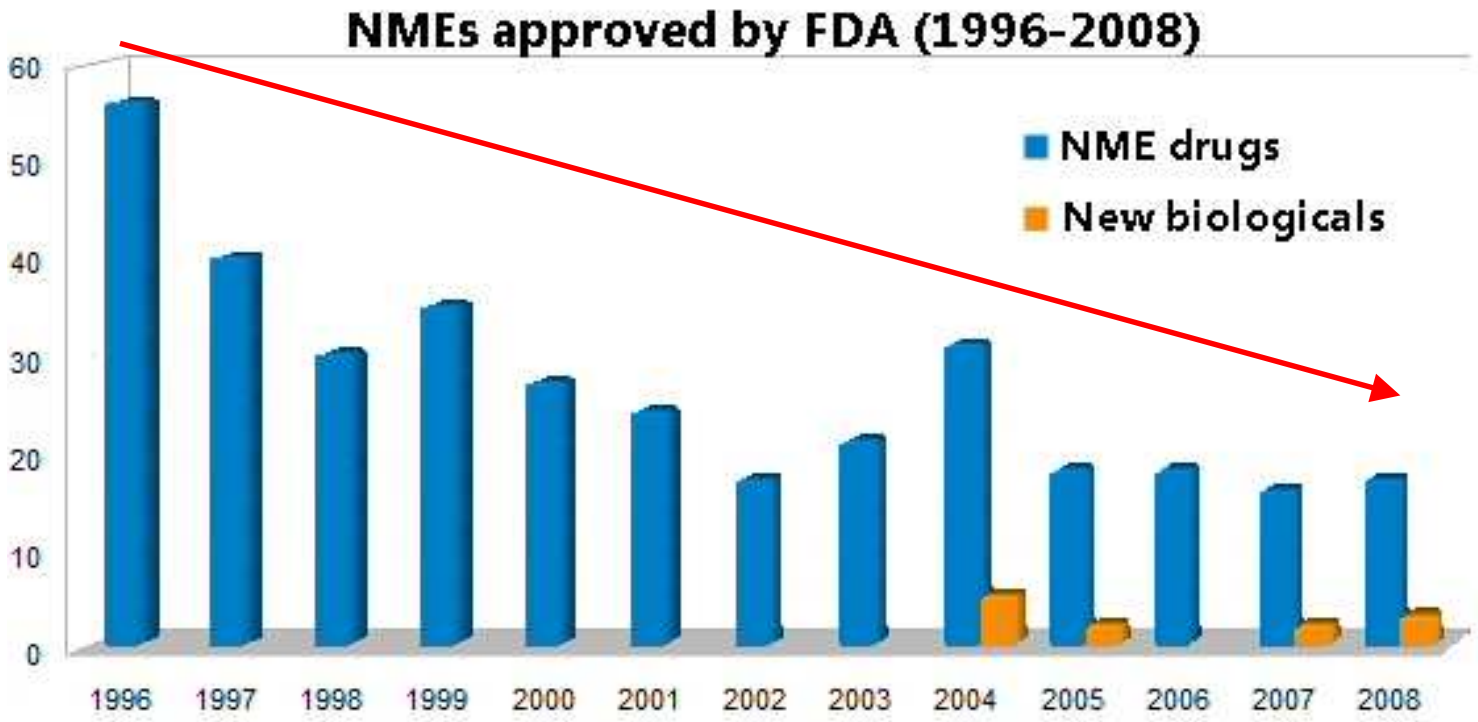
PLATAFORMA ESPAÑOLA DE ENSAYOS CLÍNICOS

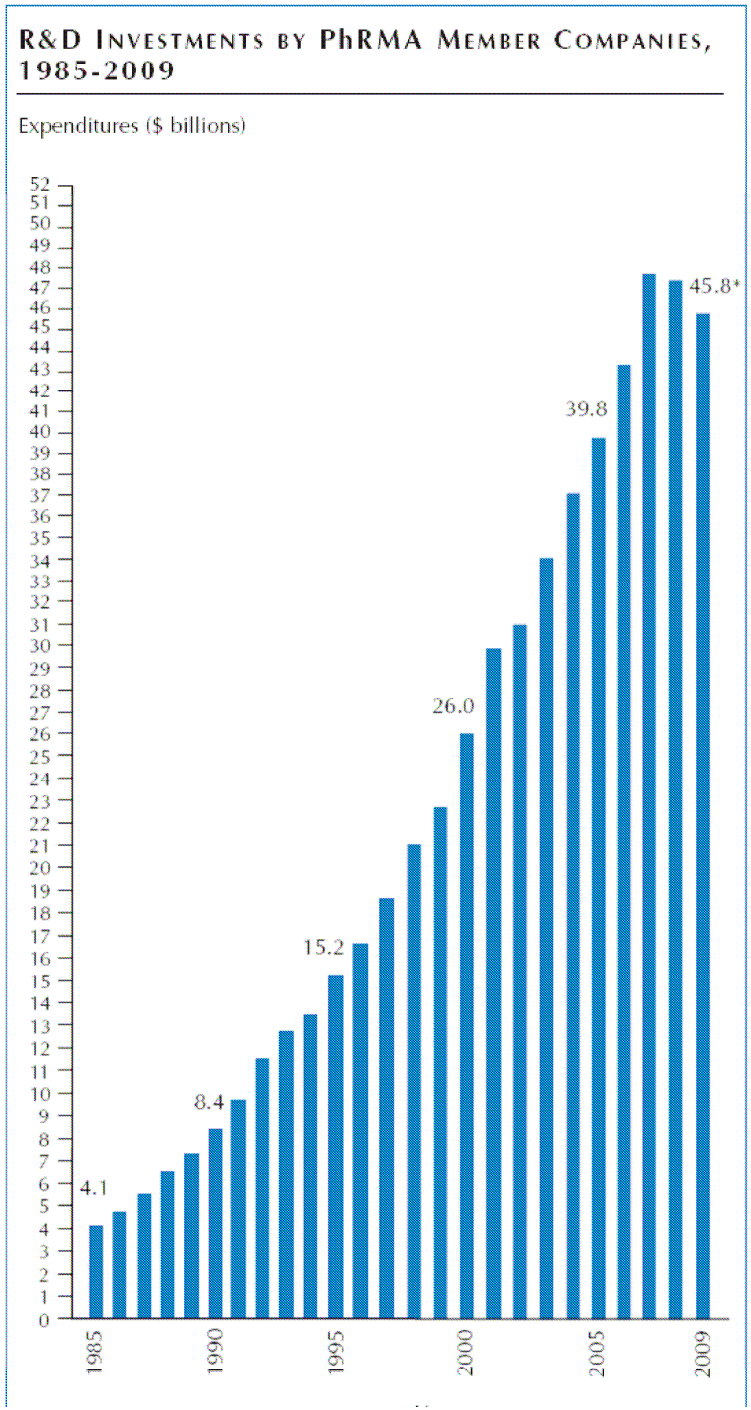
Noemí: el único cambio que van a experimentar los pacientes es un empeoramiento considerable en su economía, los que puedan hacer frente al incremento del precio.

J. Manuel: fraude legal

David: fragilidad del sistema.

