



天然藥物與保健食品 研發與進展

溫致群

2018/11/18



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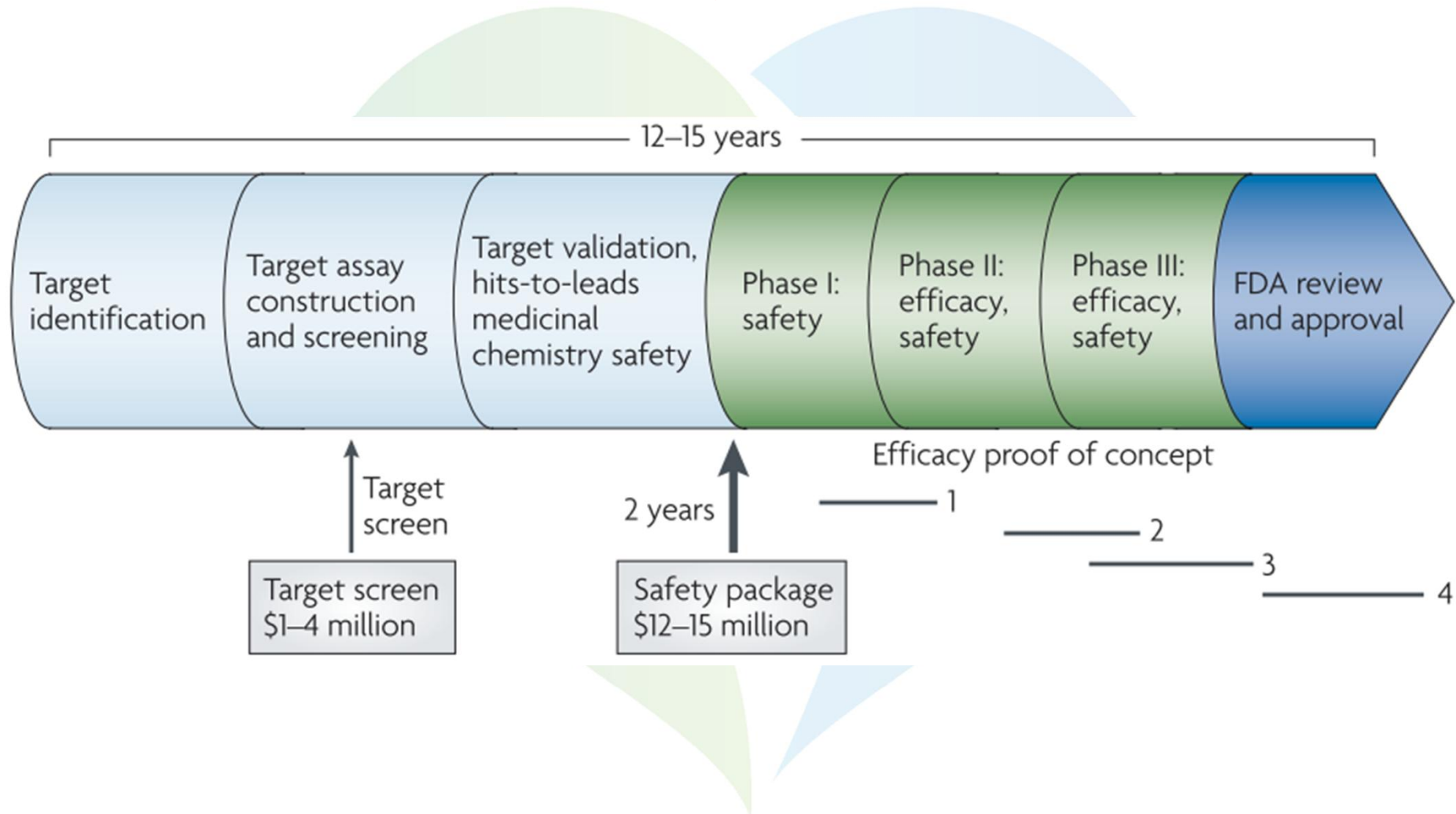
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台北醫學大學2016全球生醫健康企業家班

學歷

中國醫藥學院藥學系
中國醫藥大學藥物化學研究所
碩士/博士

藥物研發歷程



Roses, A. D. (2008). Pharmacogenetics in drug discovery and development: a translational perspective. *Nature Reviews Drug Discovery*, 7(10), 807–817. doi:10.1038/nrd2593

