

INVITACIÓN

Diálogos sobre políticas de salud y buen gobierno

(organizados por Jaume Puig-Junoy, F.E. Lluch y Félix Lobo, Funcas)

Los precios de los nuevos tratamientos oncológicos y la sostenibilidad del Sistema Nacional de Salud

En el acto intervendrán:

Josep Tabernero Caturla, presidente de la Sociedad Europea de Oncología Médica (ESMO), director del Instituto de Oncología (VHIO) y jefe del Servicio de Oncología Médica del Hospital Vall d'Hebron, Barcelona

Beatriz González López-Valcárcel, catedrática de Métodos Cuantitativos en Economía y Gestión de la Universidad de Las Palmas

Beatriz González López-Valcárcel

ULPGC

6 marzo 2019

A large, bold, white number '1' is centered on a solid red rectangular background. The number has a slightly curved top-left corner.

**Grandes avances,
grandes sacrificios**
Innovación acelerada a
precios altos

2. Data

2a. Complete list of included BTDs

Commercial Firms

Sponsor	Ticker	Agent / Alternative Name (Trade Name)	Date of BTD disclosure
Abbvie	ABBV	Elotuzumab (Empliciti)	2014-05-19
Abbvie	ABBV	Glecaprevir + Pibrentasvir (Mavyret)	2016-09-30
AbbVie	ABBV	Ibrutinib (Imbruvica)	2016-06-29
AbbVie	ABBV	Paritaprevir / ABT-450 (Viekira Pak)	2013-05-06
Abbvie	ABBV	Upadacitinib / ABT-494	2018-01-09
AbbVie	ABBV	Venetoclax (Venclexta)	2015-05-07
AbbVie	ABBV	Venetoclax (Venclexta)	2016-01-20
AbbVie	ABBV	Venetoclax (Venclexta)	2016-01-28
Abbvie	ABBV	Venetoclax (Venclexta)	2017-07-28
Alexion	ALXN	Asfotase Alfa (Strensiq)	2013-05-28
Alexion	ALXN	cPMP / ALXN1011	2013-10-24
Allergan	AGN	Rapastinel / GLYX-13	2016-01-29
Amgen	AMGN	Blinatumomab (Blinicyto)	2014-07-01
Ariad	ARIA	Brigatinib / AP26113 (Alunbrig)	2014-10-02
Astellas	ALPMY	Enfortumab Vedotin	2018-03-26
AstraZeneca	AZN	Acalabrutinib (Calquence)	2017-08-01
AstraZeneca	AZN	Durvalumab (Imfinzi)	2016-02-17
AstraZeneca	AZN	Durvalumab (Imfinzi)	2017-07-31
AstraZeneca	AZN	Olaparib (Lynparza)	2016-01-28
AstraZeneca	AZN	Osimertinib (Tagrisso)	2017-10-09
Biomarin	BMRN	Valoctocogene Roxaparvovec	2017-10-26
Bristol-Myers Squibb	BMY	Daclatasvir (Daklinza) + Asunaprevir	2014-02-24
Bristol-Myers Squibb	BMY	Elotuzumab (Empliciti)	2014-05-19
Bristol-Myers Squibb	BMY	Fostemsavir / BMS-663068	2015-07-21
Bristol-Myers Squibb	BMY	Nivolumab (Opdivo)	2014-05-14
Bristol-Myers Squibb	BMY	Nivolumab (Opdivo)	2014-09-26
Bristol-Myers Squibb	BMY	Nivolumab (Opdivo)	2015-09-02
Bristol-Myers Squibb	BMY	Nivolumab (Opdivo)	2015-09-16
Bristol-Myers Squibb	BMY	Nivolumab (Opdivo)	2016-04-25
Bristol-Myers Squibb	BMY	Nivolumab (Opdivo)	2016-06-27
Bristol-Myers Squibb	BMY	Nivolumab (Opdivo)	2017-10-16
Bristol-Myers Squibb	BMY	Nivolumab (Opdivo) + Ipilimumab (Yervoy)	2018-03-27
Celgene	CELG	Lisocabtagene maraleucel / JCAR017	2016-12-20
Daiichi Sankyo	DSNKY	DS-8201	2017-08-30

Entre 2012 y 2018, la FDA aprobó **112 'breakthrough therapy designation' (BTD)** (medicamentos distintos)

De ellas, **50 (45%) son oncológicas**

OUTLOOK — BIOMARKERS

Stratified medicine: strategic and economic implications of combining drugs and clinical biomarkers

Mark R. Trusheim, Ernst R. Berndt and Frank L. Douglas

Abstract | The potential to use biomarkers for identifying patients that are more likely to benefit or experience an adverse reaction in response to a given therapy, and thereby better match patients with therapies, is anticipated to have a major effect on both clinical practice and the development of new drugs and diagnostics. In this article, we consider current and emerging examples in which therapies are matched with specific patient population characteristics using clinical biomarkers — which we call stratified medicine — and discuss the implications of this approach to future product development strategies and market structures.

Most medicines are currently prescribed empirically. Some work for almost all relevant patients, such as non-steroidal anti-inflammatory drugs (NSAIDs) for pain relief, the proton-pump inhibitors (PPIs) for gastroesophageal reflux disorder or the newly approved Gardasil vaccine (Merck) to prevent human papilloma virus infections. For other therapeutic classes, such as the antidepressant selective serotonin-reuptake inhibitors (SSRIs), although responses are variable, there is at present no way to identify patients who are likely to respond well to a particular agent. In such cases, a number of agents might need to be tried until a satisfactory response is attained.

However, advances in understanding the mechanisms underlying diseases, as well as drug response, are increasingly creating opportunities to match patients with therapies that are more likely to be effective and safe. At the extreme of patient matching are 'individualized' medicines, which vary inherently for each patient. The cancer vaccine Oncophage, which is currently in development, provides an example of an individualized medicine. To produce this vaccine, tumour cells are taken from a patient during surgery¹. A heat-shock protein and its associated peptides, which represent a unique 'signature' of that patient's cancer, are then isolated from the tumour cells and formulated into a vaccine for administration when the patient has recovered from surgery. This vaccine, which is only suitable for the patient from whom it is derived, stimulates an immune response that attacks tumour

cells remaining in the body after surgery. Stem-cell-based therapies could also potentially increase the role of individualized medicine in the future.

Less extreme examples of patient matching to a medicine include therapies for which some form of marker is available to indicate that a given patient is likely to show a response to the therapy. Some call this approach of proactively testing and selecting populations for specific treatments 'personalized' medicine, but we believe a more useful description is 'stratified' medicine. In stratified medicine, a patient can be found to be similar to a cohort that has historically exhibited a differential therapeutic response using a biomarker that has been correlated to that differential response.

Here, we call this special class of biomarkers that links patient subpopulations to treatments clinical biomarkers. An example of a clinical biomarker that is linked to drug efficacy is the BCR-ABL-positive tyrosine kinase genotype, which is used to identify patients with chronic myeloid leukaemia who are likely to respond to imatinib mesylate (Gleevec; Novartis), an inhibitor of this kinase². An example of a clinical biomarker that is linked to drug toxicity is a genetic variant of the UDP-glucuronosyltransferase 1A1 enzyme UGT1A1, which can be used to identify patients that are likely to experience serious toxicity in response to the anticancer drug irinotecan (Camptosar; Pfizer); the rate of metabolism of the active metabolite of irinotecan by UGT1A1 is reduced in these patients³. Beyond genotypes, clinical

biomarkers include any diagnostic test or clinical observation that indicates a preferred treatment for a patient subpopulation. Clinical biomarkers can be based on gene-expression patterns, individual proteins, proteomic patterns, metabolomics, histology, imaging, physicians' clinical observations and even self-reported patient surveys. A clinical biomarker is not defined by its technology or biological basis, but rather by its reliable, predictive correlation to differential patient responses.

In summary, we believe that individualized medicine represents one end of a continuum of patient therapy, with empirical medicine at the other end of this continuum, and that in between lies the field of stratified medicine (FIG 1). The ability of stratified medicine to match a therapy with specific patient population characteristics through clinical biomarkers has important implications for:

- Defining the field for which a drug is used.
- Determining the economic value of the field.
- Establishing the economic barriers to defend the field.
- Allocating the value between the gatekeeper clinical biomarkers and the therapy.

In this article, we highlight selected examples of stratified medicine, and discuss the strategic and economic significance of the points above to the discovery and development of new drugs and associated diagnostics.

Stratified medicine and clinical decisions

Stratified medicine adds a step to traditional clinical practice (FIG 2). After the differential diagnosis is made on the basis of patient history and physical assessment, and following diagnosis confirmation from laboratory tests and clinical observation, stratified medicine adds a clinical biomarker-assessment step to associate a patient with a specific therapy. Individualized medicines take this process a step further by custom producing the therapeutic — often using the patient's own fluid, cells or tissue to 'seed' production.

Stratified medicine is already practiced in several contexts, albeit often after first-line empirical treatment proves unsatisfactory because of poor efficacy or intolerable toxicity. Antibiotics are matched to specific resistant infections, HIV therapies are tailored to the viral variant present and oncology treatment regimens prioritize agents based on molecular tests. Accelerating clinical biomarker development by both drug developers and diagnostic companies will correspondingly expand the clinical opportunities for stratified medicine.

¡Ya hemos llegado!