Amanda: legalidad vs interés público


NMEs approved by FDA (1996-2008)
60
50
40
30
20
10
0
NME drugs
New biologicals
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008



Either companies are finding it increasingly difficult to find new drugs, or that commercial pressure is also driving them towards a preferred strategy of **life cycle management** with existing products

Table 1 | **Drug development scorecard: January 2006 to December 2007**

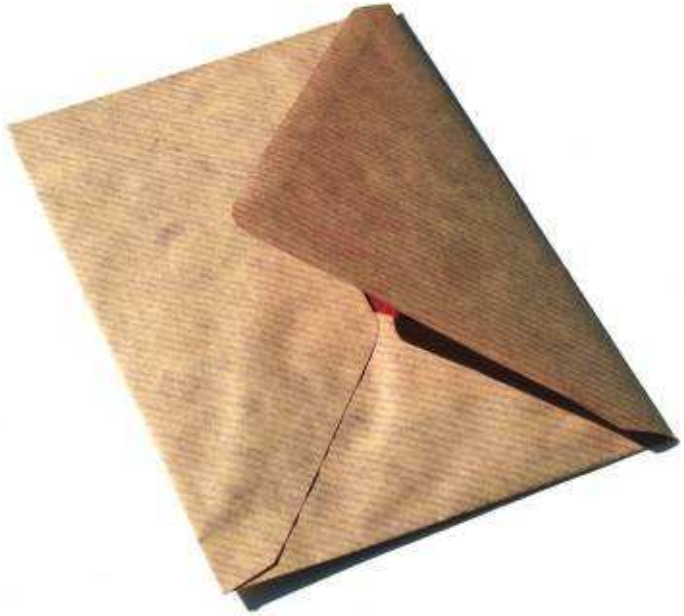
Source	FDA approvals	Phase III failures
Biotech industry	47 (45%)	68 (74%)
Biotech–pharma alliances	16 (16%)	18 (21%)
Acquisitions/licenses by pharma	4 (4%)	0
Pharma industry	36 (35%)	5 (5%)
Total	103	91

¿Dónde nacen los fármacos innovadores?

Eugene Goldwasser

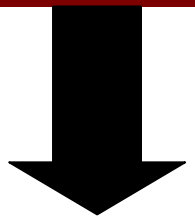
- Universidad de Chicago
- Inicio en 1955
- Producción renal
- Matadero Bradley, IL
- 15 años


Takaji Miyake, 1973
Kumamoto University
Isla de Kyushu = anemia aplásica
Recolección de orina (2.550 L)
Otoño de 1975
Palmer House