智慧財產

專利

- 發明/新型/設計
- 20年/10年/12年
- 新穎性/進步性/產業利用性

商標

- 品牌
- 商品名/圖片
- 服務名/圖片

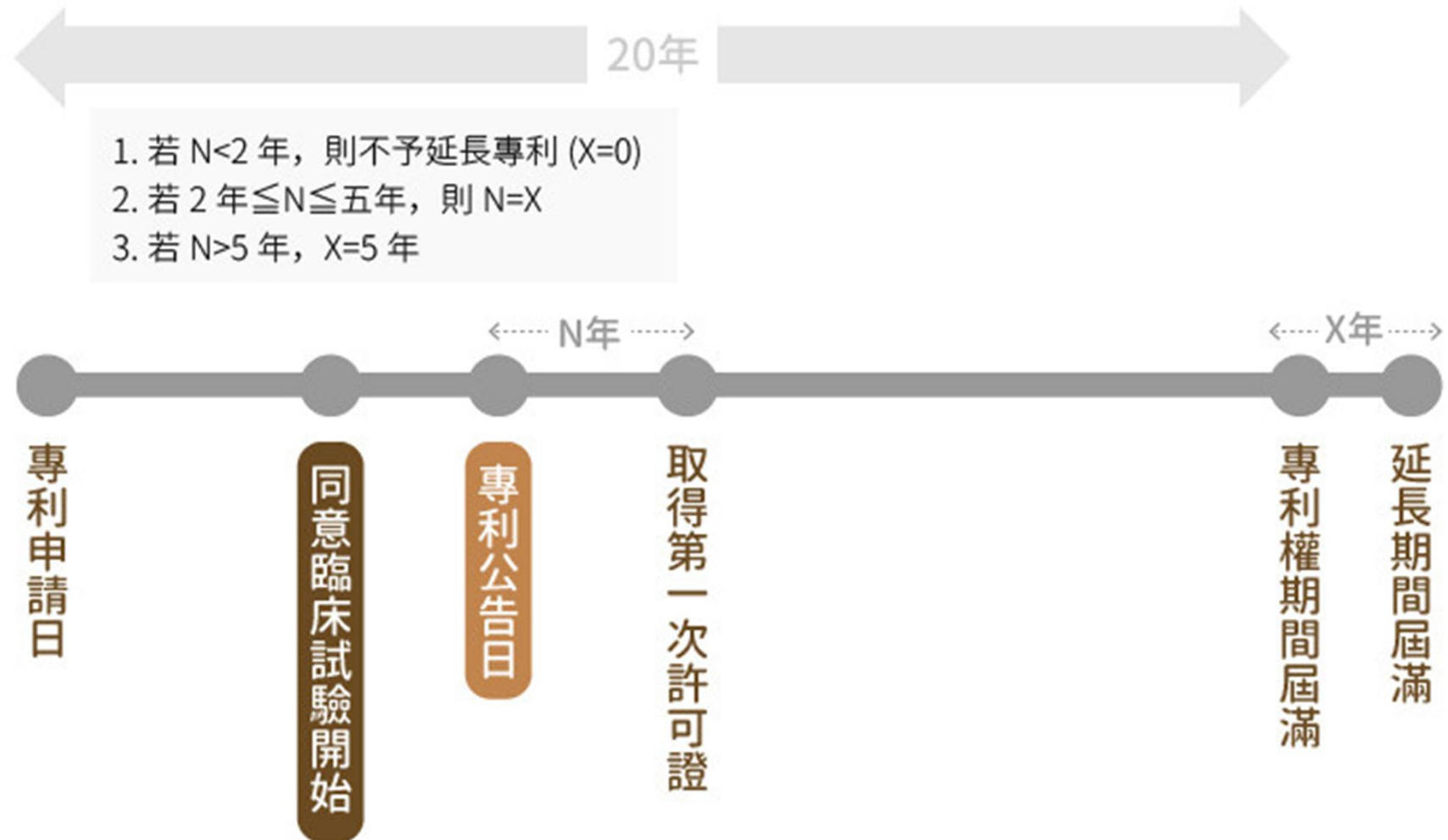
著作權

- 品牌/文章/文字/影像
- 商品名/圖片、服務名/圖片
- **刑期**

營業秘密

- 不公開
- 保密
- **刑期**

臨床試驗開始日在專利公告之前，因醫藥品審查過程所耗費的時間從專利公告日開始計算



臨床試驗開始日在專利公告日的後面，因醫藥品審查過程所耗費的時間從臨床試驗開始日起算

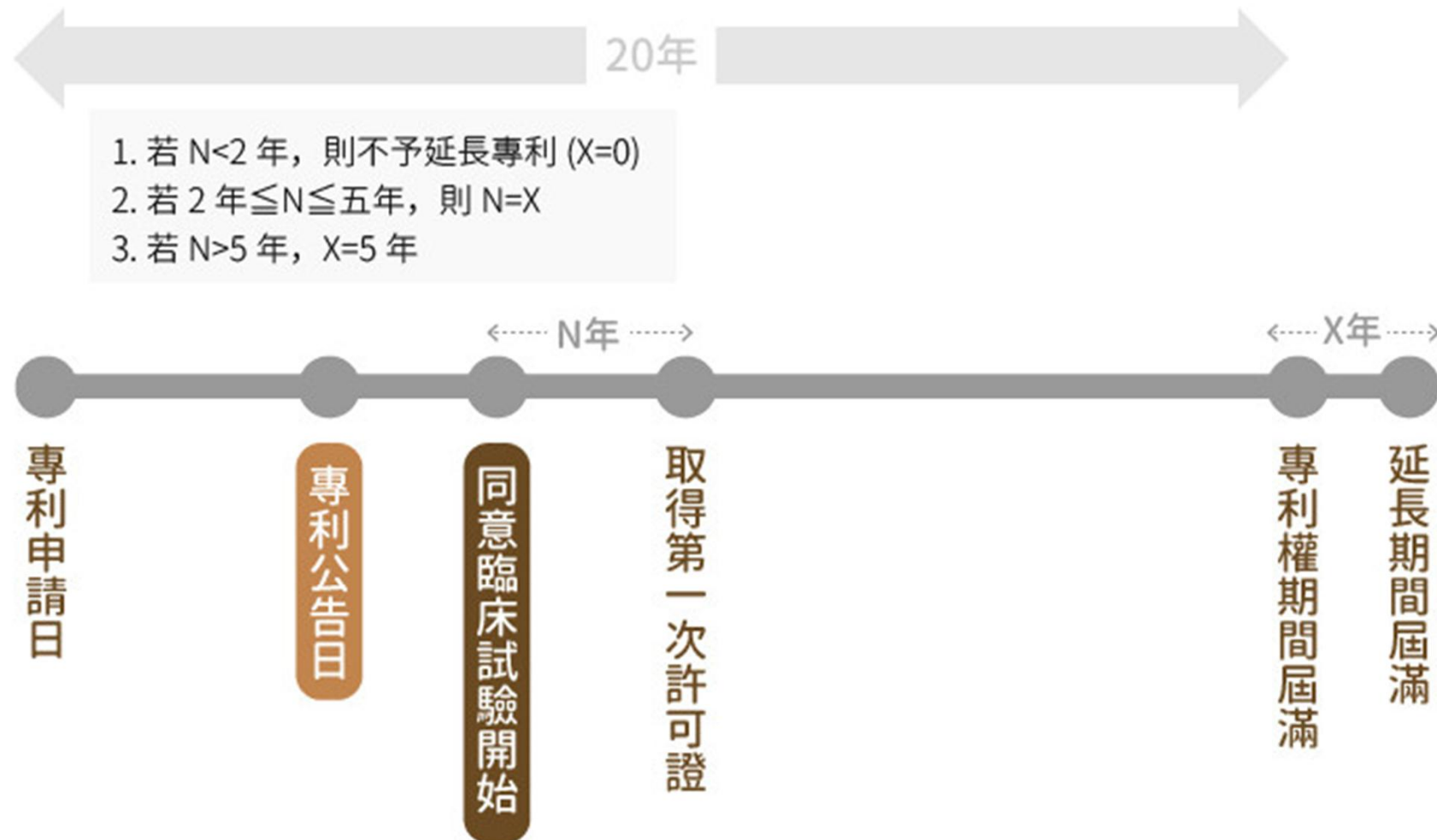
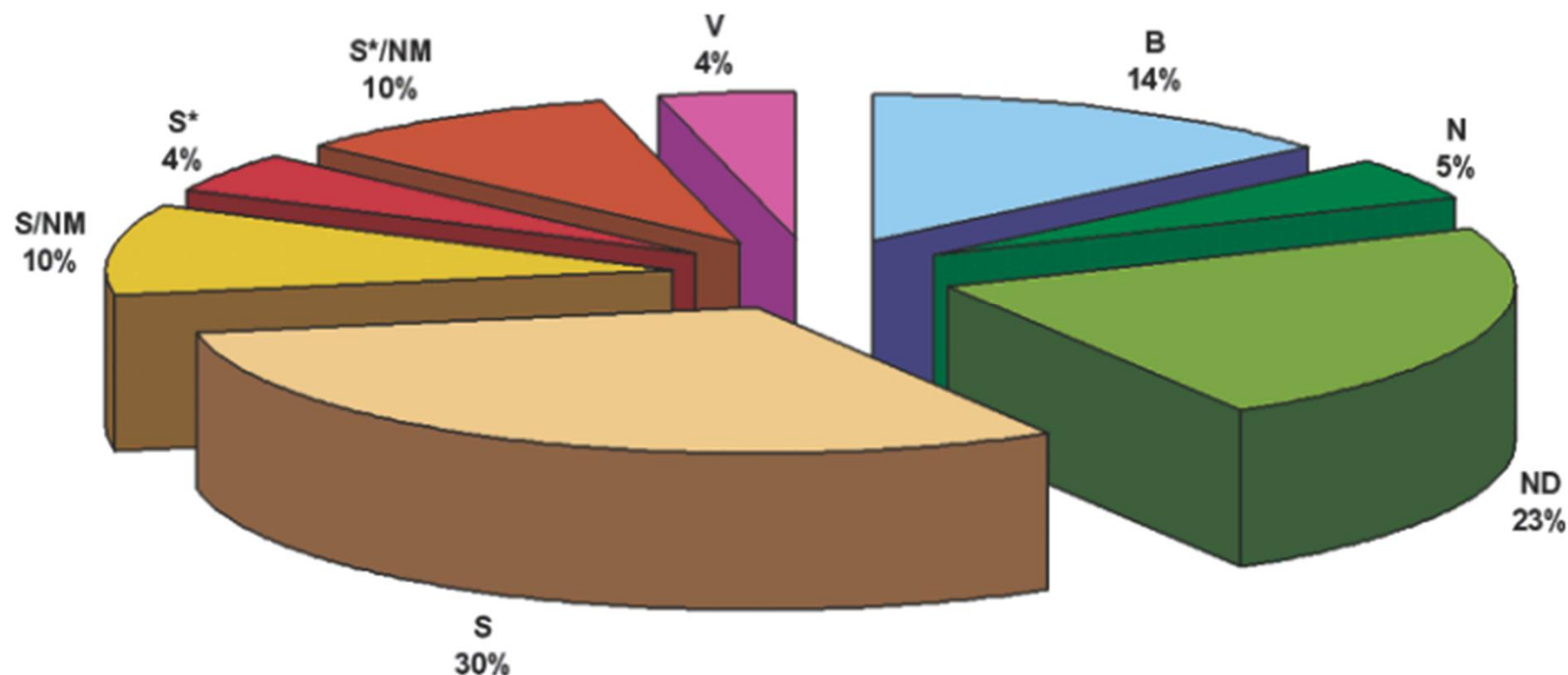


Figure 1. All new chemical entities, 01/1981–06/2006, by source ($N = 1184$).



"**B**" Biological; usually a large (> 45 residues) peptide or protein either isolated from an organism/cell line or produced by biotechnological means in a surrogate host.

"**N**" **Natural product**.

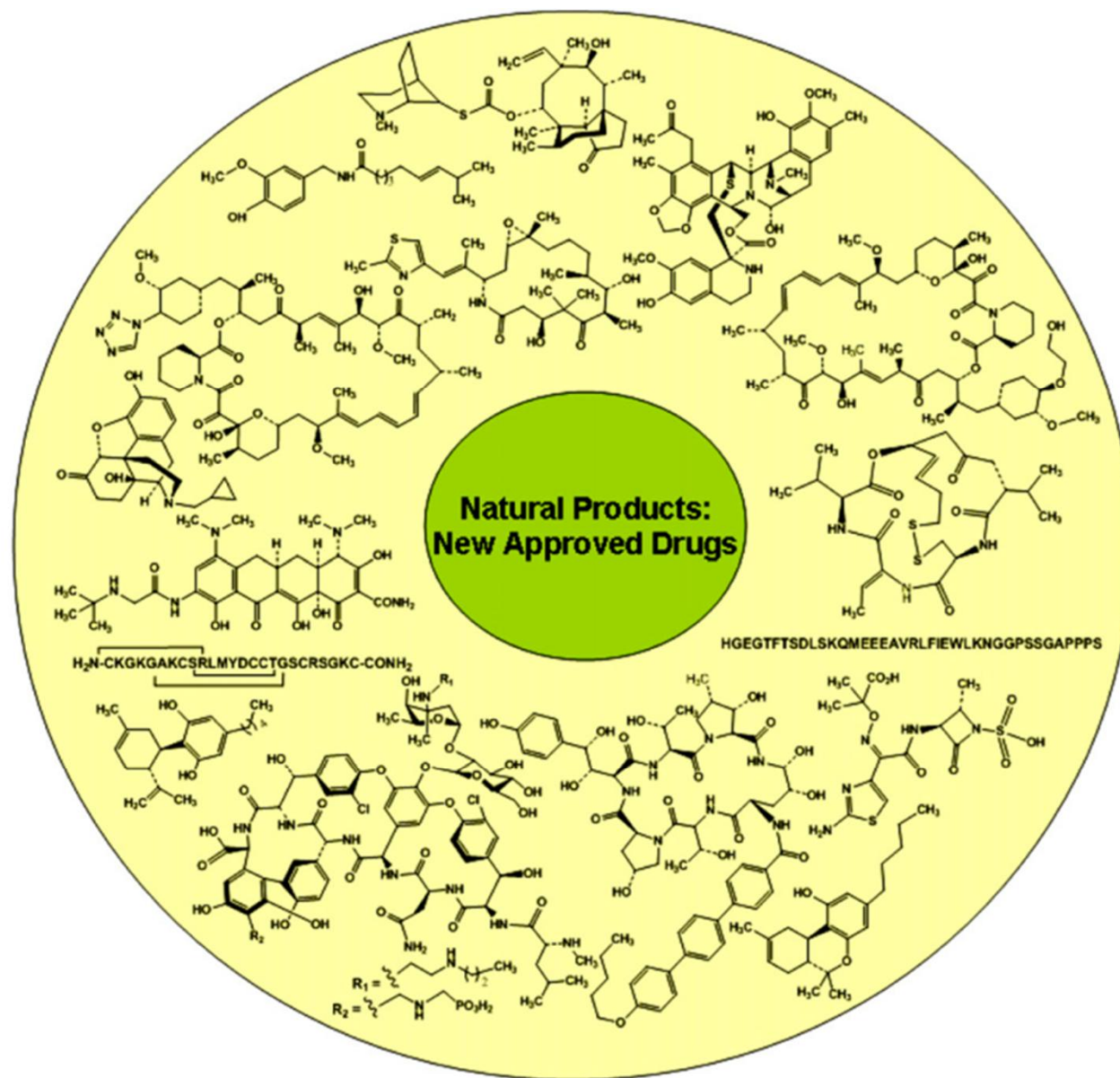
"**ND**" Derived from a **natural product** and is usually a semisyn-thetic modification.

"**S**" Totally synthetic drug, often found by random screening/modification of an existing agent.

"**S***" Made by total synthesis, but the pharmacophore is/was from a **natural product**.

"**V**" Vaccine.

Subcategory. "**NM**" **Natural product mimic**



Scheme 1. Drugs approved during 2005–2010.

Mishra, B. B. and V. K. Tiwari (2011). "Natural products: an evolving role in future drug discovery." *Eur J Med Chem* 46(10): 4769-4807.

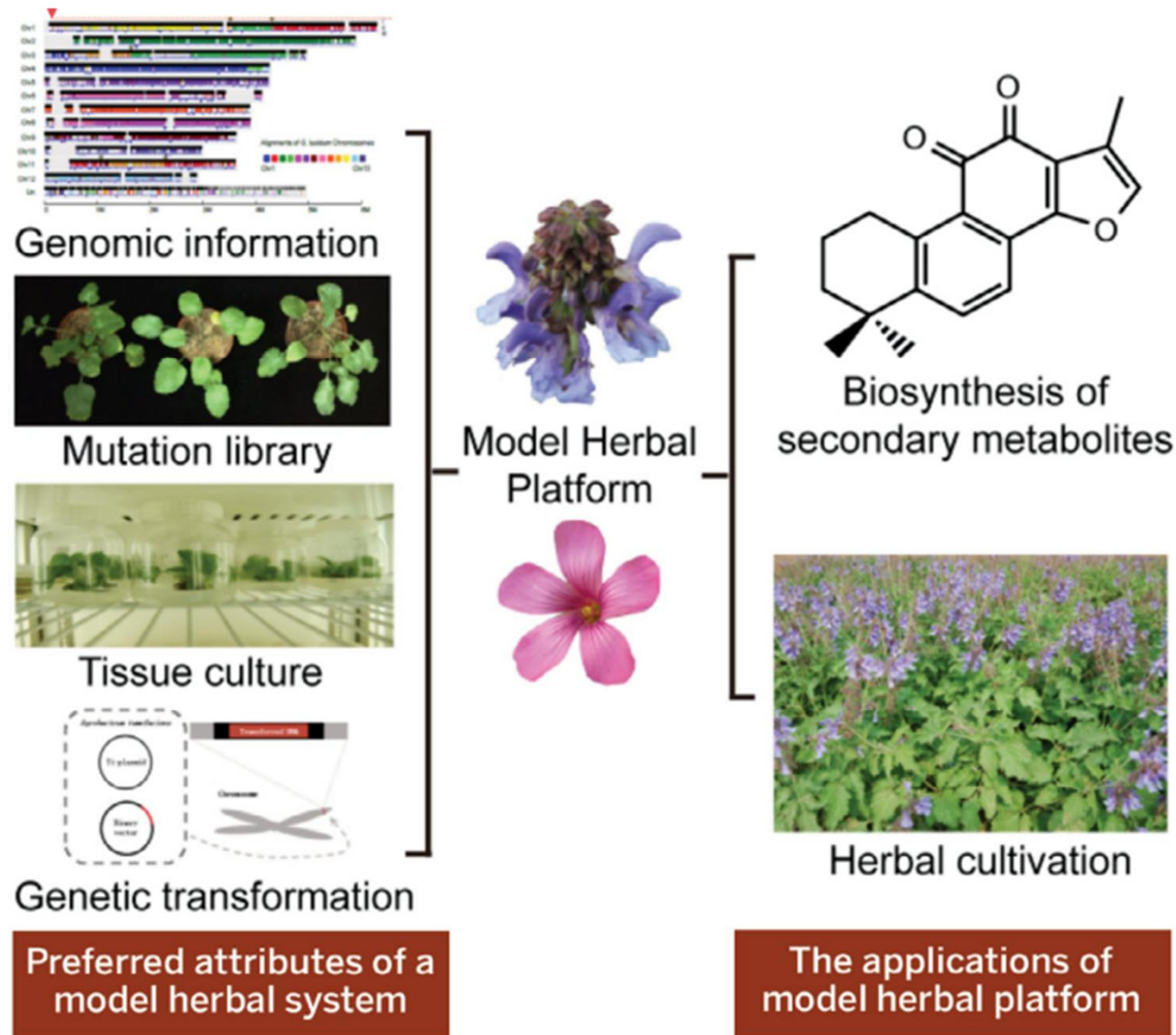
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Table 1