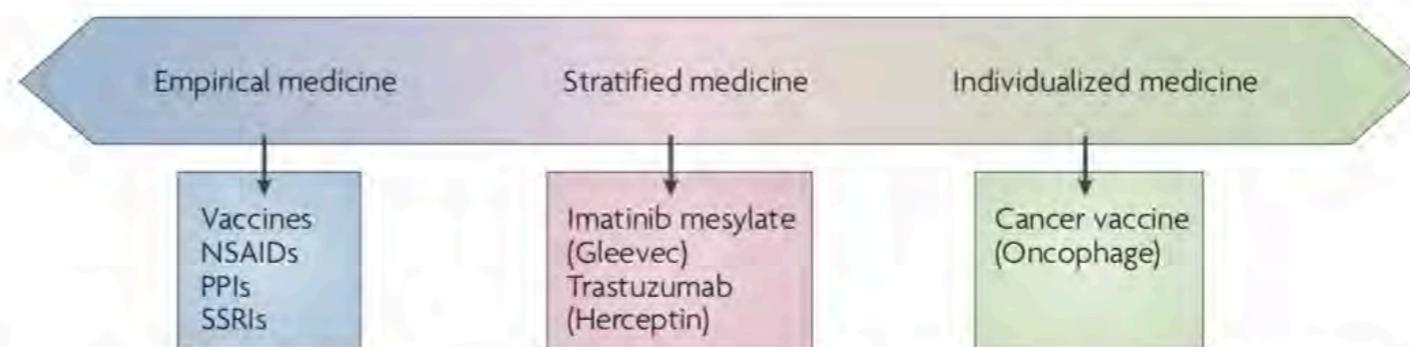


Figure 1 | The patient therapeutic continuum. Individualized medicines, such as cancer vaccines that are based on a particular patient's tumour, represent one end of a continuum of patient therapy. Empirical medicine is at the other end of this continuum: some agents work for almost all relevant patients, such as non-steroidal anti-inflammatory drugs (NSAIDs), whereas others may only work for a subset of patients but no method is available to identify these patients, such as with antidepressants. In between lies the field of stratified medicine, in which a patient can be found to be similar to a cohort that has historically showed a differential therapeutic response to a particular therapy using a clinical biomarker that has been correlated to that differential response. For example, the anticancer drug trastuzumab (Herceptin) shows superior efficacy in breast cancer patients with HER2/neu-positive cancer. PPIs, proton-pump inhibitors; SSRIs, selective serotonin-reuptake inhibitors.

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**Dos preguntas
separadas:
¿Podremos financiarlo?
¿Vale lo que cuesta?**

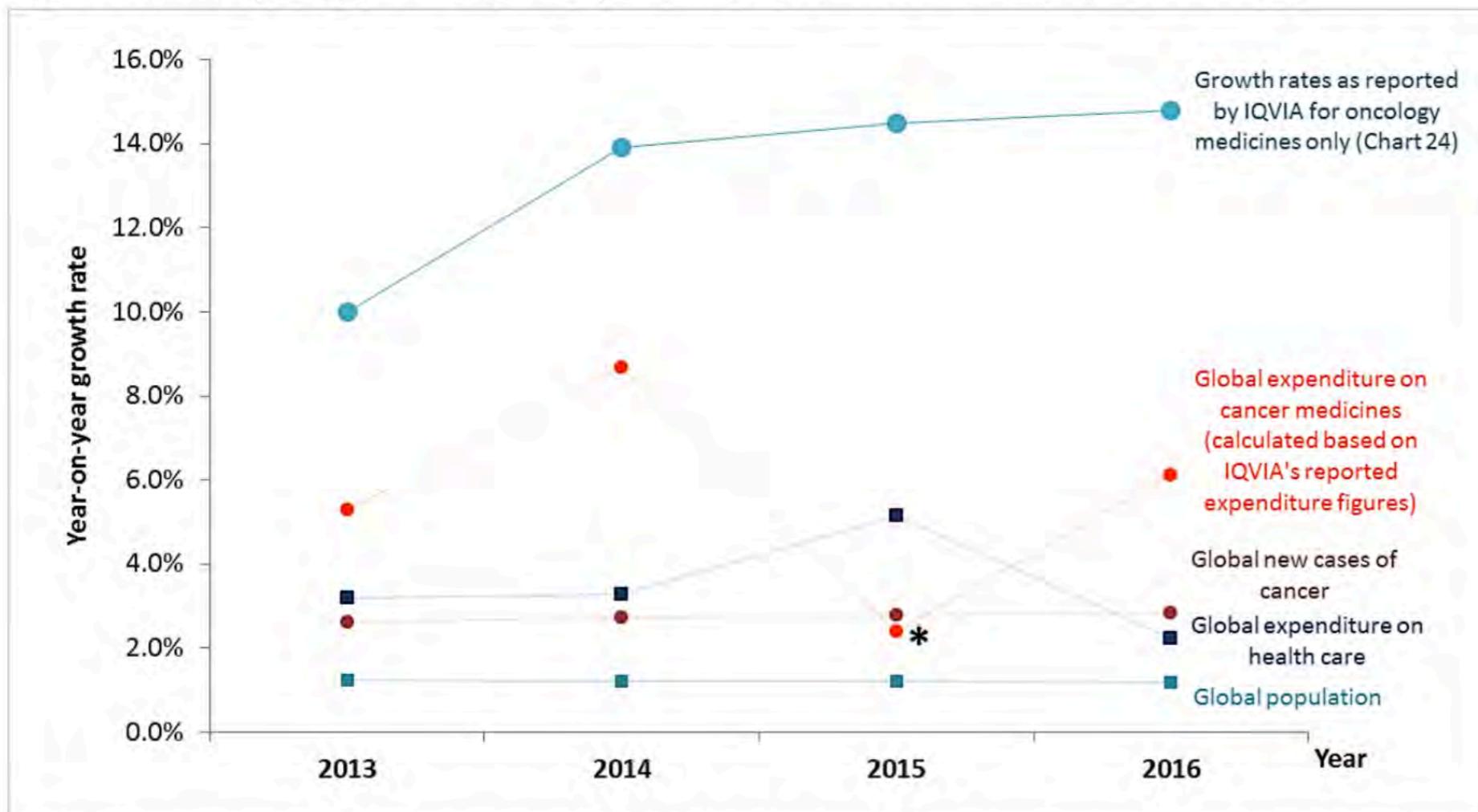
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**Dos preguntas
separadas:
¿Vale lo que cuesta?
¿Podremos financiarlo?**

2

**Dos preguntas
separadas:
¿Vale lo que cuesta?
¿Podremos financiarlo?**

Fig. 1.1: Year-on-year growth rates of expenditures on cancer medicines and health care



Note: Cancer medicines include medicines for the treatment of solid tumours and blood cancers as well as for supportive care such as anti-emetics, erythropoietins, haematopoietic growth factors, select interferons, bisphosphonates. The growth rates reported by IQVIA Institute for Human Data Science only related to oncology therapeutics, without supportive care.

Source: Author's calculations based on data from the WHO Global Health Expenditure Database (27) and IQVIA Institute for Human Data Science (19)

La tasa de crecimiento del gasto en oncología es mucho mayor que la del gasto sanitario global

(*)WHO (2018) TECHNICAL REPORT. Pricing of cancer medicines and its impacts

En España, el mercado oncológico es de **2.610 millones de euros** en 2018, **20% del total hospitalario** (*)

El mercado oncológico presentó una aceleración del crecimiento en 2015, alcanzando el 15,8% MAT8-2016 (PVL)

Se prevé que este mercado siga creciendo en los próximos años como consecuencia de nuevos lanzamientos e indicaciones, pese a la aparición de biosimilares y genéricos

Oncología en Hospitales (Consumo Mill € PVL, España)



Eventos que dirigen el crecimiento

- Lanzamiento de nuevos fármacos dirigidos a dianas moleculares específicas:**

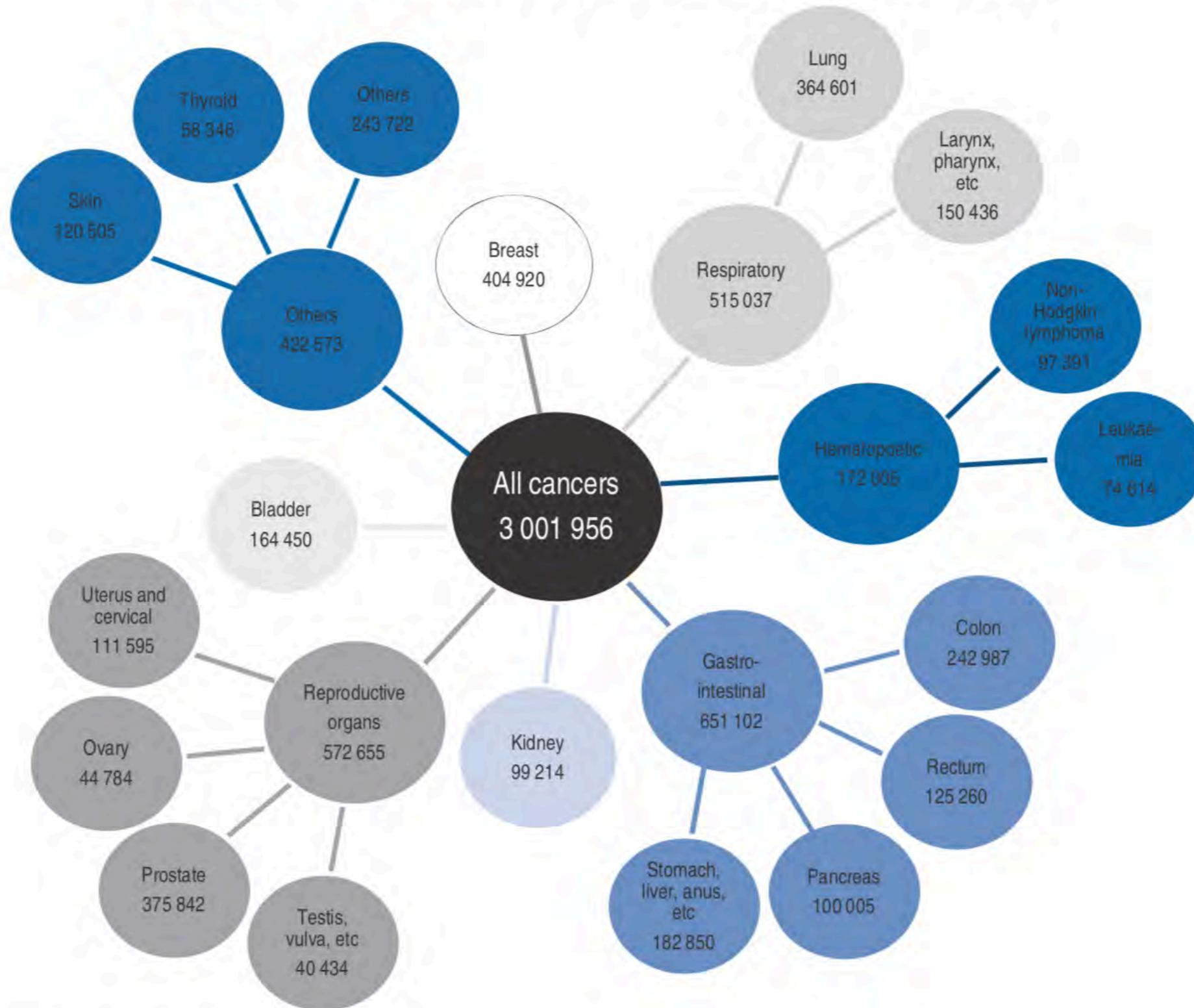
Las terapias dirigidas cobran cada vez mayor importancia por su selectividad de acción tanto en **tumores sólidos** (mama, ovario, pulmón, melanoma...) como en **tumores hematológicos** (LLC, mieloma múltiple...)
- Lanzamiento de fármacos Inmuno-oncológicos:**