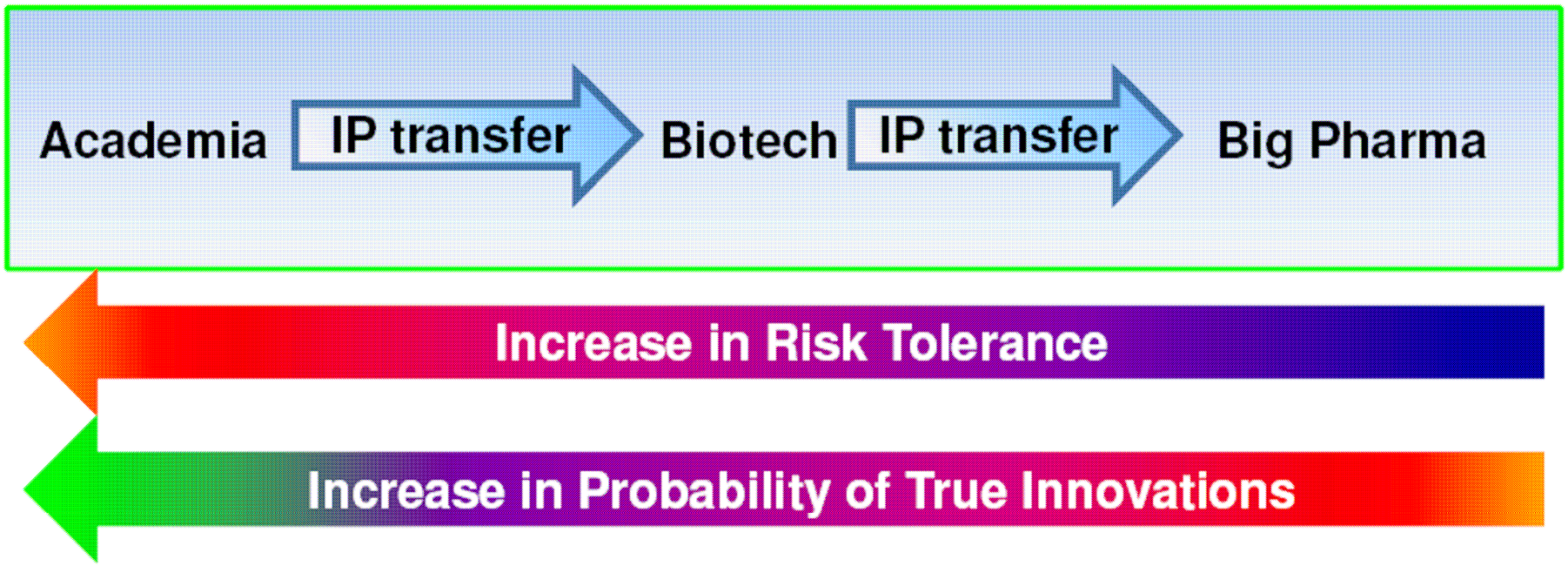


1977: BINGO

¡¡¡8 mg de EPO!!!



AMGEN®



¿Pagamos 2 veces por lo mismo?

Maite: clínicos y pacientes somos partes del proceso de investigación.

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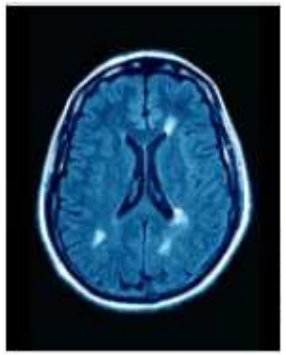
EDITORIALS

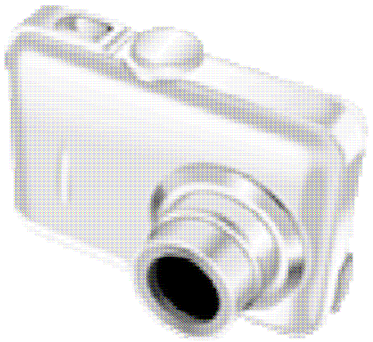
The multiple sclerosis risk sharing scheme

Despite being flawed, has had unintended beneficial consequences



Cristina:

incertidumbre



Precio: 60 Euros

Megapixeles: 6

Precio: 190 Euros

Megapixeles: 7

Precio: 400 Euros

Megapixeles: 8

TIPOS DE PRC

- Acuerdos Precio Volumen
- Acuerdos Globales de Retorno Devolución–Payback
- Acuerdos Individuales con Garantia de Devolución
- Acuerdos Basados en Coste Efectividad
- Acuerdos Basados en Resultados Clínicos

"No cure, no pay strategies"

Corresponsabilizar a la industria junto a prescriptores y financiadores.