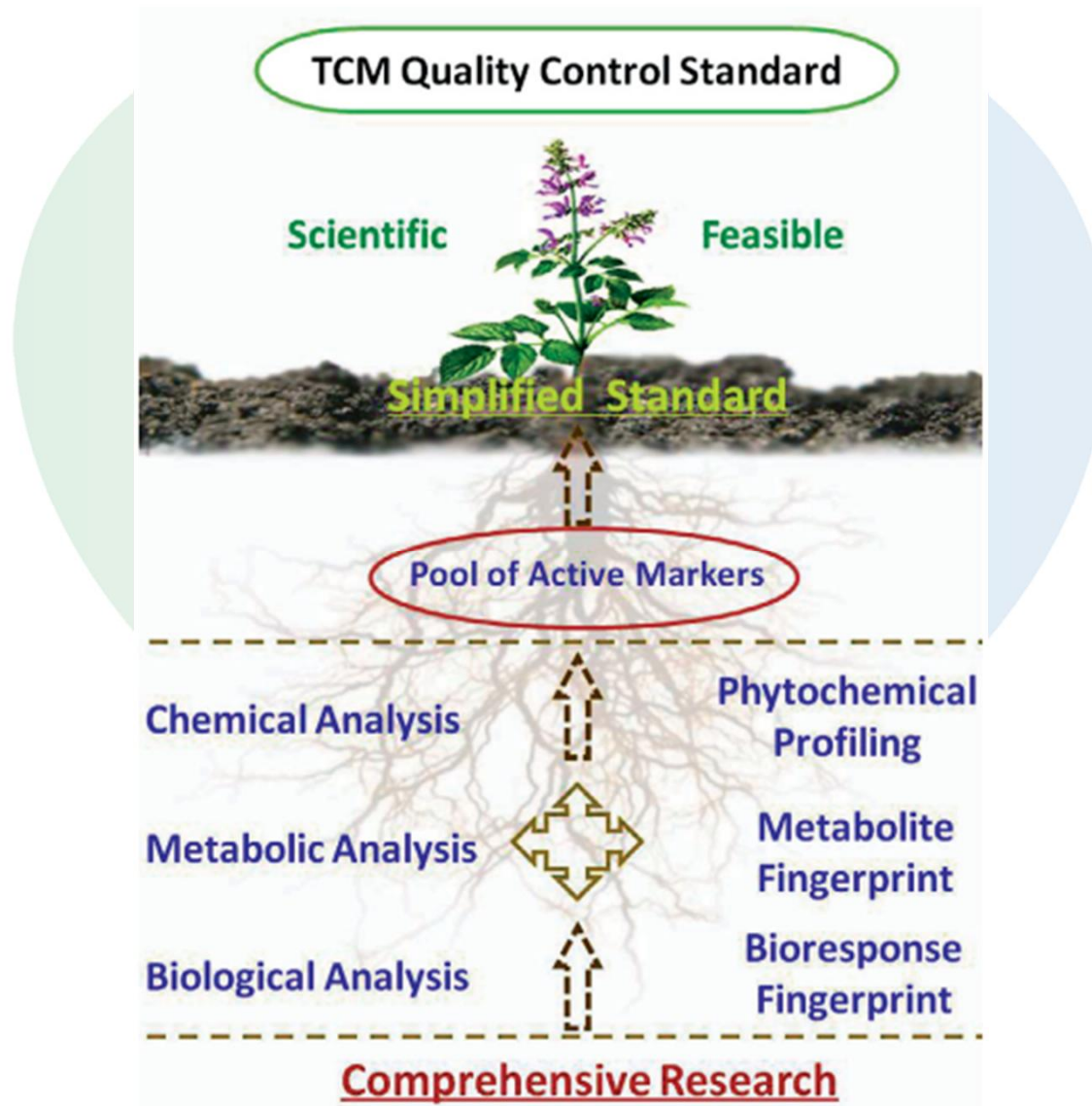
NP-derived drugs launched since 2005; lead compounds, classification and therapeutic area [17–117].

Year	Generic name (trade name)	Lead compound	Classification	Disease area
2005	Dronabinol 1 /Cannabidol 2 (Sativex®)	Dronabinol 1 /cannabidol 2	NPs	Pain
2005	Fumagillin 3 (Flisint®)	Fumagillin 3	NPs	Antiparasitic
2005	Doripenem 4 (Finibax®/Doribax™)	Thienamycin 5	NP-derived	Antibacterial
2005	Tigecycline 6 (Tygacil®)	Tetracycline 7	Semi-synthetic NP	Antibacterial
2005	Ziconotide 8 (Prialt®)	Ziconotide 8	NP	Pain
2005	Zotarolimus 9 (Endeavor™ stent)	Sirolimus 10	Semi-synthetic NP	Cardiovascular surgery
2006	Anidulafungin 11 (Eraxis™/Ecalta™)	Echinocandin B 12	Semi-synthetic NP	Antifungal
2006	Exenatide 13 (Byetta®)	Exenatide-4 13	NP	Diabetes
2007	Lisdexamfetamine 14 (Vyvanse™)	Amphetamine 15	NP-derived	ADHD
2007	Retapamulin 16 (Altabax™/Altargo™)	Pleuromutilin 17	Semi-synthetic NP	Antibacterial
2007	Temsirolimus 18 (Torisel™)	Sirolimus 10	Semi-synthetic NP	Oncology
2007	Trabectedin 19 (Yondelis™)	Trabectedin 19	NP	Oncology
2007	Ixabepilone 20 (Ixempra™)	Epothilone B 21	Semi-synthetic NP	Oncology
2008	Methylnaltrexone 22 (Relistor®)	Naltrexone 23	Semi-synthetic NP	Pain
2009	Everolimus 24 (Afinitor®)	Sirolimus 10	Semi-synthetic NP	Oncology
2009	Telavancin 25 (Vibativ™)	Vancomycin 26	Semi-synthetic NP	Antibacterial
2009	Romidepsin 27 (Istodax®)	Romidepsin 27	NP	Oncology
2009	Capsaicin 28 (Qutenza®)	Capsaicin 28	NP	Pain
2010	Monobactam aztreonam 29 (Cayston™)	Aztreonam 29	Semi-synthetic NP	Antibacterial

Model herb systems and their applications.



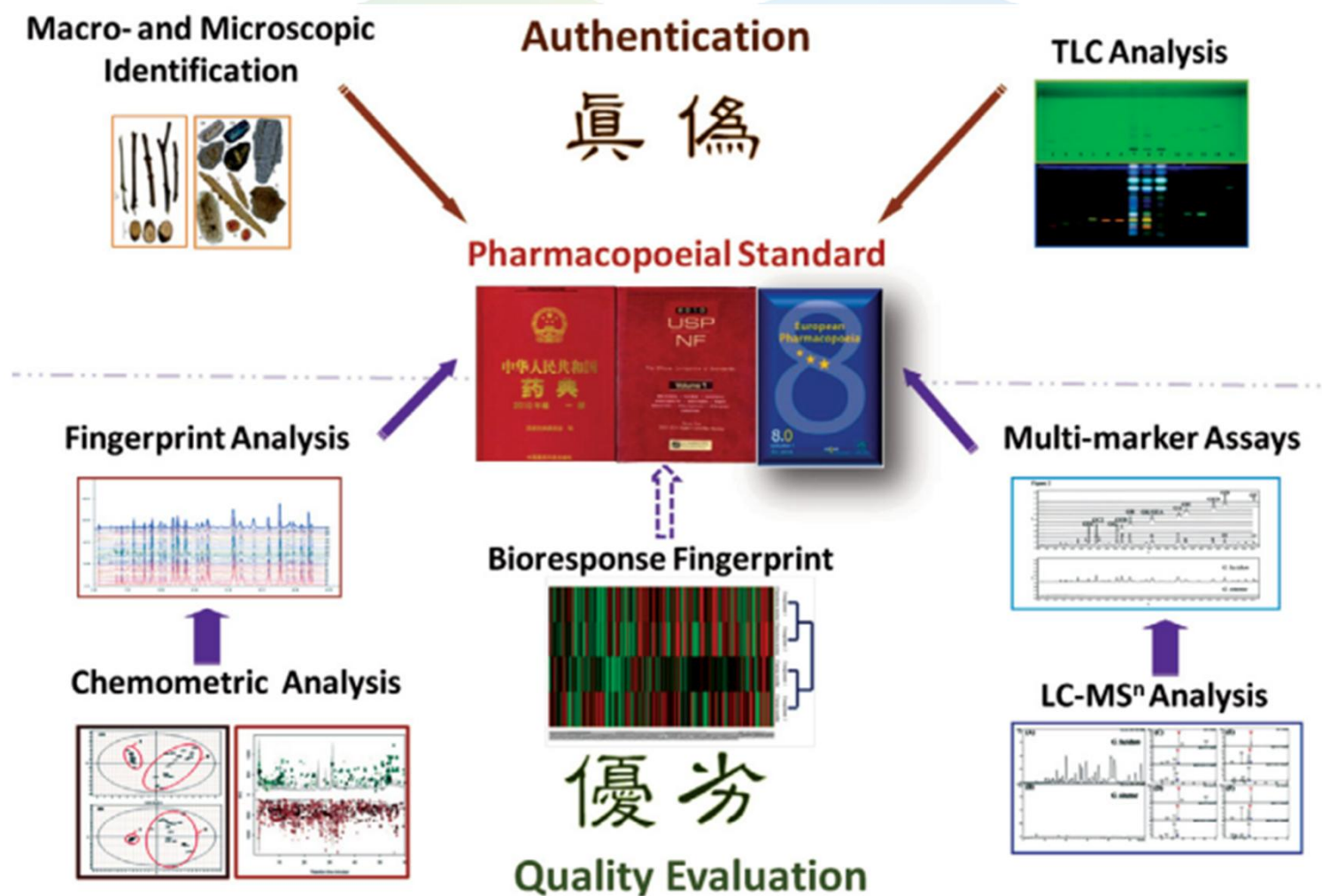
A systemic traditional Chinese medicine (TCM) quality research approach: from comprehensive research to simplified standard



Guo, D.-a., W.-Y. Wu, M. Ye, X. Liu and G. A. Cordell (2015). "A holistic approach to the quality control of traditional Chinese medicines." Science 347(6219): S29-S31.

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Holistic quality control model for traditional Chinese medicines. TLC, thin layer chromatography; LC-MSⁿ, liquid Chromatography/multiple-stage mass spectrometry.



Guo, D.-a., W.-Y. Wu, M. Ye, X. Liu and G. A. Cordell (2015). "A holistic approach to the quality control of traditional Chinese medicines." *Science* 347(6219): S29-S31.