Fármacos dirigidos, en este caso a dianas inmunológicas, que han demostrado resultados exitosos en tumores nicho (melanoma, pulmón, renal) y que actualmente se están estudiando en otros tumores
- Aprobación de nuevas indicaciones:**

Aumento de las opciones de tratamiento en cada indicación para los pacientes afectados
- Aumento de la esperanza de vida y avances que permiten un diagnóstico más temprano:**

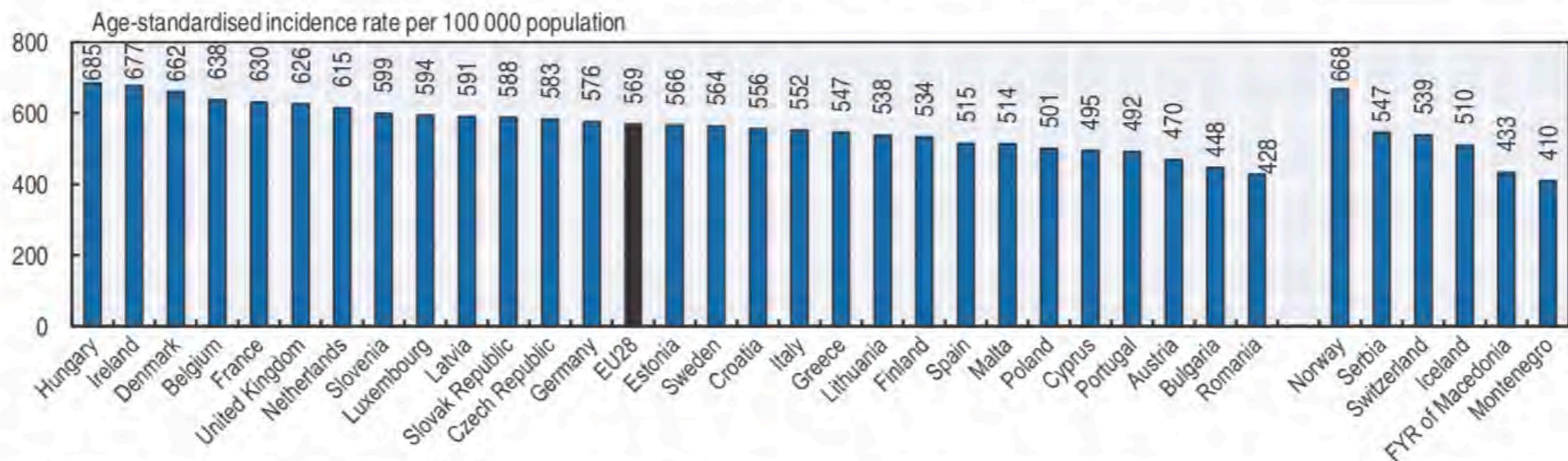
Todo ello incrementa la población susceptible de poder beneficiarse de un tratamiento oncológico

3.28. Estimated number of new cancer cases, all EU countries, 2018



Note: Non-melanoma skin cancer is excluded.
 Source: JRC (European Cancer Information System).

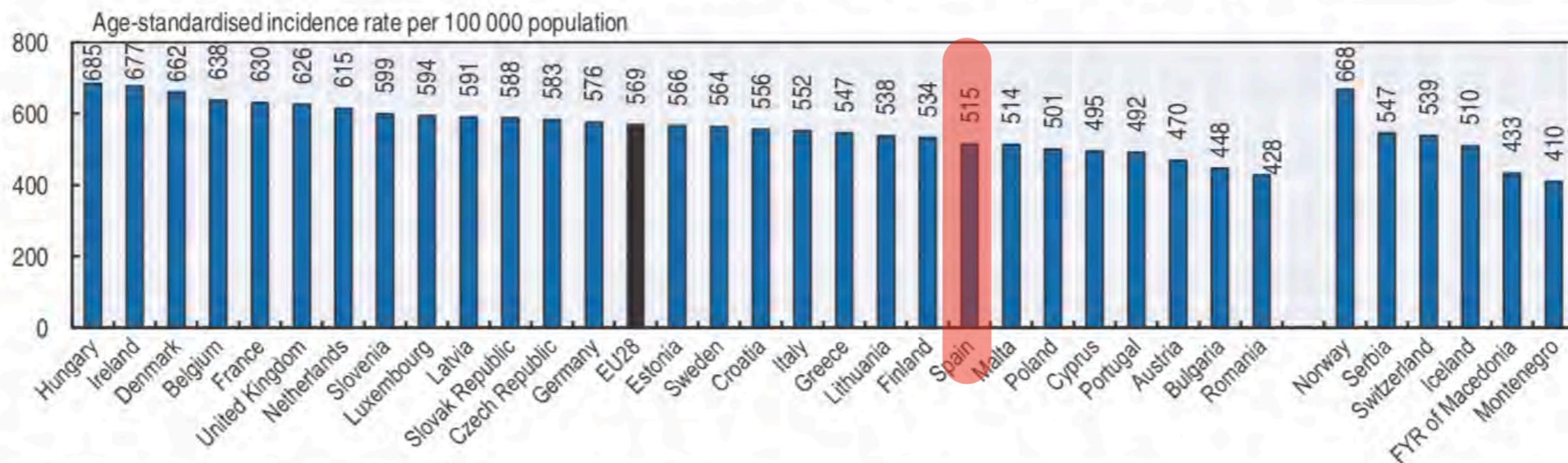
3.29. Estimated incidence rate for all cancers, by country, 2018



Note: All cancers are included except non-melanoma skin cancer. Numbers are age-standardised based on the European Standard Population.

Source: JRC (European Cancer Information System).

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Source: JRC (European Cancer Information System).

The high price of anticancer drugs: origins, implications, barriers, solutions

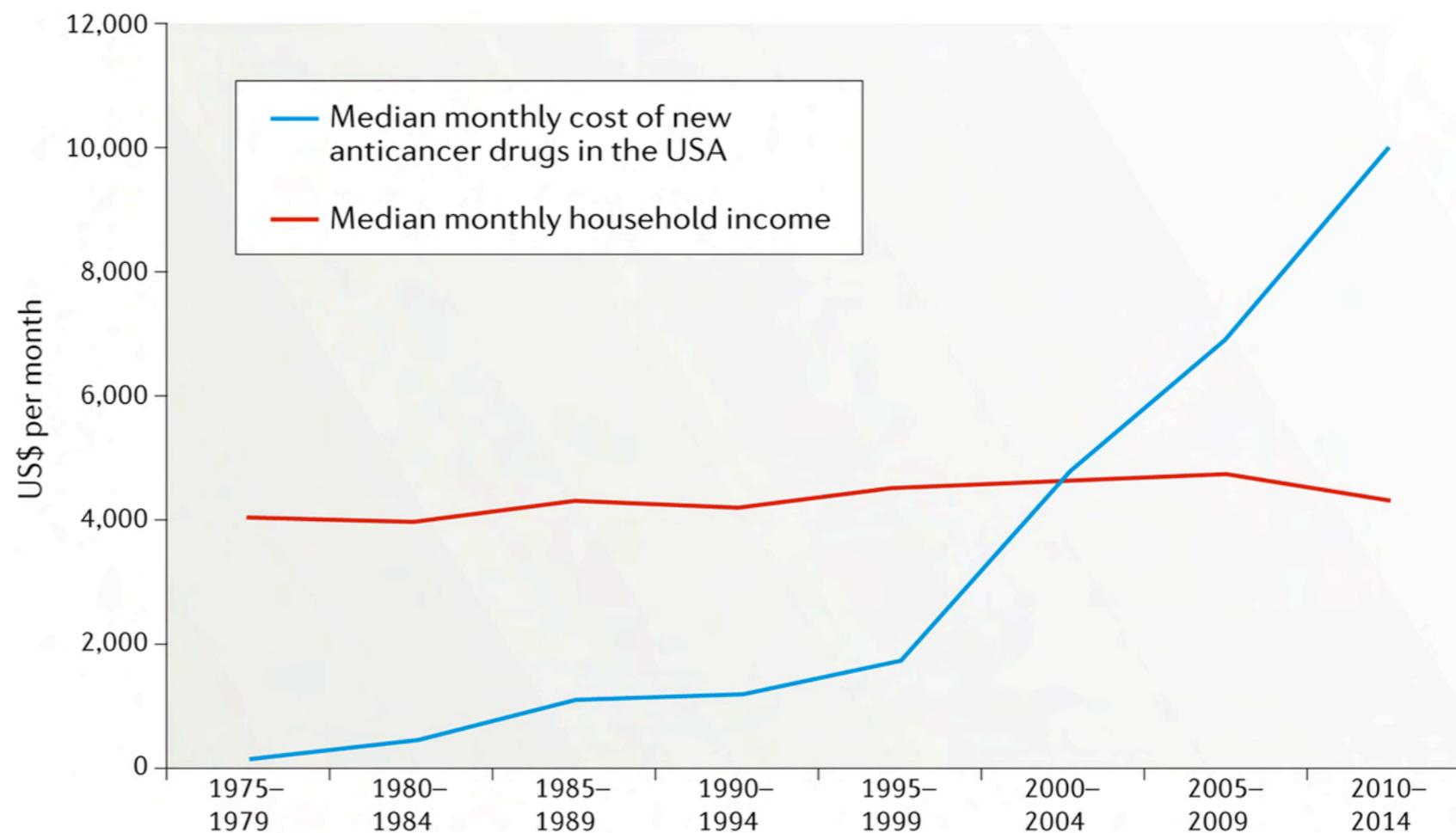
Vinay Prasad, Kevin De Jesús & Sham Mailankody