Cambio tendencia

Políticas farmacéuticas basadas en regulación del precio

↓

Acuerdos macro

Nuevas políticas farmaceuticas basadas en racionalización y coste efectividad

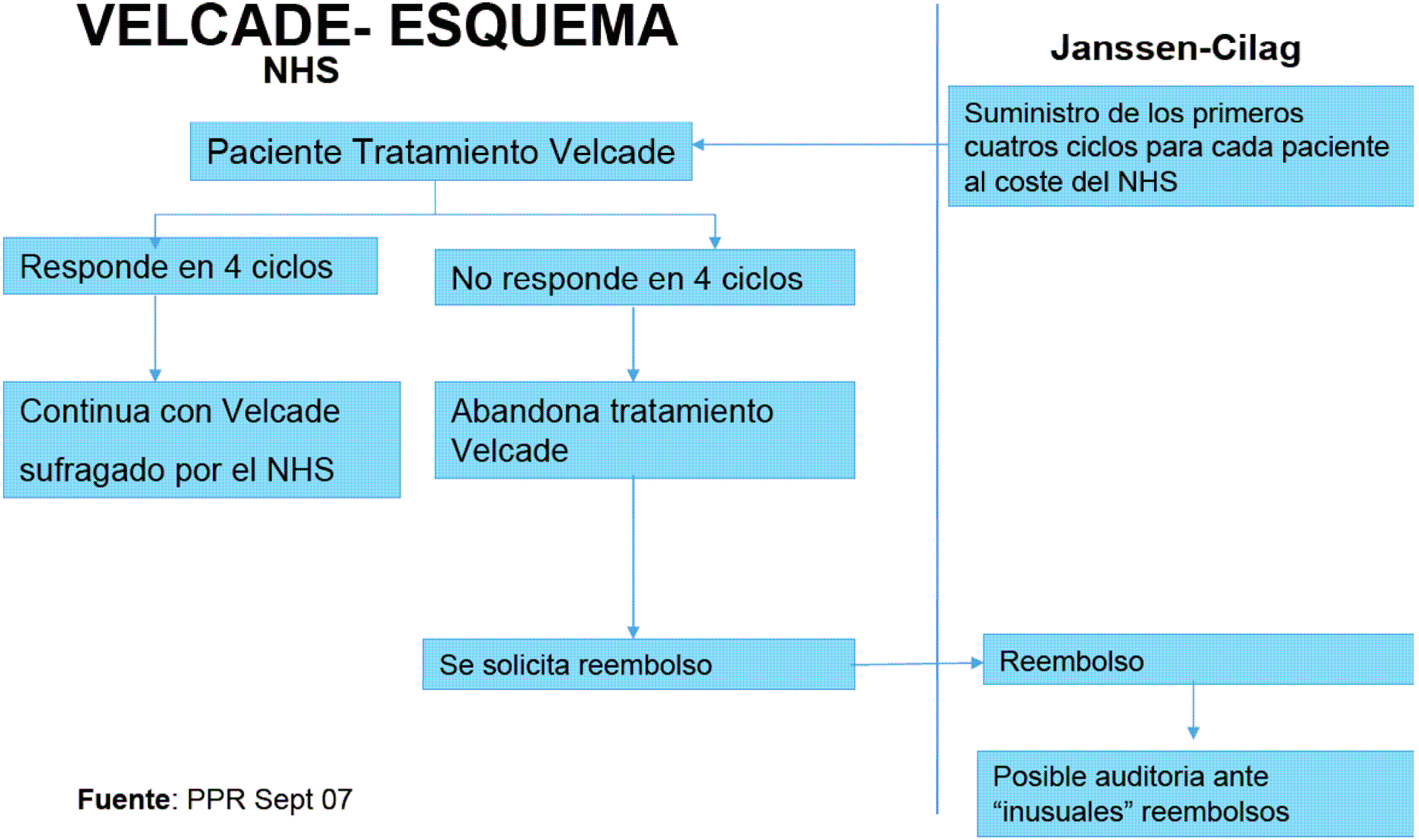
↓

Acuerdos micro

Access to high cost drugs in Australia

Risk sharing scheme may set a new paradigm

VELCADE- ESQUEMA
NHS



Fuente: PPR Sept 07

Denmark: “No play, no pay”

Simvastatina, Clozapina, Valsartán...

DESVENTAJAS

Marta: carga de burocracia y dificultad de evaluación.

Falta de transparencia y CI.

Mª José: necesidad de un “NICE”

PRC en situaciones específicas

Escasa calidad de los estudios.

Evaluación de resultados insuficiente

Riesgo compartido en EM

Profilaxis de enfermedades poco frecuentes altamente discapacitante

Carmen: retirada o reducción de precio???