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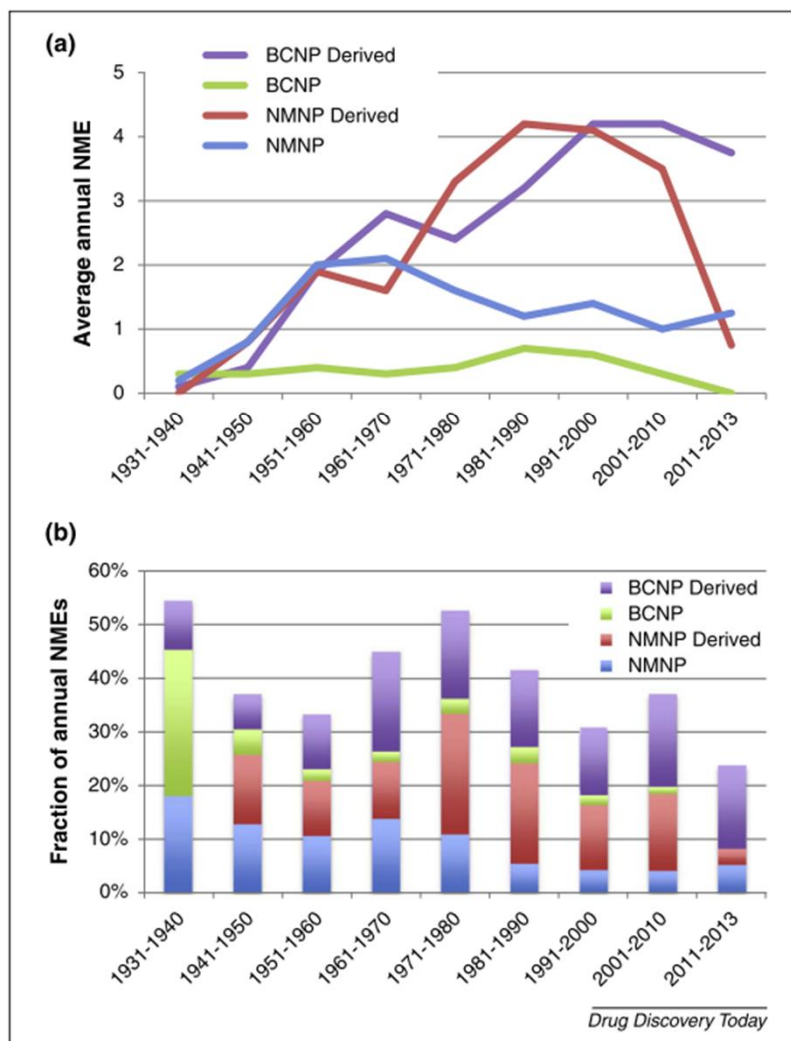


FIGURE 1

Natural product new molecular entity (NME) derivatives. **(a)** The average number of FDA-approved NMEs is shown on an annual basis. Note these numbers solely represent approvals and do not address drugs subsequently withdrawn. **(b)** The fraction of annually approved NMEs is separated into non-mammalian natural products (NMNPs) and biochemical natural products (BCNPs), as well as their semisynthetic or synthetic derivatives.

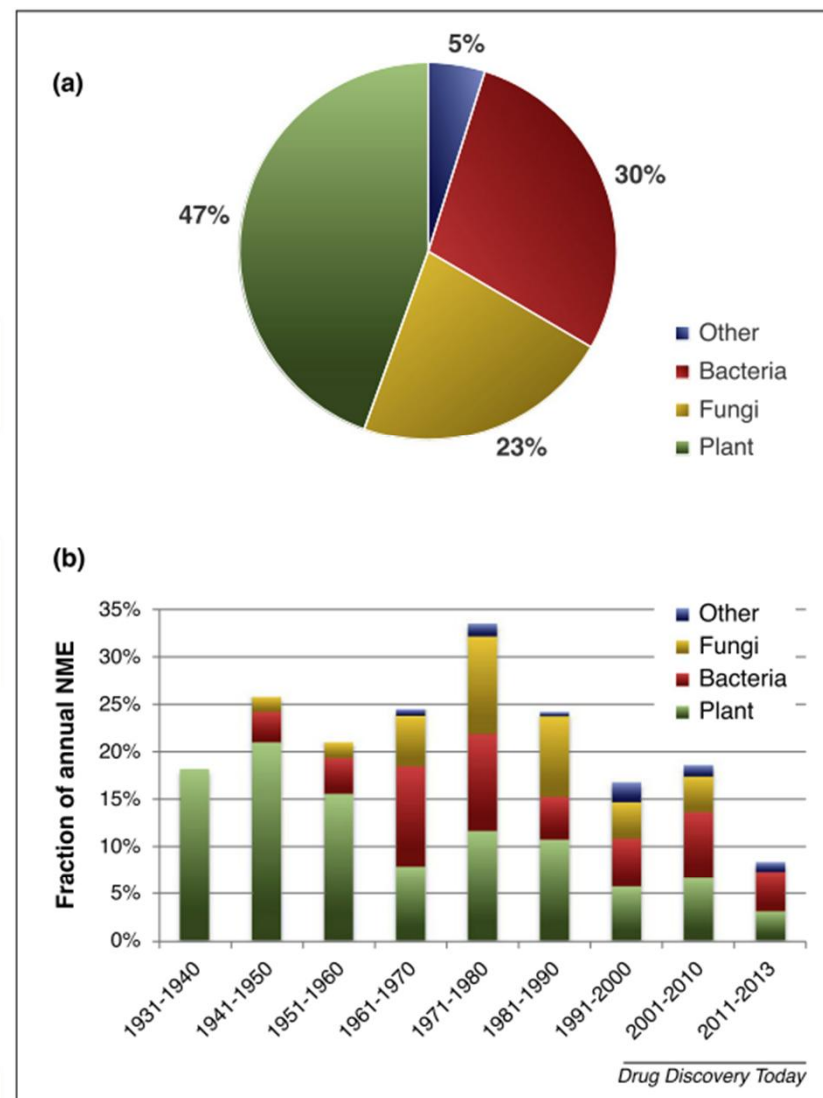


FIGURE 2

Microbial enrichment of natural product new molecular entities (NMEs). **(a)** The cumulative percentage of FDA-approved natural product NMEs, separated by environmental source. **(b)** The fraction of annually approved NMEs is separated by environmental sources, over time.

Patridge, E., P. Gareiss, M. S. Kinch and D. Hoyer (2016). "An analysis of FDA-approved drugs: natural products and their derivatives." *Drug Discov Today* 21(2): 204-207.

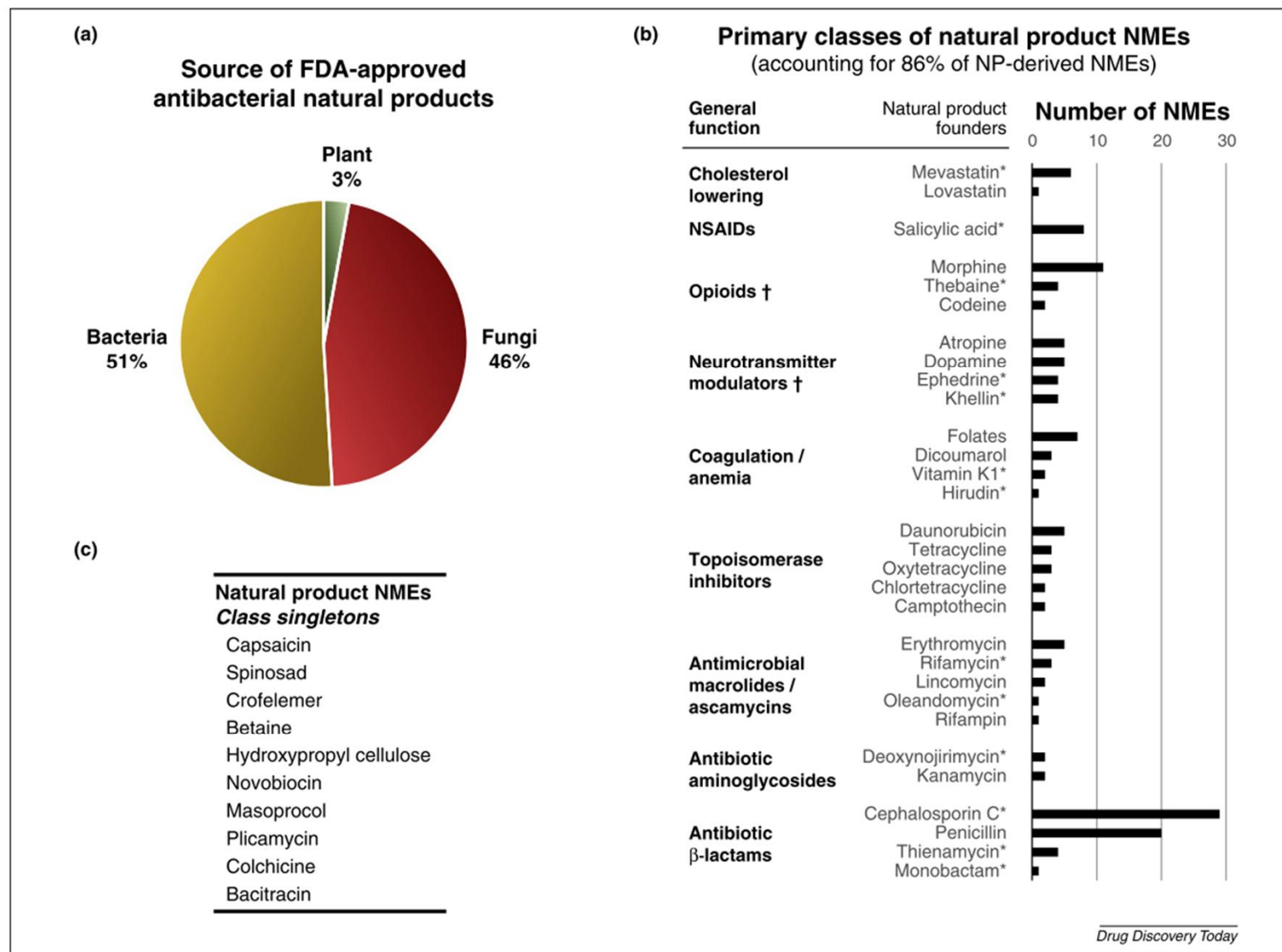


FIGURE 3

Therapeutic classes rich in natural product new molecular entities (NMEs). (a) The cumulative percentage of FDA-approved natural product antibacterials, separated by environmental source. (b) Nine leading functional areas for natural products (accounting for 86% of all natural product derivatives). The asterisk (*) indicates the founding natural products which are not FDA approved. The dagger (†) indicates classes involving G-protein-coupled receptors (GPCRs). (c) Ten class singletons for FDA-approved natural product NMEs.

Patridge, E., P. Gareiss, M. S. Kinch and D. Hoyer (2016). "An analysis of FDA-approved drugs: natural products and their derivatives." *Drug Discov Today* 21(2): 204-207.

Qinghaosu (Artemisinin 青蒿素)

- Hien and White, Lancet 1993;341:603-608.
- White NJ.: **Qinghaosu (Artemisinin): The price of success.** *Science* 2008;320:330-4
- **First extracted from** the leaves of *Artemisia annua* **in China in 1971.**
- **The endoperoxide bridge** essential for **antimalarial activity.**
- Concentrated in parasitized erythrocytes;
- Over **1 million patients** treated with qinghaosu, meta-analysis indicated superiority in **fever and parasite clearance time** over conventional drugs.

Asian governments hope that high-volume screening and rigorous clinical trials will unlock the secrets of ancient herbal remedies—and that the results will pass muster with Western scientists

The New Face of Traditional Chinese Medicine

Qinghao (*Artemisia annua*, sweet wormwood)

Traditional use: To treat fevers.

The source of artemisinin, an antimalarial compound that may also have anticancer properties.



Huangchi (*Astragalus membranaceus*, yellow root)

Traditional use: All-around tonic to boost energy.

The source of the active compound in Xue Bao PG2, which ameliorates the side effects of chemotherapy. Approved by China, preparing for phase III clinical trials in Taiwan.



Mahuang (*Ephedra sinica*, country mallow)

Traditional use: To treat respiratory congestion.

The source of ephedrine, an amphetamine-like stimulant used in decongestants and asthma medications.



Iijen (*Coix lachryma-jobi*, Job's tears)

Traditional use: To treat tumors.

Source of the active compound in the Kanglaite Injection. Approved in China as an anticancer drug, preparing for phase II clinical trials in the United States.