[Affiliations](#) | [Contributions](#) | [Corresponding author](#)

Nature Reviews Clinical Oncology (2017) | doi:10.1038/nrclinonc.2017.31

Published online 14 March 2017

Figure 2 Median monthly launch price of a new anticancer drug, compared with median monthly household income from 1975–2014 in the USA



Nature Reviews | [Clinical Oncology](#)

Soluciones de “ingeniería financiera” y fiscales para financiar

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- Aumentar presión fiscal

Soluciones de “ingeniería financiera” y fiscales para financiar

- Aumentar presión fiscal
- Integrar seguros de vida con seguros sanitarios(1)

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- Co-pagos? No en España

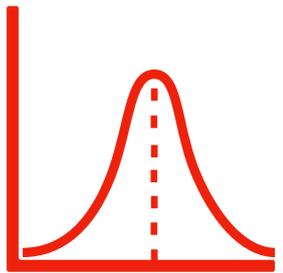
Soluciones de “ingeniería financiera” y fiscales para financiar

- Aumentar presión fiscal
- Integrar seguros de vida con seguros sanitarios(1)
- Co-pagos? No en España
- Coste de oportunidad (otros problemas sociales/otras enfermedades/otros inputs)

3

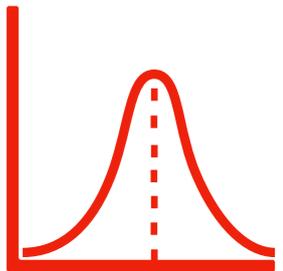
**¿Vale lo que cuesta?
¿Cuál es el precio justo?**

Beneficio clínico, efectividad, coste-efectividad, otros valores sociales



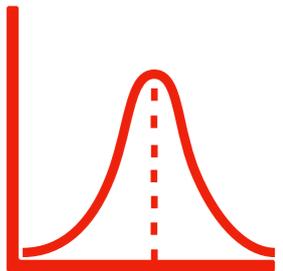
Beneficio clínico, efectividad, coste-efectividad, otros valores sociales

- **Medidas** de valor: AVACs, ASCO, ESMO-MCBS,...



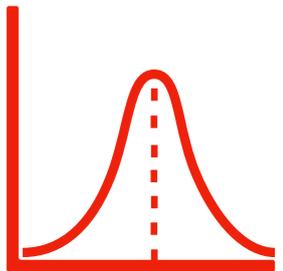
Beneficio clínico, efectividad, coste-efectividad, otros valores sociales

- **Medidas** de valor: AVACs, ASCO, ESMO-MCBS,...
- **Métodos** para evaluar: ACE, MultiCriterio, SROI, ...



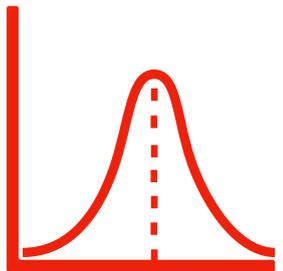
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- **Incertidumbre** “intrínseca”. Comprar billete de lotería



Beneficio clínico, efectividad, coste-efectividad, otros valores sociales

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Pricing in the Market for Anticancer Drugs[†]

David H. Howard, Peter B. Bach, Ernst R. Berndt,
and Rena M. Conti

In 2004, Genentech introduced the drug bevacizumab—brand name Avastin—for patients with late-stage colorectal cancer. The drug cost \$50,000 per treatment episode and was associated with an incremental increase in life expectancy of five months. Following Genentech’s pricing announcement, newspapers ran stories with titles like “Cancer Weapons, Out of Reach” in the *Washington Post* (Wittes 2004) and “Price of Cancer Drugs Called ‘Mind-Boggling’” in *USA Today* (Szabo 2004). Some Wall Street analysts worried that bevacizumab’s pricing would prompt the US Congress to regulate drug prices (Anand 2007). By 2011, the backlash against bevacizumab was a distant memory. Bristol-Myers Squibb set the price of its newly approved melanoma drug ipilimumab—brand name Yervoy—at \$120,000 for a course of therapy. The drug was associated with an incremental increase in life expectancy of four months.

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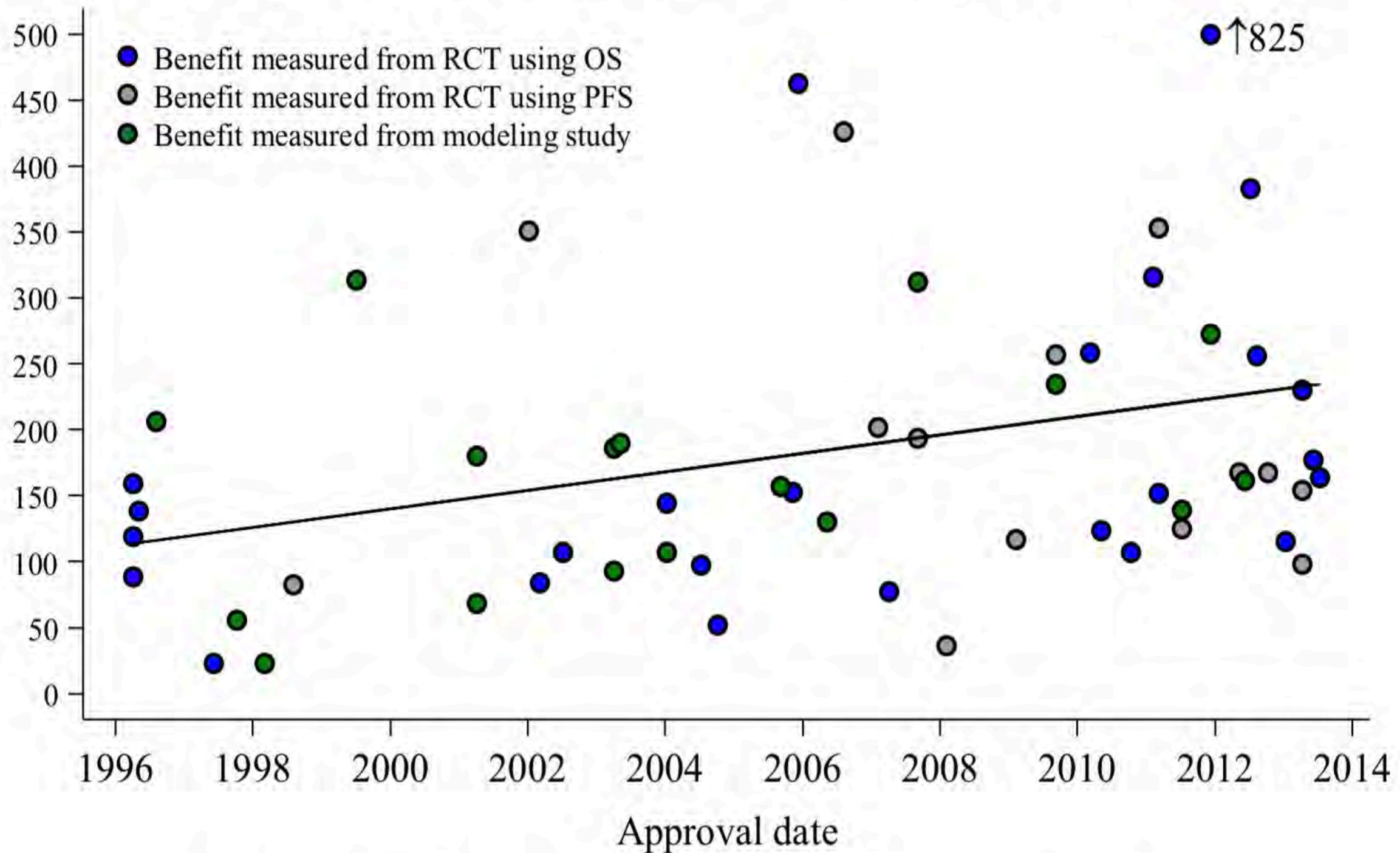
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Figure 2: Price per year of life gained versus approval date



The best fit line is: Price per year of life gained = $\$101,077 + \$7,396 \times \text{Approval year}$.
 For purposes of display, we re-coded one value from \$825,000 to \$500,000.
 RCT: randomized controlled trial. OS: Overall survival. PFS: Progression-free survival