Outcomes controvertidos

Ausencia de alternativas

OBJETIVOS DEL PRC

Industria

- Eludir el riesgo de exclusión

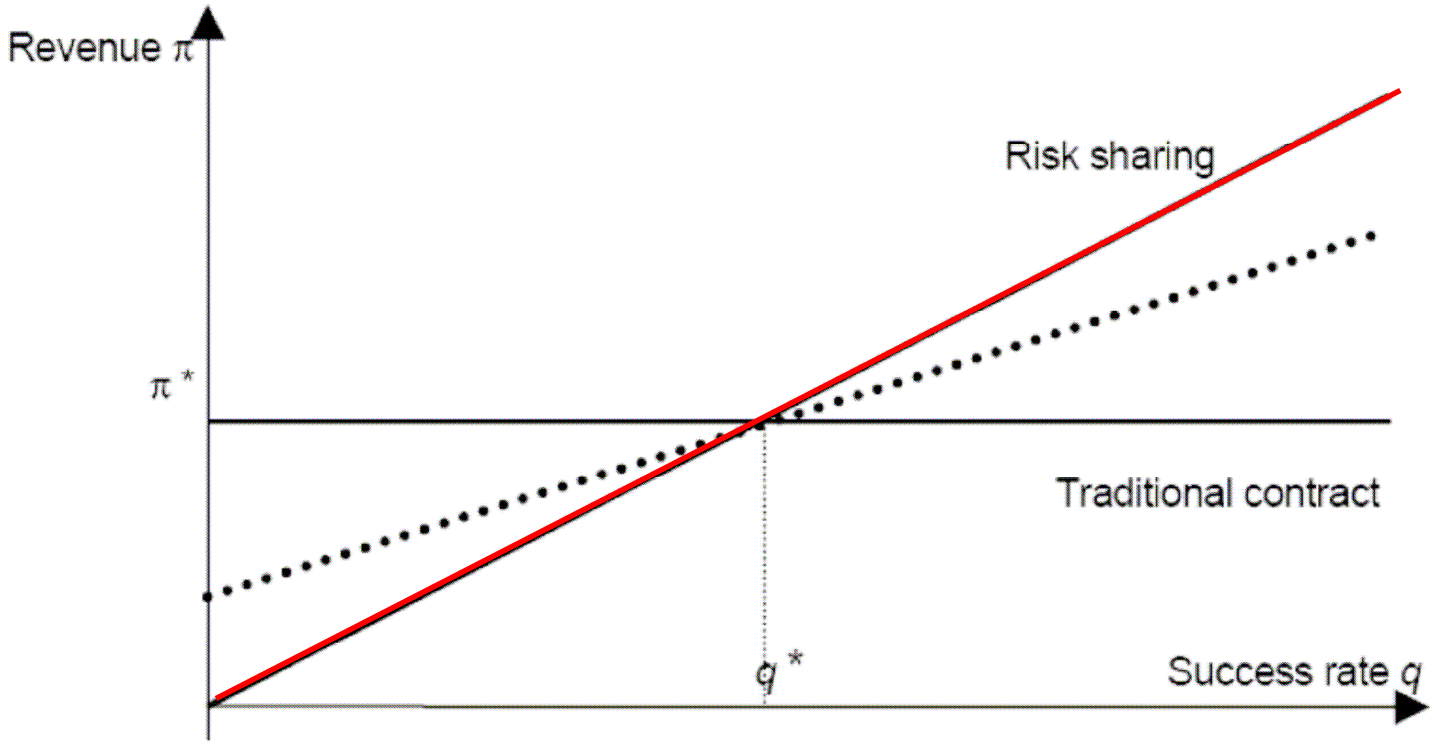
Financiador

- Accesibilidad
- Evitar crecimiento descontrolado de gasto

Incrementar conocimiento efectividad real del producto

Disminución de costes no es el único objetivo

Pagamos más por fármacos más valiosos...



El futuro tiene muchos nombres:

Para los débiles es lo inalcanzable. Para los temerosos, lo desconocido. Para los valientes es la oportunidad...