Qinghaosu (Artemisinin): The Price of Success

N. J. White
Science **320**, 330 (2008);

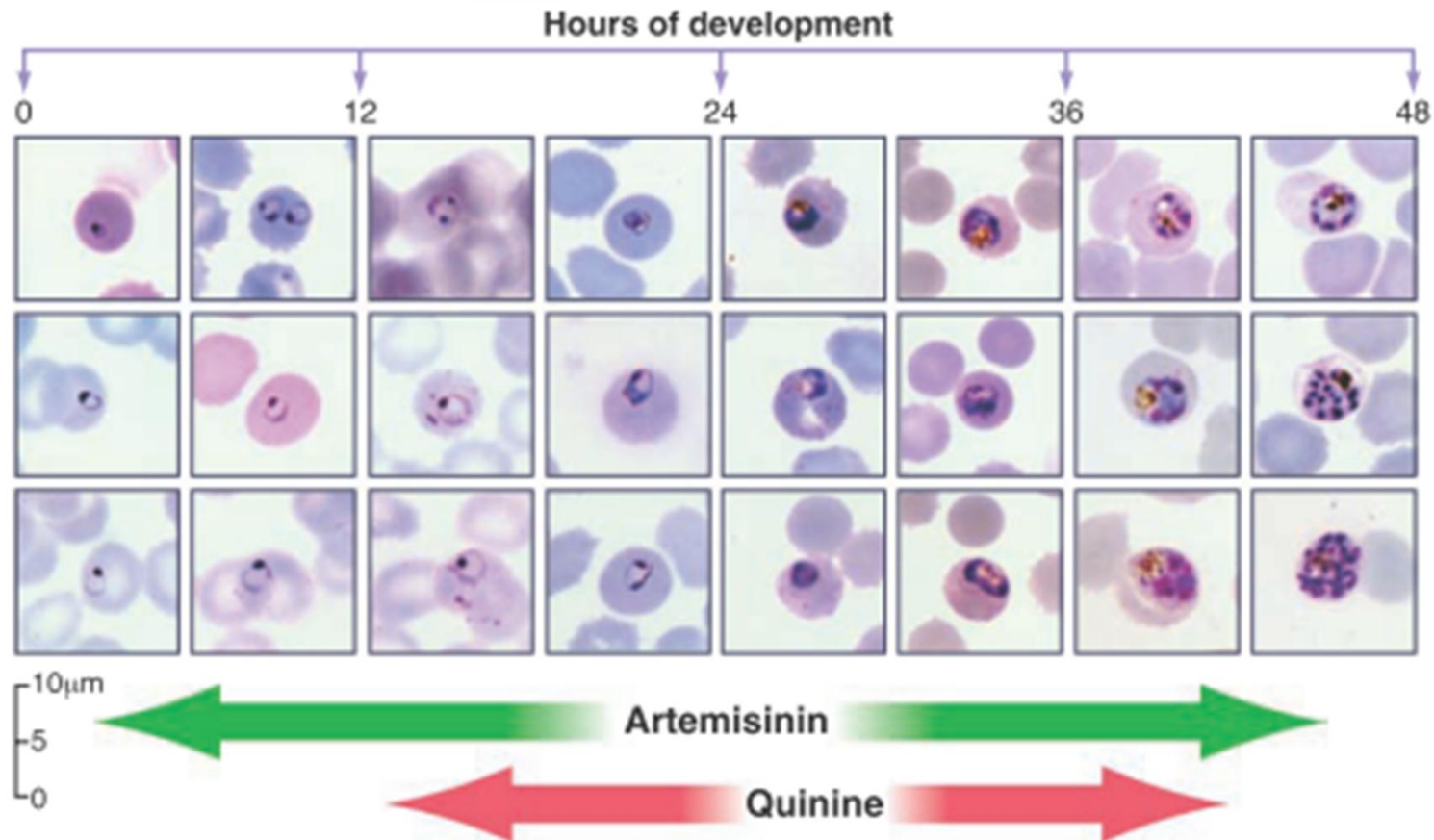


Fig. 1. The intraerythrocytic life cycle of *P. falciparum*. Parasitized red cells circulate for the first third of the 48-hour cycle and then sequester in capillaries and venules. Artemisinins inhibit development of a broader age range of the parasites than do quinine and other antimalarial drugs. The effect on the young rings prevents their development to the more pathological mature parasites that sequester.

Qinghaosu (Artemisinin): The Price of Success

N. J. White
Science **320**, 330 (2008);

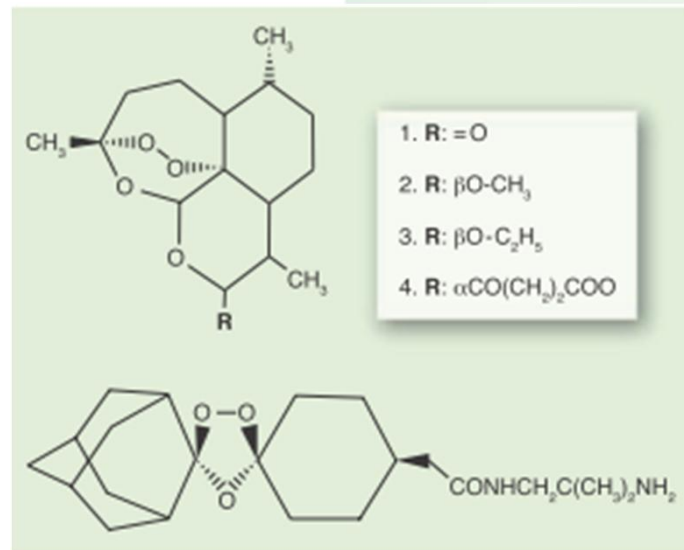


Fig. 3. Chemical structures. (Top) Artemisinin and its derivatives. 1, artemisinin; 2, artemether; 3, artemotil (arteether); 4, artesunate. (Bottom) The synthetic trioxolane OZ 277 (51).

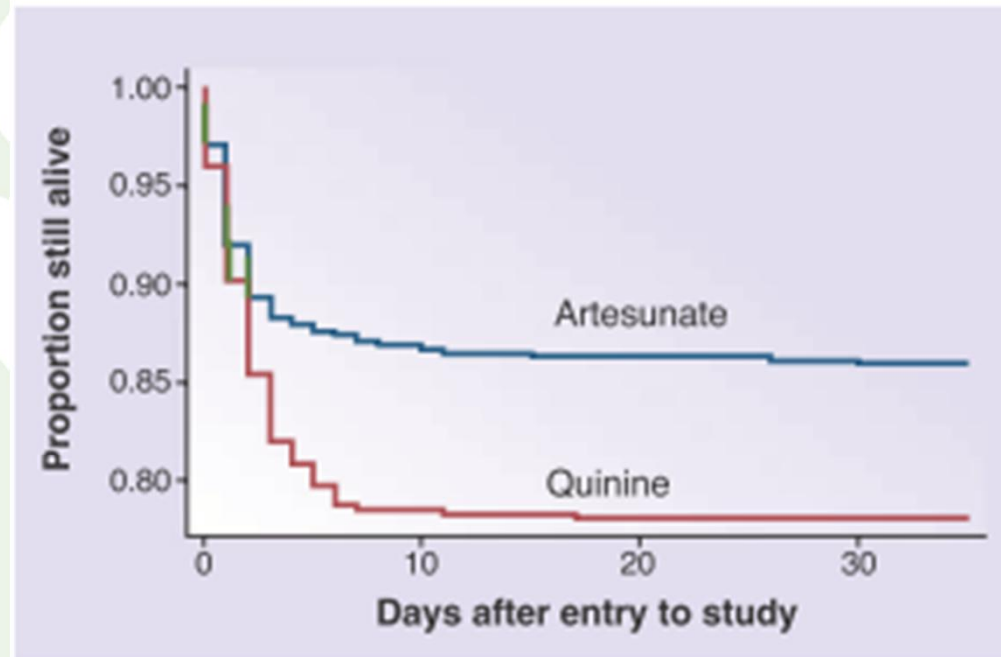


Fig. 6. Treatment with intravenous artesunate was associated with a 35% reduction in mortality from severe malaria compared with intravenous quinine in a randomized trial of 1461 adults and children in Southeast Asia (36). The vertical axis shows the proportion of patients surviving.

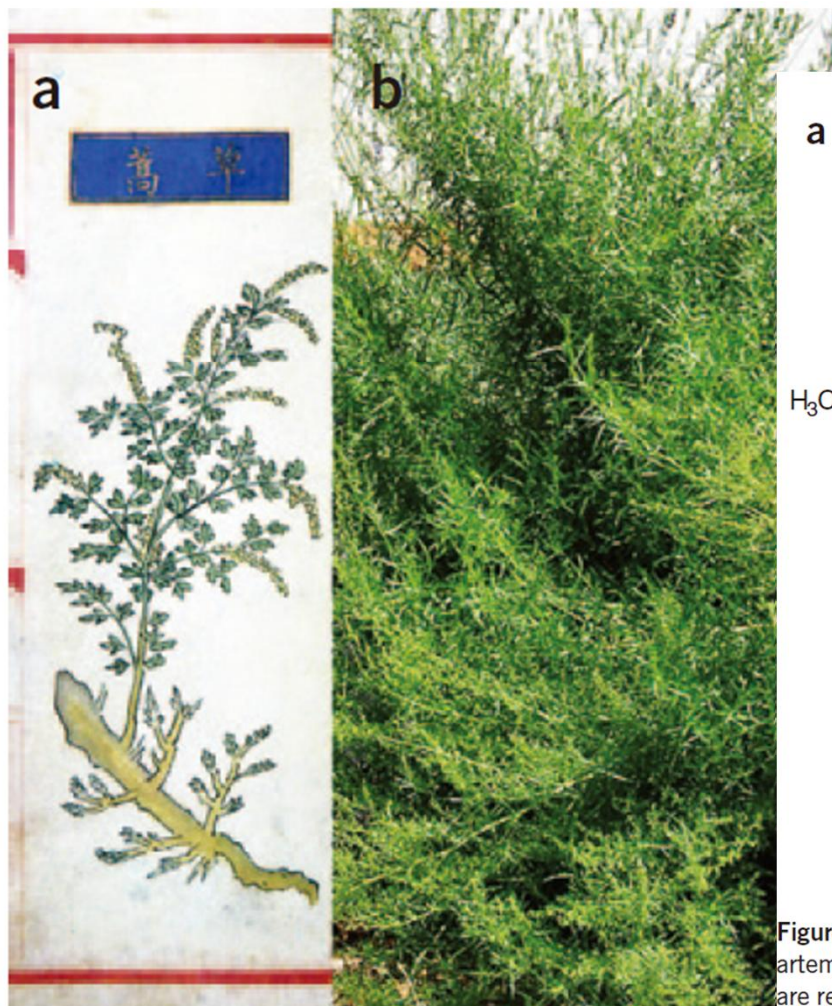


Figure 2 *Artemisia annua* L. (a) A hand-colored drawing of qinghao in Bu Yi Lei Gong Pao Zhi Bian Lan (Ming Dynasty, 1591 CE). (b) *Artemisia annua* L. in the field.

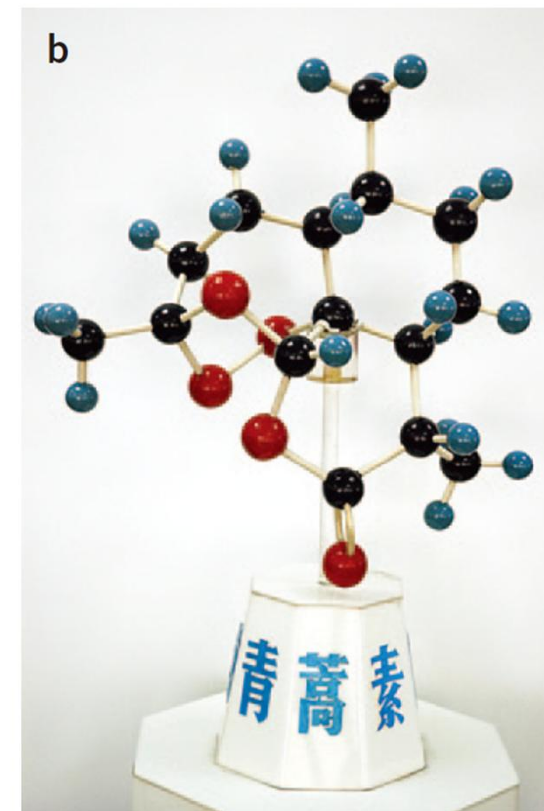
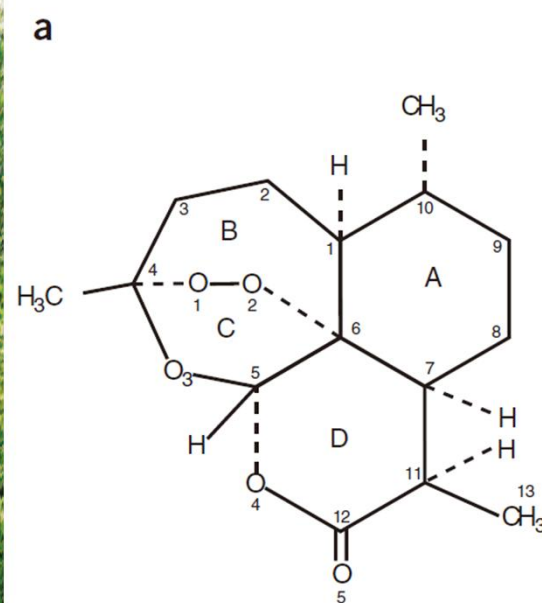


Figure 3 Artemisinin. (a) Molecular structure of artemisinin. (b) A three-dimensional model of artemisinin. Carbon atoms are represented by black balls, hydrogen atoms are blue and oxygen atoms are red. The Chinese characters underneath the model read *Qinghaosu*.