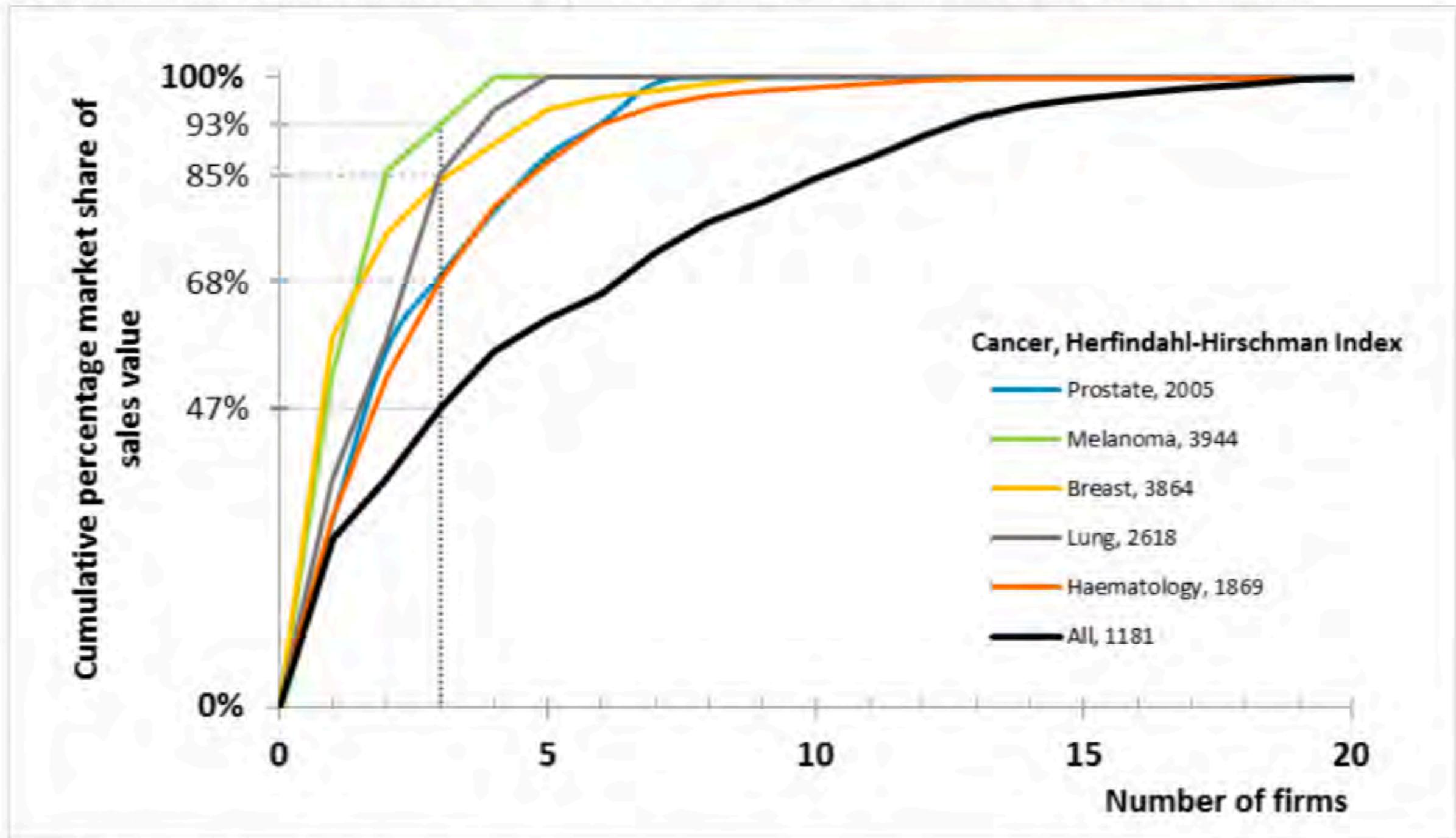
4

Los precios altos son un **efecto secundario de las patentes** y de la disposición a pagar de los países ricos (demanda inelástica)

A large, bold, white number '5' is centered on a solid red rectangular background. The number is stylized with a thick stroke and a rounded bottom curve.

**Mercado más concentrado lleva
a precios más altos**

Fig. 3.6: Distribution of market share by 2017 sales value and Herfindahl-Hirschman Index



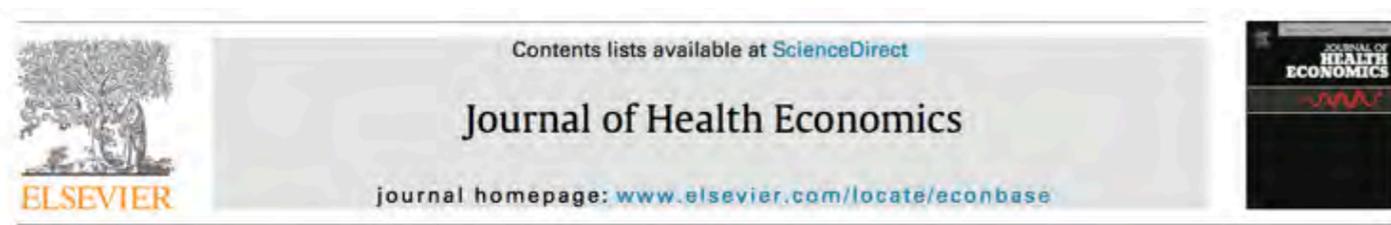
Source: Author's calculation based on 2017 sales figures of products presented in companies' annual reports

(*)WHO (2018) TECHNICAL REPORT. Pricing of cancer medicines and its impacts

6

La regulación de
precios basada en
costes y/o
beneficios **NO** es
socialmente
conveniente.

Asimetría de información



¿Cuánto cuesta lanzar un nuevo medicamento?

Innovation in the pharmaceutical industry: New estimates of R&D costs[☆]



Joseph A. DiMasi^{a,*}, Henry G. Grabowski^b, Ronald W. Hansen^c

^a Tufts Center for the Study of Drug Development, Tufts University, United States

^b Department of Economics, Duke University, United States

^c Simon Business School, University of Rochester, United States

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Pharmaceutical industry
Discount rate
Technical success rates

ABSTRACT

The research and development costs of 106 randomly selected new drugs were obtained from a survey of 10 pharmaceutical firms. These data were used to estimate the average pre-tax cost of new drug and biologics development. The costs of compounds abandoned during testing were linked to the costs of compounds that obtained marketing approval. The estimated average out-of-pocket cost per approved new compound is \$1395 million (2013 dollars). Capitalizing out-of-pocket costs to the point of marketing approval at a real discount rate of 10.5% yields a total pre-approval cost estimate of \$2558 million (2013 dollars). When compared to the results of the previous study in this series, total capitalized costs were shown to have increased at an annual rate of 8.5% above general price inflation. Adding an estimate of post-approval R&D costs increases the cost estimate to \$2870 million (2013 dollars).

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Table 1

Prior studies and analyses of pharmaceutical R&D costs (2003–2012).

Study	Study period	Clinical success rate	Real cost of capital	Inflation adjustment	Cost estimate
DiMasi et al. (2003)	First-in-humans, 1983–1994	21.5%	11.0%	2000 dollars	\$802 million
Adams and Brantner (2006)	First-in-humans, 1989–2002	24.0%	11.0%	2000 dollars	\$868 million
Adams and Brantner (2010)	Company R&D expenditures, 1985–2001	24.0%	11.0%	2000 dollars	\$1.2 billion
DiMasi and Grabowski (2007)	First-in-humans, 1990–2003 (large molecule)	30.2% (large molecule)	11.5%	2005 dollars	\$1.2 billion
Gilbert et al. (2003)	2000–2002 (launch)	8.0%	NA	2003 dollars	\$1.7 billion
O'Hagan and Farkas (2009)	2009 (launch)	NA	NA	2009 dollars	\$2.2 billion
Paul et al. (2010)	≈2007	11.7%	11.0%	2008 dollars	\$1.8 billion
Mestre-Ferrandiz et al. (2012)	In clinical development, 1997–1999	10.7%	11.0%	2011 dollars	\$1.5 billion

Asimetría de información



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Estimaciones varían
entre 200 m\$ y
2.900m\$

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Mestre-Ferrandiz et al. (2012)	In clinical development, 1997–1999	10.7%	11.0%	2011 dollars	\$1.5 billion

Asimetría de información



¿Cuánto cuesta lanzar un nuevo medicamento?

Innovation in the pharmaceutical industry: New estimates of R&D costs[☆]



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ABSTRACT

The research and development costs of 106 randomly selected new drugs were obtained from a survey of 10 pharmaceutical firms. These data were used to estimate the average pre-tax cost of new drug and biologics development. The costs of compounds abandoned during testing were linked to the costs of compounds that obtained marketing approval. The estimated average out-of-pocket cost per approved new compound is \$1395 million (2013 dollars). Capitalizing out-of-pocket costs to the point of marketing approval at a real discount rate of 10.5% yields a total pre-approval cost estimate of \$2558 million (2013 dollars). When compared to the results of the previous study in this series, total capitalized costs were shown to have increased at an annual rate of 8.5% above general price inflation. Adding an estimate of post-approval R&D costs increases the cost estimate to \$2870 million (2013 dollars).

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Estimaciones varían
entre 200 m\$ y
2.900m\$

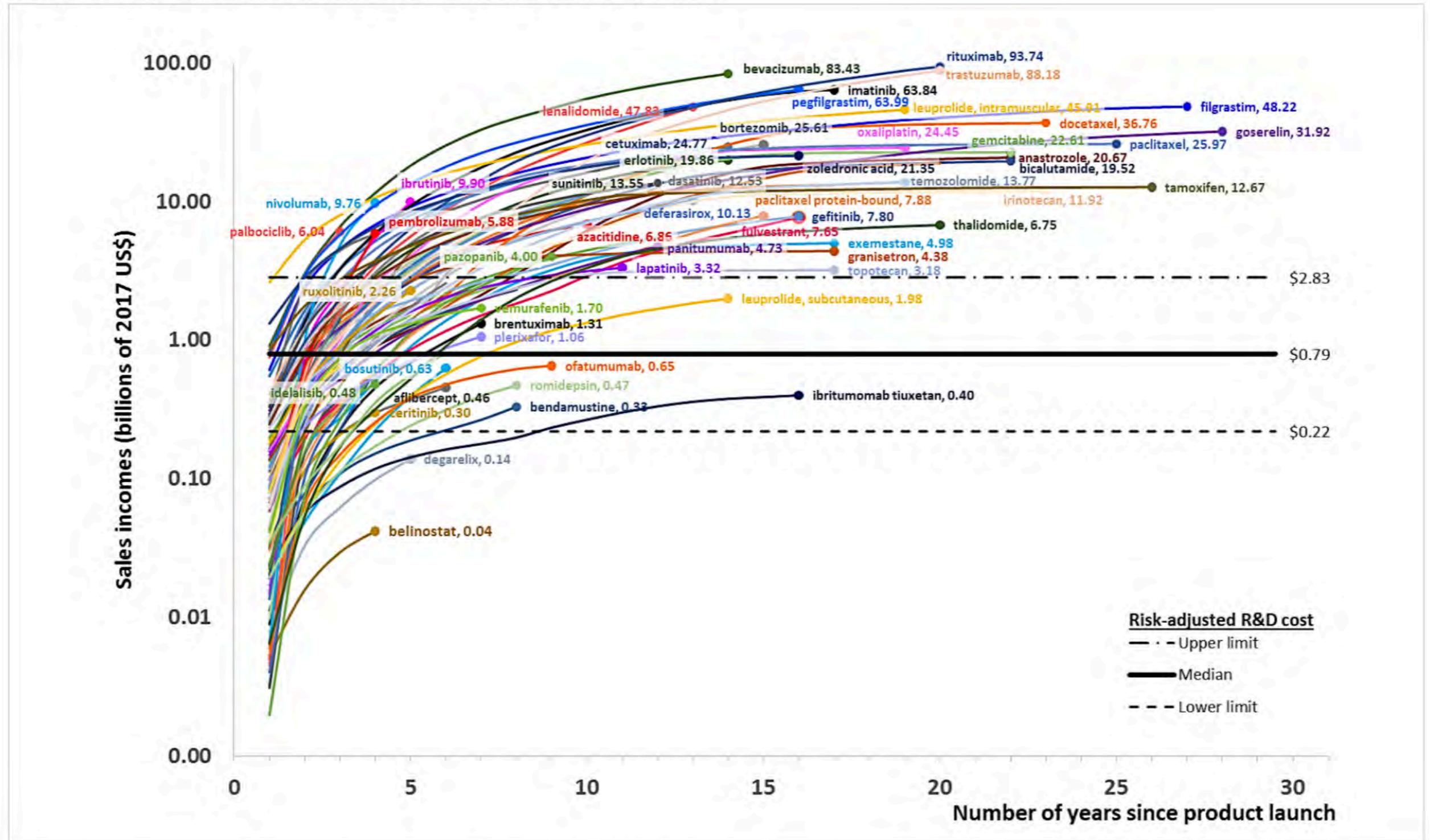
Table 1

Prior studies and analyses of pharmaceutical R&D costs (2003–2012).