Tu, Y. (2011) The discovery of artemisinin (qinghaosu) and gifts from Chinese medicine, *Nature medicine* 17, 1217-1220.

The discovery of artemisinin (qinghaosu) and gifts from Chinese medicine

Youyou Tu

Joseph Goldstein has written in this journal that creation (through invention) and revelation (through discovery) are two different routes to advancement in the biomedical sciences¹. In my work as a phytochemist, particularly during the period from the late 1960s to the 1980s, I have been fortunate enough to travel both routes.

I graduated from the Beijing Medical University School of Pharmacy in 1955. Since then, I have been involved in research on Chinese herbal medicine in the China Academy of Chinese Medical Sciences (previously known as the Academy of Traditional Chinese Medicine). From 1959 to 1962, I was released from work to participate in a training course in Chinese medicine that was especially designed for professionals with backgrounds in Western medicine. The 2.5-year training guided me to the wonderful treasure to be found in Chinese medicine and toward understanding the beauty in the philosophical thinking that underlies a holistic view of human beings and the universe.

LASKER~DEBAKEY CLINICAL MEDICAL
RESEARCH AWARD

屠呦呦女士

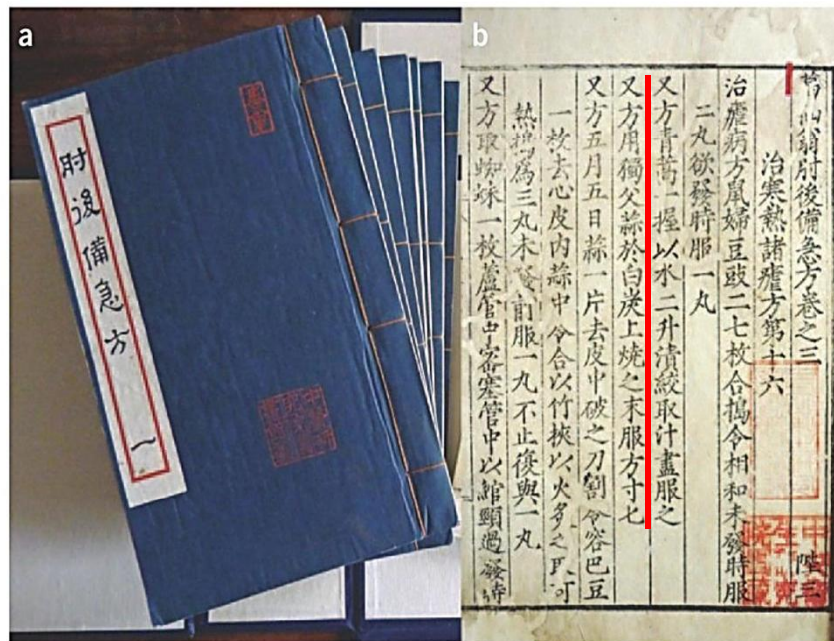


Figure 1 A Handbook of Prescriptions for Emergencies by Ge Hong (284–346 CE). (a) Ming dynasty version (1574 CE) of the handbook. (b) “A handful of qinghao immersed with 2 liters of water, wring out the juice and drink it all” is printed in the fifth line from the right. (From volume 3.)

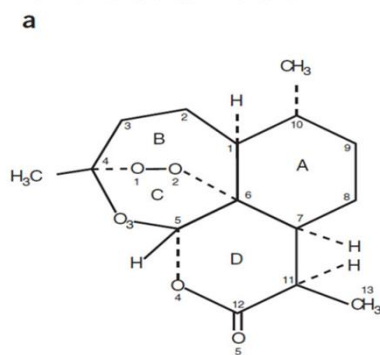


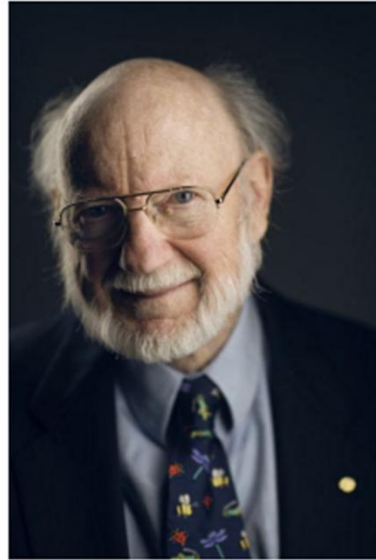
Figure 3 (a) Molecular structure of artemisinin. (b) A three-dimensional model of artemisinin.

Carbon atoms are represented by black balls, hydrogen atoms are blue and oxygen atoms are red. The Chinese characters underneath the model read *Qinghaosu*.



Figure 2 (a) A hand-colored drawing of qinghao in Bu Yi Lei Gong Pao Zhi Bian Lan (Ming Dynasty, 1591 CE). (b) *Artemisia annua* L. in the field.

The Nobel Prize in Physiology or Medicine 2015



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William C. Campbell

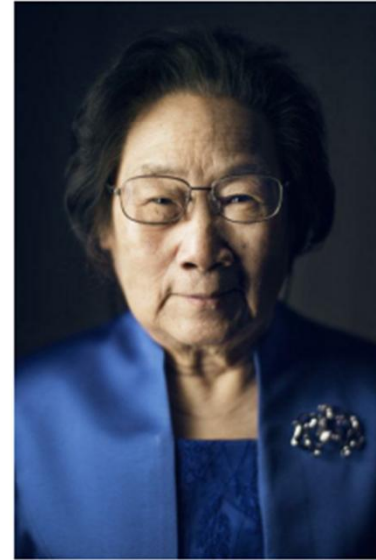
Prize share: 1/4



© Nobel Media AB. Photo: A. Mahmoud

Satoshi Ōmura

Prize share: 1/4



© Nobel Media AB. Photo: A. Mahmoud

Youyou Tu

Prize share: 1/2

The Nobel Prize in Physiology or Medicine 2015 was divided, one half jointly to William C. Campbell and Satoshi Ōmura "for their discoveries concerning a novel therapy against infections caused by roundworm parasites" and the other half to Youyou Tu "for her discoveries concerning a novel therapy against Malaria."

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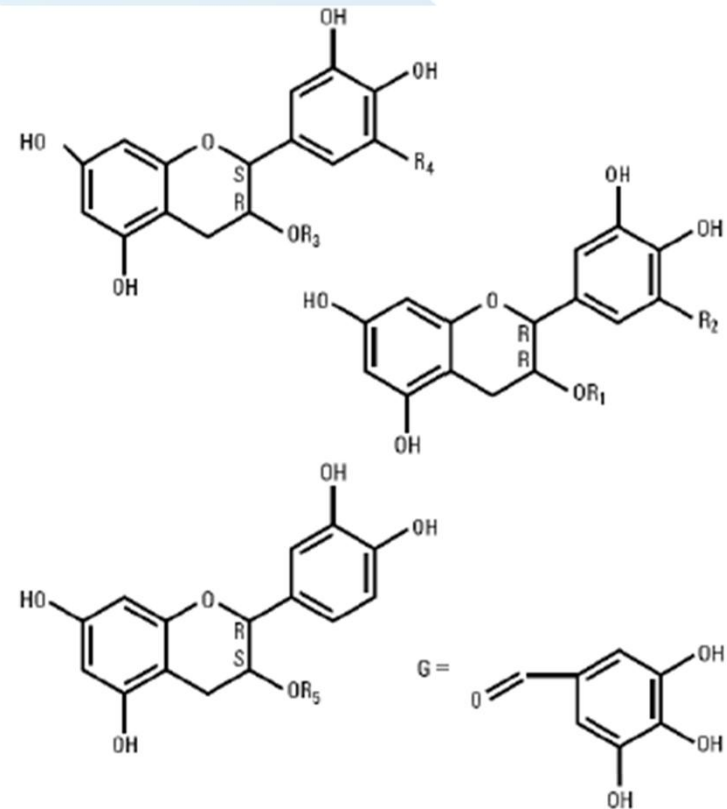
TABLE 1. Number of botanical pre-INDs and INDs submitted to CDER (2004-2013).

Submissions	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Total
Pre-IND	12	6	11	7	14	10	10	8	5	8	91
IND	21	38	22	39	27	27	27	33	33	51	318
Pre-IND and IND	33	44	33	46	41	37	37	41	38	59	409

第一個USFDA核准的植物新藥



Available in early January 2008 by prescription only



Component	Abbrev.	R1	R2	R3	R4	R5
(-)-Epigallocatechin Gallate	(-)-EGCg	G	OH	-	-	-
(-)-Epicatechin Gallate	(-)-ECg	G	H	-	-	-
(-)-Epigallocatechin	(-)-EGC	H	OH	-	-	-
(-)-Epicatechin	(-)-EC	H	H	-	-	-
(-)-Gallocatechin Gallate	(-)-GCg	-	-	G	OH	-
(-)-Gallocatechin	(-)-GC	-	-	H	OH	-
(-)-Catechin Gallate	(-)-Cg	-	-	G	H	-
(+)-Catechin	(+)-C	-	-	-	-	H

New therapies from old medicines

Shaw T Chen, Jinhui Dou, Robert Temple, Rajiv Agarwal, Kuei-Meng Wu & Susan Walker



Green tea leaves are the source for sin catechins, the active ingredients of Veregen—the first botanical product to be approved as a prescription drug by the FDA.

Table 1 Primary endpoint efficacy results of intent-to-treat trial

	Study CT 1017			Study CT 1018		
	Placebo	10% Veregen ointment	15% Veregen ointment	Placebo	10% Veregen ointment	15% Veregen ointment
n	103	199	201	104	202	196
Success (%)	38 (36.0)	99 (49.7)	102 (50.7)	35 (33.7)	111 (55.0)	111 (56.6)
Fail (%)	65 (63.1)	100 (50.3)	99 (49.3)	69 (66.3)	91 (45.0)	85 (43.3)
<i>P</i> value	—	0.0384	0.0284	—	<0.001	<0.001

Data were analyzed by Fisher's exact test. Source: US Food and Drug Administration



酚瑞淨 軟膏10%

Veregen 10% Ointment

適應症

治療18歲以上成人之外生殖器及肛門周圍的尖形濕疣 (Condylomata acuminata)。

使用限制

治療超過16週及復發再治療病患使用酚瑞淨® 軟膏的有效性與安全性尚未確立。本藥品使用於免疫不全/免疫抑制病患的有效性與安全性尚未確立。

用法用量

塗抹於外生殖器和肛門周圍的尖形濕疣上，一天 3 次。

取約0.5公分長的酚瑞淨® 軟膏塗抹於每個尖形濕疣上。以手指輕輕塗開，使整個濕疣都覆蓋上一層薄薄的軟膏。使用酚瑞淨® 軟膏前後必須洗淨雙手。

每次塗藥前不需要先洗去治療部位上殘餘的軟膏。

酚瑞淨® 軟膏不可用於眼部、口腔、陰道內或肛門內。

療程

酚瑞淨® 軟膏必須持續使用，直到尖形濕疣完全清除為止，但療程不可超過16週。

治療部位常有局部皮膚反應(如紅斑)發生。只要局部皮膚反應的嚴重程度尚可接受，仍應持續治療。

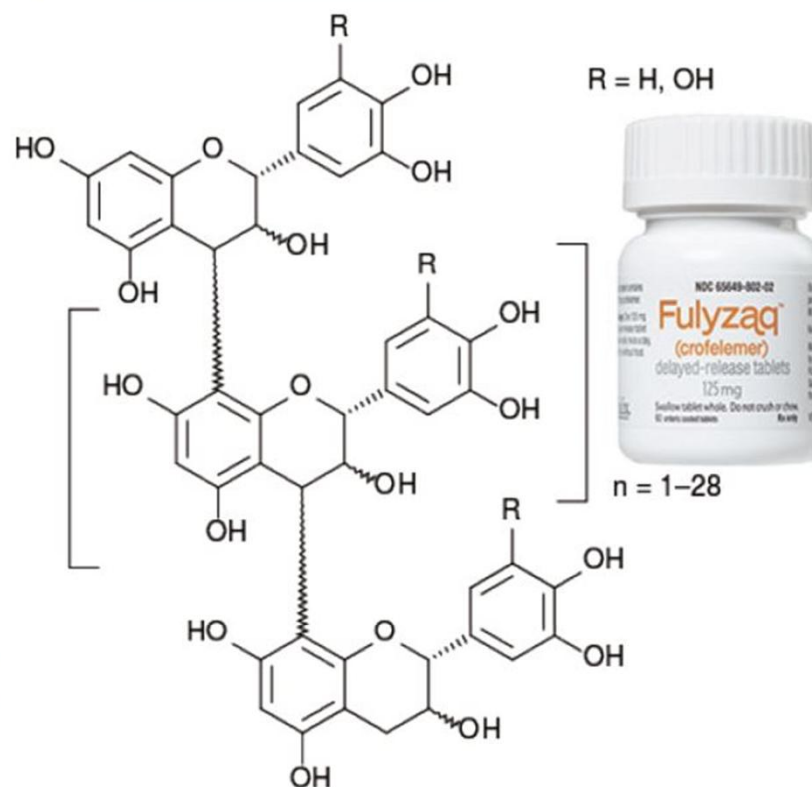
第二個USFDA核准的植物新藥

Introduction

- **Brand name:** Fulyzaq
- **Generic name:** Crofelemer
- **Pharmacological class:** Antidiarrheal
- **Formulation:** Enteric-coated delayed-release tablets
- **Strengths:** 125mg
- **Manufacturer:** Salix
- **How supplied:** Bottle—60
- **Legal Classification:** Rx



Salix Pharmaceuticals, Inc.



Napo Pharmaceuticals Inc.

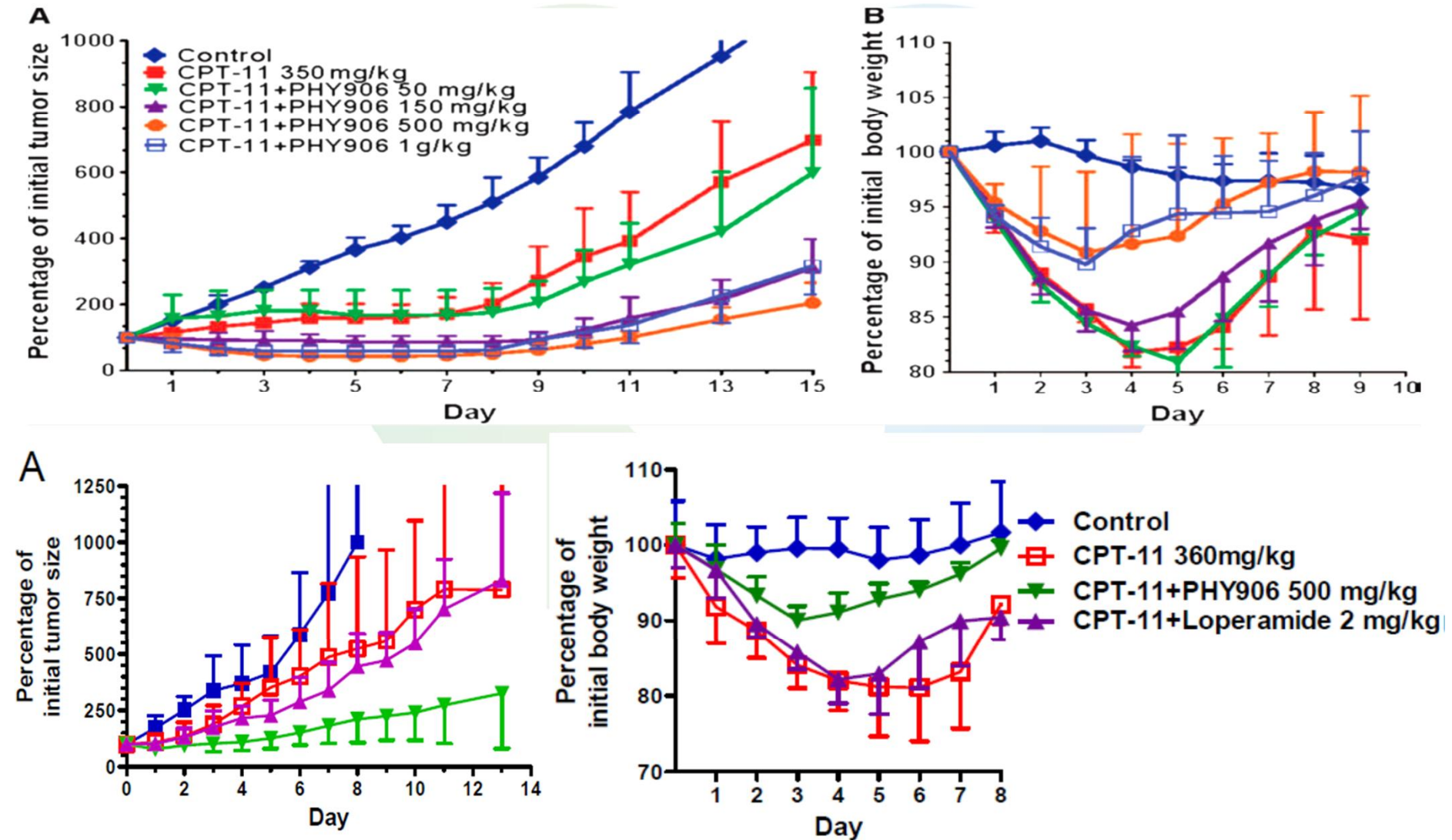
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第三個USFDA核准的植物新藥？

From: Lam W et al. Sci. Transl. Med. 2010;2:45ra59
The Four-Herb Chinese Medicine PHY906 Reduces
Chemotherapy-Induced Gastrointestinal Toxicity

PHY906(黃芩湯), a four-herb Chinese medicine formula first described 1800 years ago, decreases gastrointestinal toxicity induced by the chemotherapeutic drug CPT-11 (irinotecan), as shown in a phase I/II clinical study. Similarly, **in a murine colon 38 allograft model, PHY906 increased the antitumor activity of CPT-11 while decreasing animal weight loss caused by CPT-11.** Here, we have further examined the effect of PHY906 on the intestinal toxicity caused by CPT-11 in mice. PHY906 did not protect against the initial DNA damage and apoptosis triggered by CPT-11 in the intestine, but by 4 days after CPT-11 treatment, PHY906 had restored the intestinal epithelium by promoting the regeneration of intestinal progenitor or stem cells and several Wnt signaling components. PHY906 also potentiated Wnt3a activity in human embryonic kidney–293 cells. Furthermore, PHY906 exhibited anti-inflammatory effects in mice by decreasing the infiltration of neutrophils or macrophages, tumor necrosis factor– α expression in the intestine, and proinflammatory cytokine concentrations in plasma. Chemical constituents of PHY906 potently inhibited nuclear factor κ B, cyclooxygenase-2, and inducible nitric oxide synthase. **Our results show that the herbal medicine PHY906 can counteract the toxicity of CPT-11 via several mechanisms that act simultaneously.**



From: Lam W et al. *Sci. Transl. Med.* 2010;2:45ra59

表一 臺灣植物藥新藥與中藥新藥管理規範比較

	植物藥新藥	中藥新藥
主管機關	食品藥物管理局	中醫藥委員會
相關管理規範	2009年植物藥新藥臨床試驗基準 2010年植物藥新藥查驗登記審查基準(草案)	1998中藥新藥查驗登記須知2006 中藥新藥查驗登記基準(草案) 2008中藥新藥臨床試驗基準
定義	植物藥品，包括植物材料、藻類、大型真菌或前述的複方製成的藥品，但不包括植物性來源的高純度物質或化學修飾物。	指不包含業經高度純化，或經化學合成或修飾之下列各款藥品：(1)典籍記載之傳統中藥；(2)民間使用或其他國家使用之草藥，經傳統或現代抽提方法獲得之藥品。
化學、製造與管制資料	臨床試驗申請時應提供。	臨床試驗申請時應提供。
初期臨床試驗之試驗減免	申請者可視情況(已於國內及/或國外以食品合法上市，且無任何已知安全性疑慮的植物性產品)減免部分非 床(臨床前)文件。	已具備廣泛傳統人體使用經驗之中藥新藥，得備具足以支持臨床試驗之安全性資料，得申請暫不提供毒理藥理試驗，即進入初期療效探索臨床試驗。
臨床試驗申請之技術性資料要求	依據是否合法上市、有無安全性疑慮之植物產品類型，在第一期與二期臨床試驗，有不同的檢附資料要求；第三期臨床試驗則無產品差異。	依據新藥材、新藥用部位，及超過或未超過傳統使用經驗範圍之部分純化中藥、新複方、固有方劑之新療效或新使用途徑，有不同的檢附資料要求。已通過中藥新藥查驗登記之新使用途徑、新療效或新劑型，應有相當程度完備之試驗資料。
查驗登記核准上市	依產品的適應症與特性，可尋求以處方藥或非處方藥取得上市許可。	不同中藥新藥種類其核准後監視年限不同。
迄今(2012)已審核通過新藥查驗登記案件	1. 2010年，懷特生技的「懷特血寶注射劑」植物新藥。	1. 2005年，彥臣生技的「壽美降脂一號」中藥新藥。 2. 2011年，中天生技的「化療漾內服液」中藥新成藥。

資料來源：行政院衛生署；台灣經濟研究院生物科技產業研究中心整理。

植物新藥開發現況

公司名稱	藥品名稱	適應症	開發階段
懷特生技	痛寶	疼痛舒緩	Phase III完成
健永生技	MCS-2	前列腺肥大	Phase III完成
德英生技	SR-T100	日光角化症	Phase III完成
杏國	SB05	胰臟癌	Phase III
合一生技	ON101	糖尿病足潰瘍	Phase III
台灣利得	LEAC-102	大腸直腸癌	Phase I/IIa
耀德生技	DCB-AD1	阿茲海默症	Phase II
萊特先進生醫	PDC-1421	注意力不足過動症	Phase I/II
中美生技	DCB-BO1301	黑色素癌	IND核准
貝爾克斯生技	BEL-X	肝癌	IND核准