Study	Study period	Clinical success rate	Real cost of capital	Inflation adjustment	Cost estimate
DiMasi et al. (2003)	First-in-humans, 1983–1994	21.5%	11.0%	2000 dollars	\$802 million
Adams and Brantner (2006)	First-in-humans, 1989–2002	24.0%	11.0%	2000 dollars	\$868 million
Adams and Brantner (2010)	Company R&D expenditures, 1985–2001	24.0%	11.0%	2000 dollars	\$1.2 billion
DiMasi and Grabowski (2007)	First-in-humans, 1990–2003 (large molecule)	30.2% (large molecule)	11.5%	2005 dollars	\$1.2 billion
Gilbert et al. (2003)	2000–2002 (launch)	8.0%	NA	2003 dollars	\$1.7 billion
O'Hagan and Farkas (2009)	2009 (launch)	NA	NA	2009 dollars	\$2.2 billion
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Hay suficiente evidencia de que el cancer genera beneficios extraordinarios

Fig. 3.5: Cumulative sales incomes of cancer medicines in 2017 US dollars, by molecule



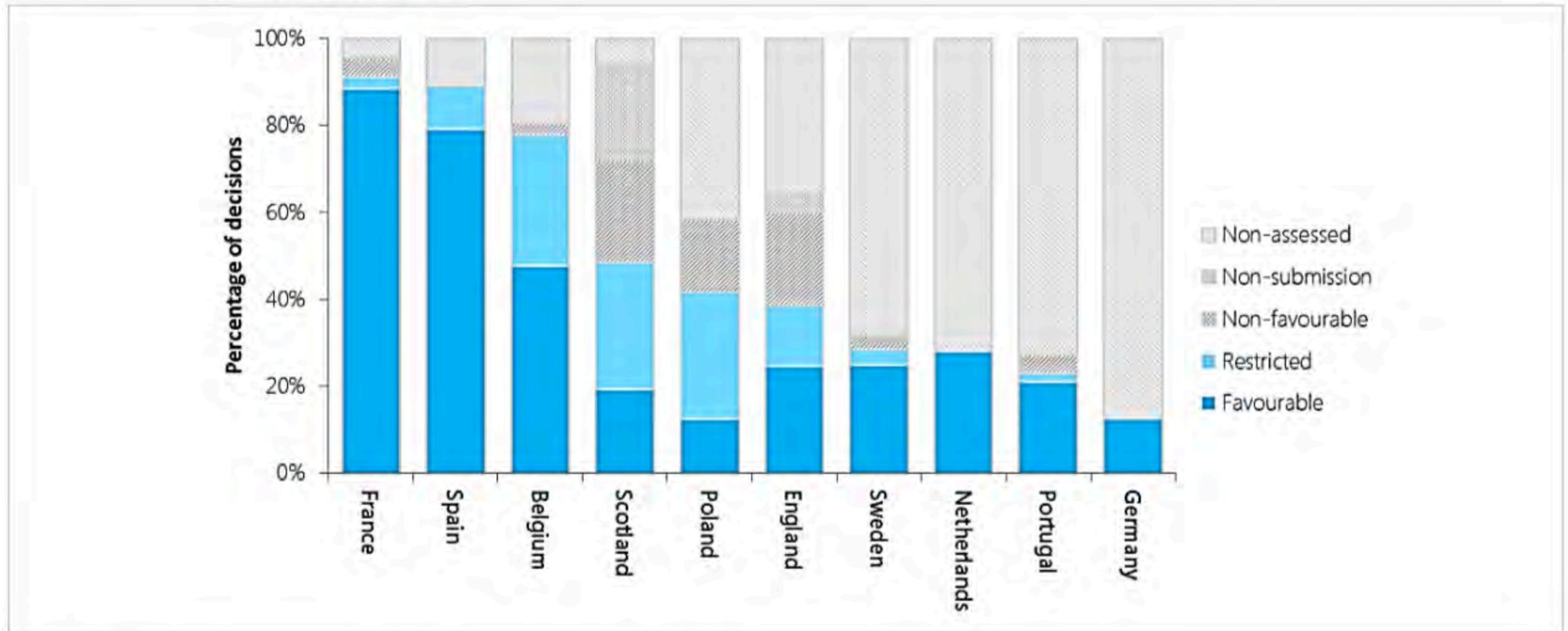
Source: Author's analysis based on sales figures of products from 1989–2017 presented in companies' annual reports and public reports (117)

(*)WHO (2018) TECHNICAL REPORT. Pricing of cancer medicines and its impacts

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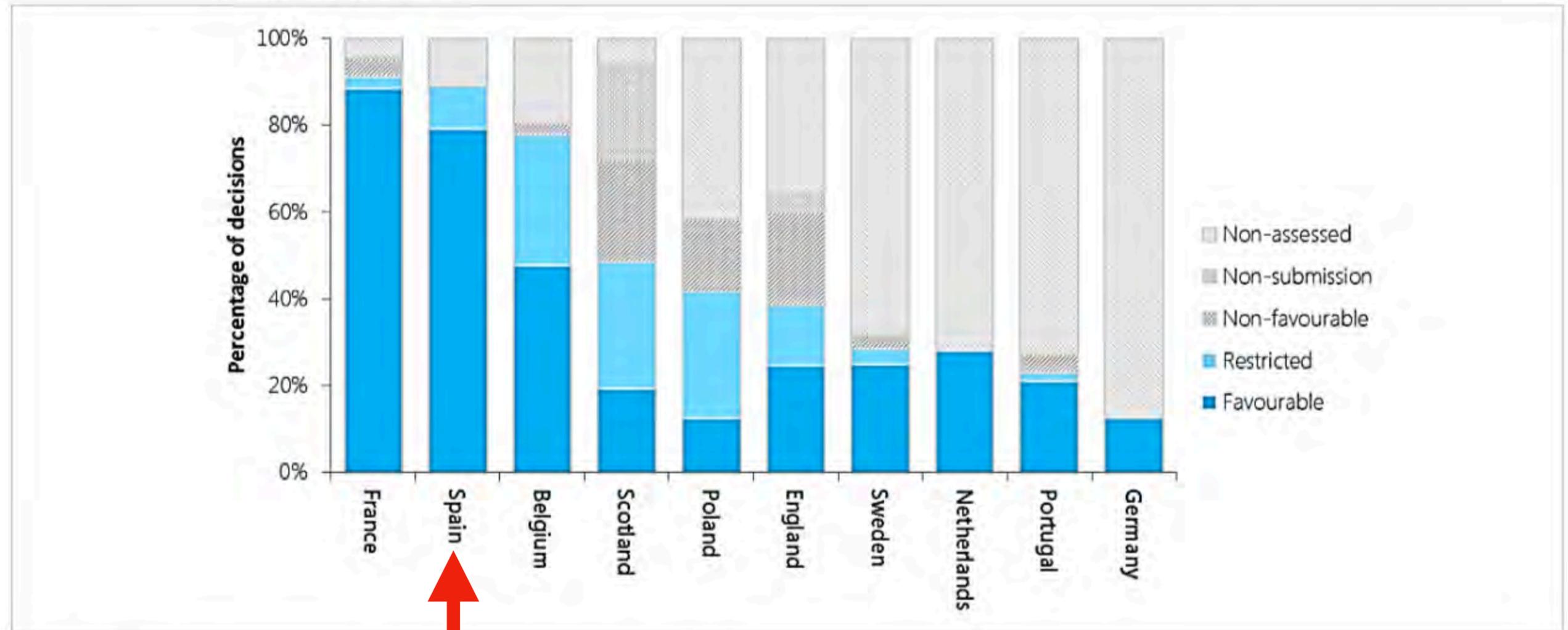
**No priorizar =
priorizar mal
(MBS, MBC, FIFO,)**

Fig. 4.10: Decision outcomes on the coverage of cancer medicines (2002–2014) in 10 European countries or areas



Source: (148)

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**El paradigma del Precio
Basado en el Valor
(expresado a través de la
disposición a pagar)
corresponde al
comportamiento clásico
racional del monopolista**

Table 4.3: Estimated costs of cancer pharmacotherapies, by cancer type and country

Cancer	Standard regimen ^a	Estimated annual cost of cancer medicines ^b			
		Nominal value ^c (with adjustment for purchasing power)			
		India	South Africa	Australia	USA
Breast cancer Early stage HER2 positive	doxorubicin, cyclophosphamide, docetaxel, trastuzumab [Adjuvant AC-TH]	\$ 18 500 (\$ 67 900)	\$ 33 900 (\$ 74 400)	\$ 41 800 (\$ 37 000)	\$ 71 700 (\$ 71 700)
Colon cancer Stage III	capecitabine, oxaliplatin [Adjuvant CAPOX or XELOX]	\$ 2 200 (\$ 8 100)	\$ 1 300 (\$ 2 900)	\$ 1 200 (\$ 1 000)	\$ 7 300 (\$ 7 300)
Liver cancer Advanced	sorafenib	\$ 700 (\$ 2 700)	\$ 12 700 (\$ 27 800)	\$ 28 700 (\$ 25 400)	\$ 90 800 (\$ 90 800)
Prostate cancer Castration-sensitive metastatic	goserelin, bicalutamide docetaxel [ADT plus DOCE]	\$ 3 600 (\$ 13 300)	\$ 3 300 (\$ 7 200)	\$ 4 100 (\$ 3 600)	\$ 7 100 (\$ 7 100)
Lung cancer Metastatic non-small cell	vinorelbine, cisplatin	\$ 1 800 (\$ 6 600)	\$ 800 (\$ 1 900)	\$ 1 200 (\$ 1 000)	\$ 500 (\$ 500)
	erlotinib for EGFR positive	\$ 1 700 (\$ 6 200)	\$ 27 300 (\$ 59 800)	\$ 13 400 (\$ 11 900)	\$ 76 700 (\$ 76 700)
Lymphoma Non-Hodgkin – diffuse large B-cell	rituximab, cyclophosphamide, doxorubicin, vincristine, prednisolone [R-CHOP21]	\$ 6 700 (\$ 24 600)	\$ 20 000 (\$ 43 900)	\$ 17 800 (\$ 15 700)	\$ 48 100 (\$ 48 100)
Leukaemia Chronic myeloid	imatinib	\$ 800 (\$ 2 800)	\$ 13 300 (\$ 29 100)	\$ 23 200 (\$ 20 600)	\$ 96 700 (\$ 96 700)
	dasatinib	\$ 800 (\$ 3 100)	\$ 20 000 (\$ 43 800)	\$ 40 200 (\$ 35 600)	\$ 109 400 (\$ 109 400)

Note: ^aPlease refer to the WHO Essential Medicines List and clinical guidance for specific details of the treatment regimens.

^b Costs were estimated for a full course or 12-month treatment. Cost calculations were based on body surface area of 1.8 m² or body weight of 75 kg where necessary. Please note that the cost estimates are indicative only. ^c Numbers represent US\$ in 2016.

Source: Regimens (292,293); Prices in India (294,295); South Africa (296); Australia (297); USA (298); exchange rates (237)

**Piensa globalmente, actua localmente:
discriminación de precios**

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Piensa globalmente, actua localmente:
discriminación de precios

Precios óptimos de Ramsey:
el precio del mismo medicamento será menor en países de demanda más elástica al precio (“pobres”)



A large, bold, white number '9' is centered on a solid red rectangular background. The number is stylized with a thick stroke and a circular top loop.

**Discriminar precios por
indicación responde a la
lógica del
comportamiento racional
óptimo del monopolista**

The Economics of Indication-Based Drug Pricing

Amitabh Chandra, Ph.D., and Craig Garthwaite, Ph.D.

Pharmaceutical treatments and medical devices often have varying effectiveness depending on the indication for which they're used: in oncology, for instance, response to a treatment varies with the type of tumor and stage of disease. The advent and proliferation of precision medicine in which biomarkers — whether genomic, proteomic, or structural — identify patients likely to receive greater treatment benefits only increase the range of variability in the effectiveness of the same product.

Yet manufacturers traditionally charge the same price for all indications. Recently, there have been calls for “indication-based” pricing systems, in which manufacturers are paid more when treatments are used for indications for which they have higher value (“high-value indications”) and less for indications for which they confer less benefit (“low-value indications”).^{1,2} Supporters hope that such a system will reduce prices for low-value indications but that prices for high-value indications will not increase.¹

This expectation arises from a belief that manufacturers currently set uniform prices according to the value generated for high-benefit indications and somehow get patients who receive lower value to pay the same price.

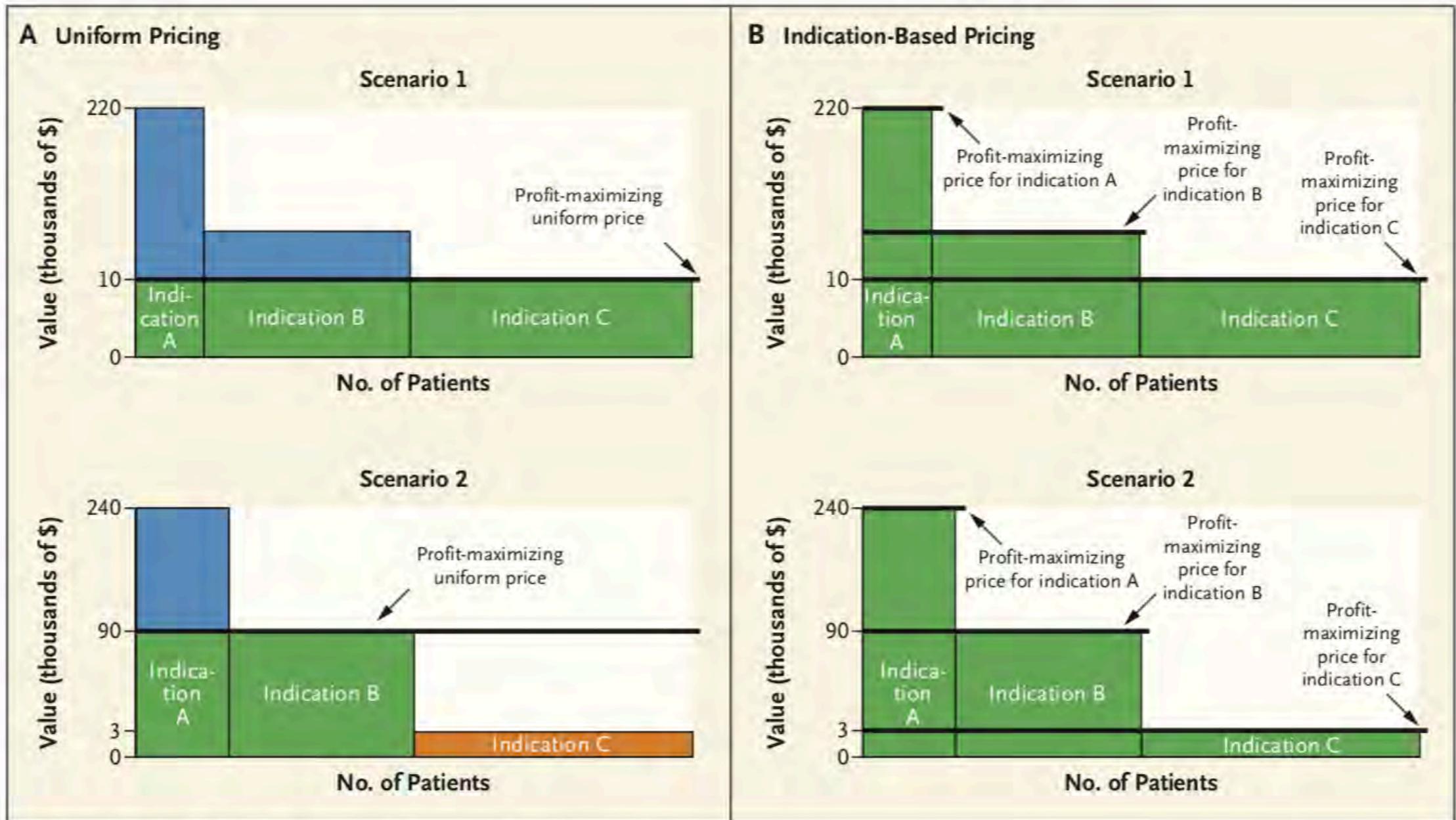
If that were true, it would mean that manufacturers have convinced insurers and patients to consistently pay prices exceeding their products' value. But simple economics makes it clear that relative to uniform pricing, indication-based pricing results in higher prices for patients who benefit

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Piensa globalmente, actua localmente:
discriminación de precios



Effects of Uniform Pricing versus Indication-Based Pricing.

In scenario 1, the value of the treatment is relatively retained across indications; in scenario 2, the value is low for indication C, which affects a relatively large population.



Multi-Indication Pricing: Nice in Theory but Can it Work in Practice?

Jorge Mestre-Ferrandiz¹ · Néboa Zozaya² · Bleric Alcalá² · Álvaro Hidalgo-Vega^{3,4}

Precio personalizado

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Abstract

For medicines with different valued indications (uses), multi-indication pricing implies charging different prices for different uses. In this article, we assess how multi-indication pricing could help achieve overall strategic objectives of pricing controls, summarise its advantages and disadvantages (vs. uniform pricing) and estimate the hypothetical impact on prices of moving towards multi-indication pricing for specific oncologic medicines in Spain. International experience shows that multi-indication pricing can be implemented in real practice, and indeed a few initiatives are currently in use, albeit mostly applied indirectly through confidential pricing agreements that offer a way to discriminate prices across countries without altering list prices. However, some more sophisticated systems are in place in Italy, and more recently in Spain, where the objective is to monitor usage per patient/indication, and ultimately pay for outcomes. Based on the existing experience, we also outline six conditions required for multi-indication pricing. Multi-indication pricing is a useful tool to determine the relative prices of a drug for multiple (different-valued) indications, but by itself will not offer the 'solution' to what the absolute price should be. That will be driven, among other things, by cost-effectiveness thresholds, if they exist. Overall, we argue multi-indication pricing is nice in theory and it could work in practice, although changes in the manner in which medicines are priced, procured and monitored in clinical practice need to be applied.

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Get face-to-face with the experts



Hi Beatriz,

It's a familiar issue in the pharmaceutical industry:

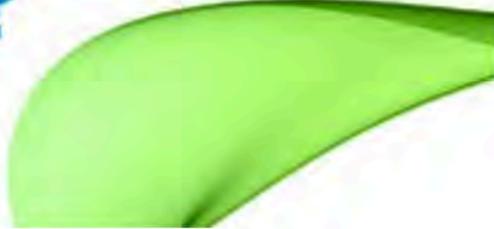
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Get the support – and evidence – you need to build a winning pitch and help turn the tide.

Don't miss your chance to engage with the experts and grow IBP advocacy across your organisation.

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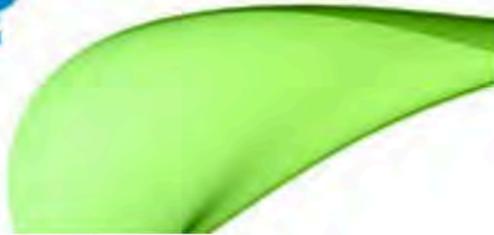
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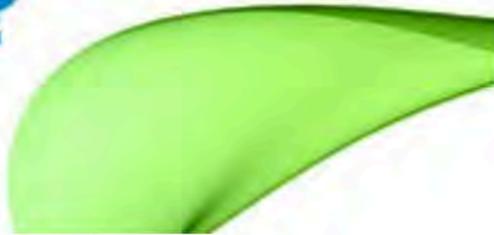
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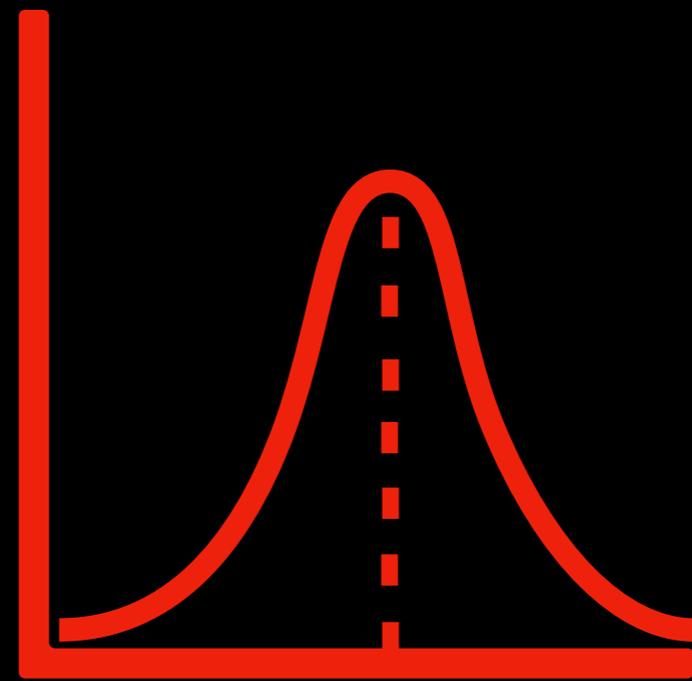
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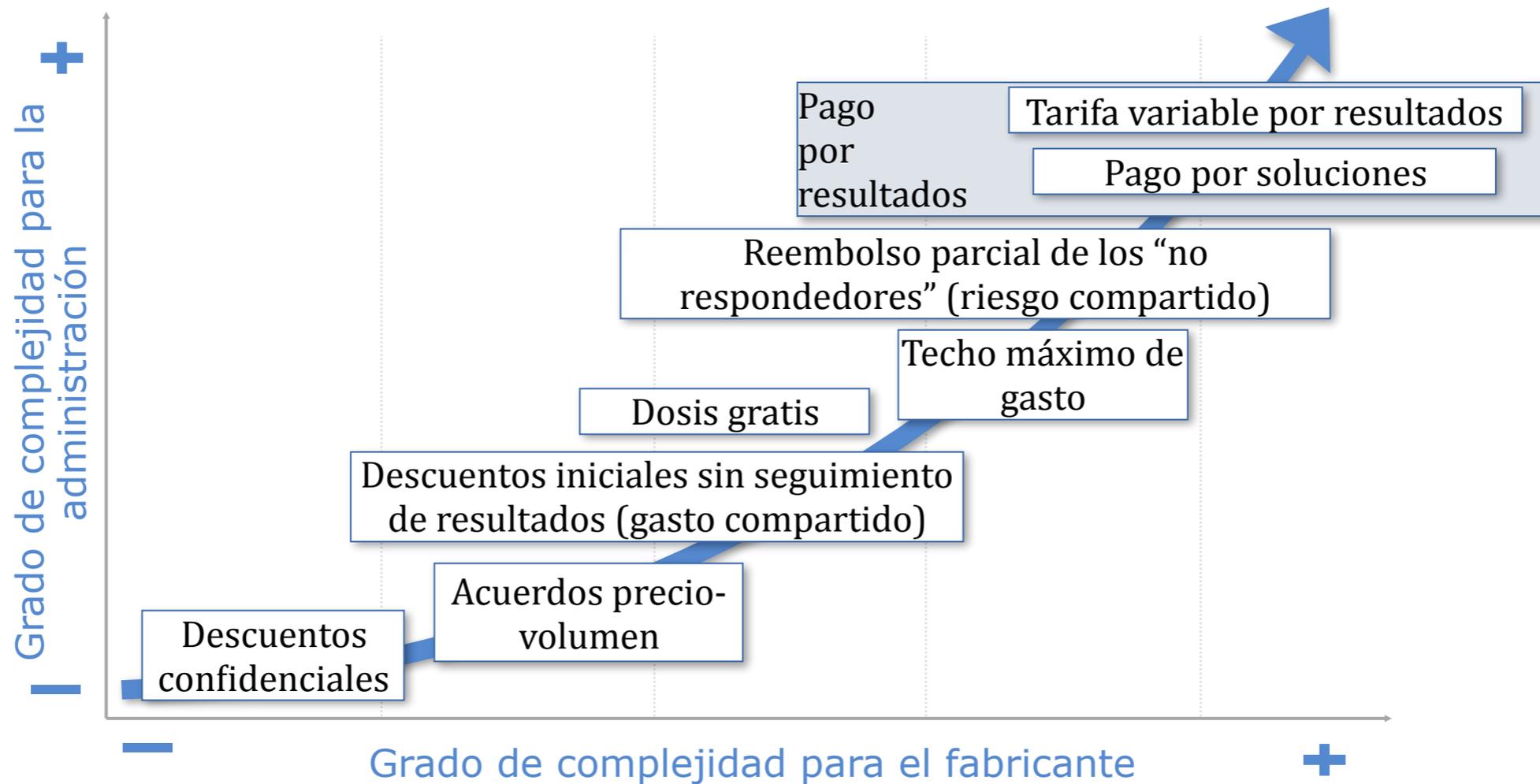
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10



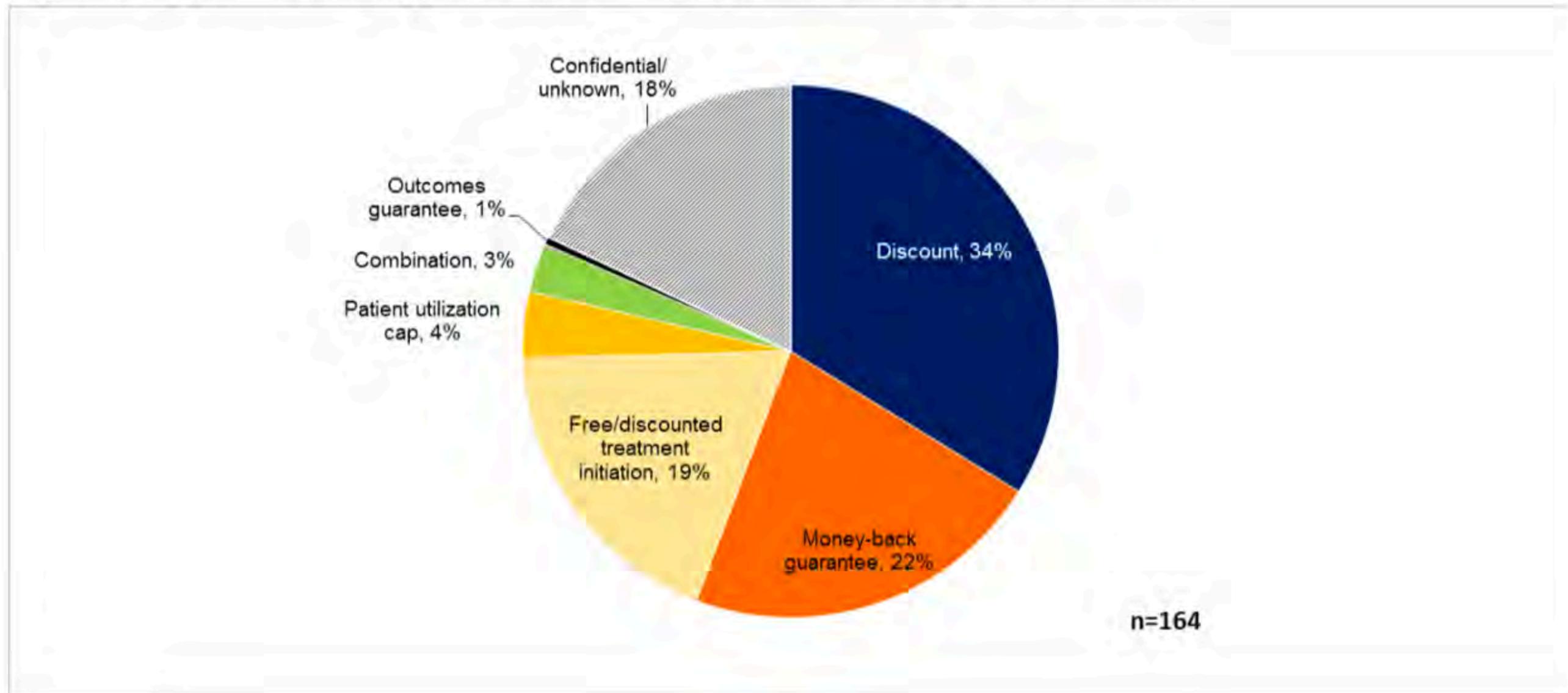
Para afrontar la
incertidumbre
sobre el valor creado
(efectividad) los
contratos de
riesgo compartido
son una **buena idea**

Instrumentos de financiación cada vez más sofisticados



MEA: Managed Entry Agreement

Fig. 3.10: Types of MEA applied for cancer medicines in European countries



Source: (193)

1 1

**Frente al poder de mercado del
vendedor conviene oponer
poder de mercado del
comprador (al menos de las 17
CCAA) y Arquitectura
Institucional (AGENCIA
EJECUTIVA)**

11

Frente al poder de mercado del vendedor conviene oponer poder de mercado del comprador (al menos de las 17 CCAA) y Arquitectura Institucional (AGENCIA EJECUTIVA)

Efectos secundarios benéficos del comprador público:
inequidades territoriales de acceso

12

**Dinámica de precios:
fomentar competencia y
revisión precoz
(biosimilares)**

13

**Transparencia vs
opacidad:
ventajas de la
transparencia**

Y el último:

14

**No olvidemos ni la
prevención
ni los cuidados
paliativos**

Muchas gracias
beatriz.lopezvalcarcel@ulpgc.es