Developing Phytocompounds from Medicinal Plants as Immunomodulators

CHIH-CHUN WEN,^{*} HUI-MING CHEN^{*,†} AND NING-SUN YANG^{*,1}

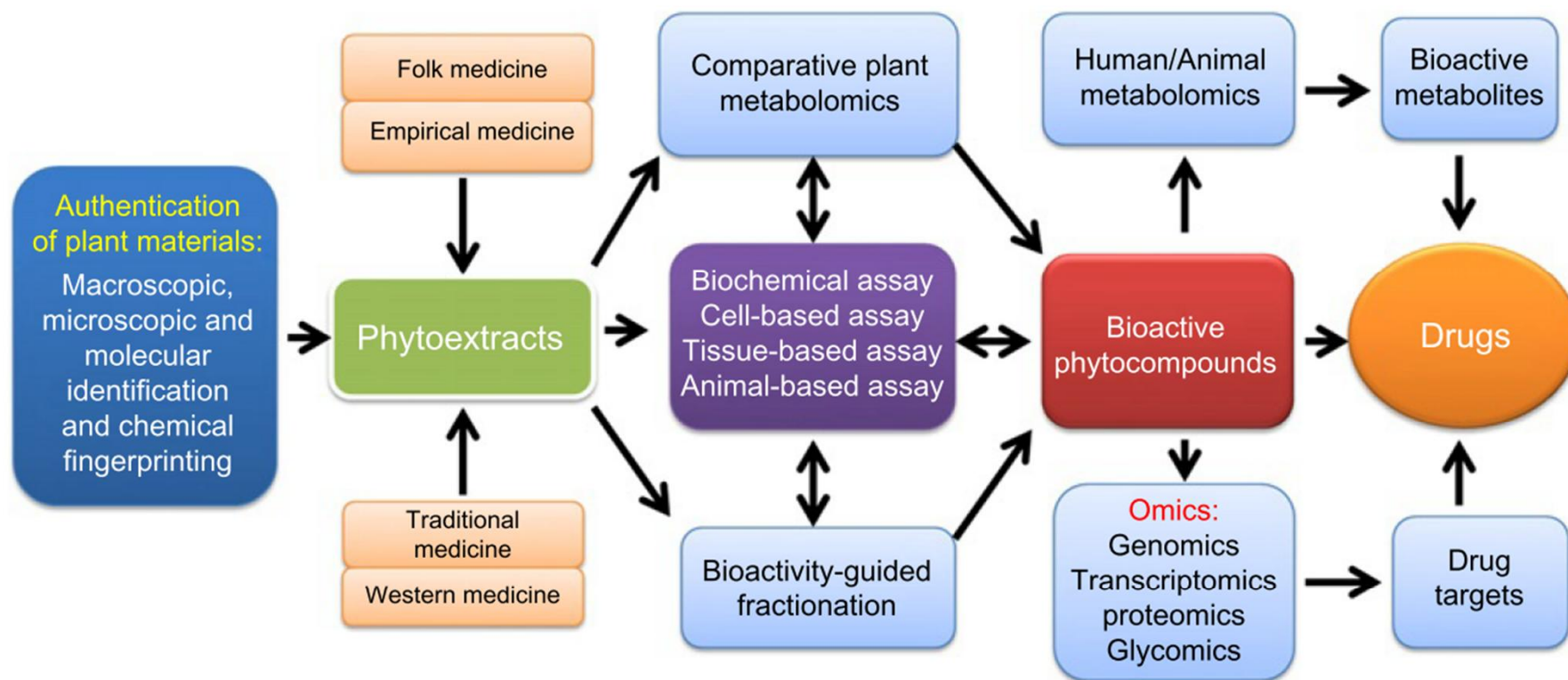
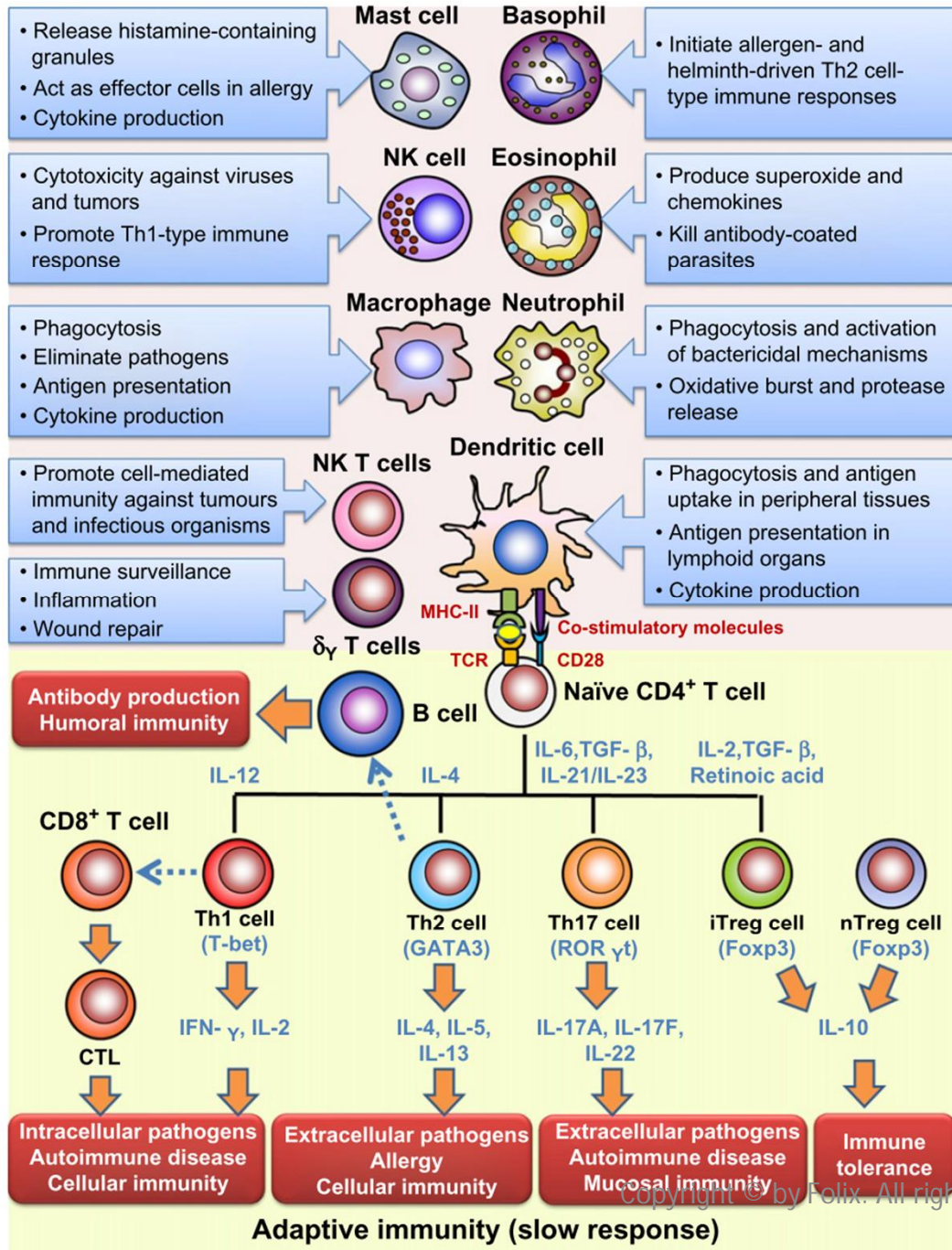


Fig. 1. Schematic representation of technological systems for drug discovery from phytocompounds of medicinal herbs as immunomodulatory agents using various experimental approaches.

Wen, C.-C., H.-M. Chen and N.-S. Yang (2012). Developing Phytocompounds from Medicinal Plants as Immunomodulators. *Advances in Botanical Research*, Elsevier. 62: 197-272.

Innate immunity (rapid response)

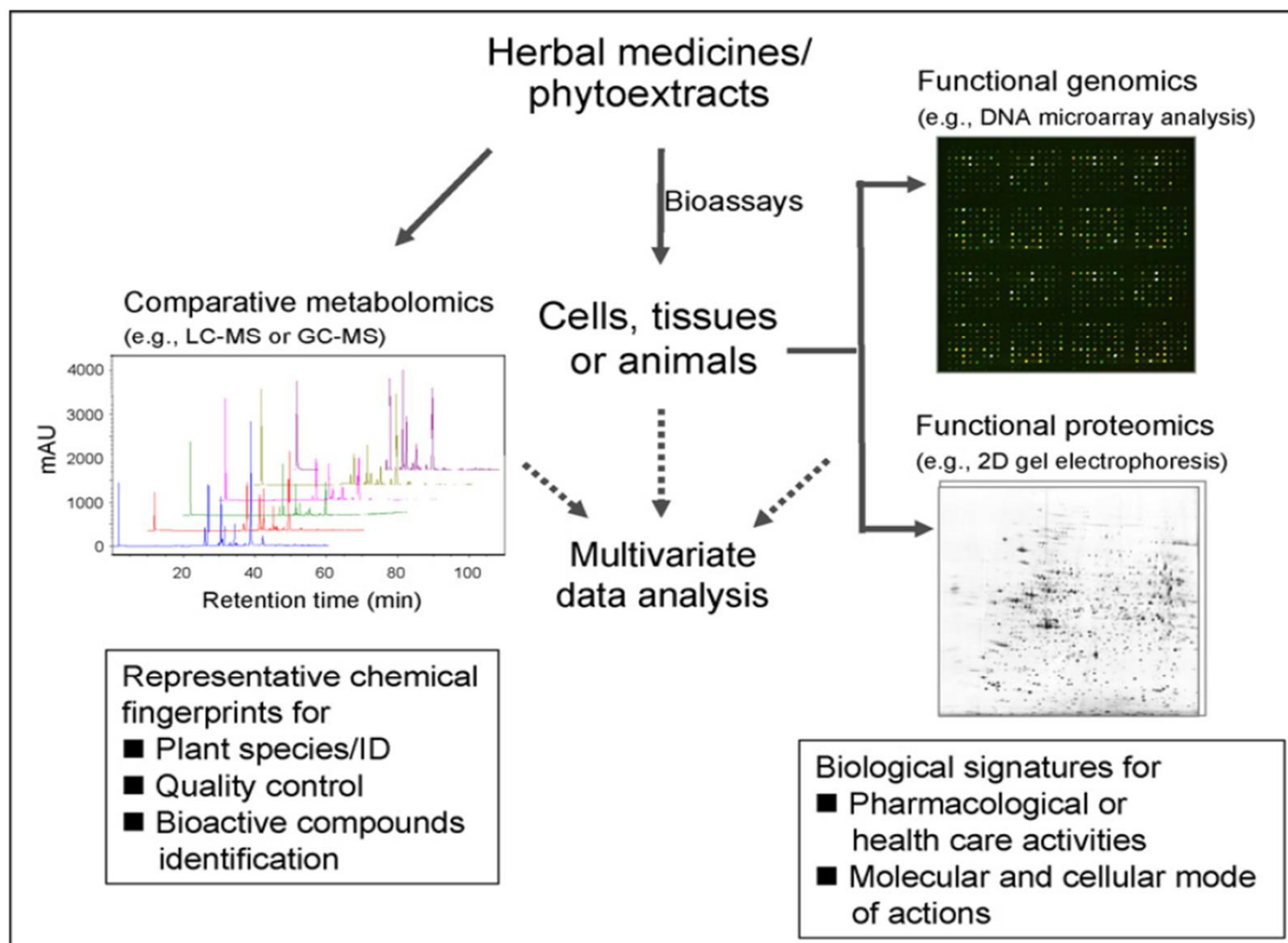


Wen, C.-C., H.-M. Chen and N.-S. Yang (2012).
Developing Phytocompounds from Medicinal
Plants as Immunomodulators. Advances in
Botanical Research, Elsevier. 62: 197-272. 34

2008 12: 66-71

Metabolomics for phytomedicine research and drug development

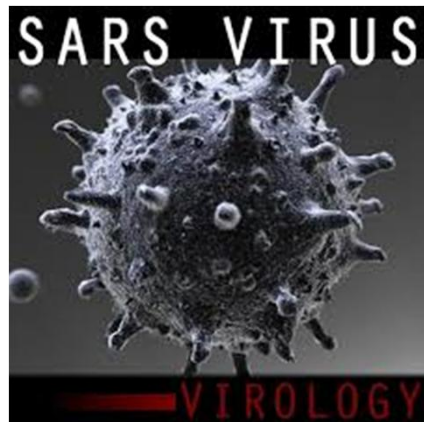
Lie-Fen Shyur and Ning-Sun Yang



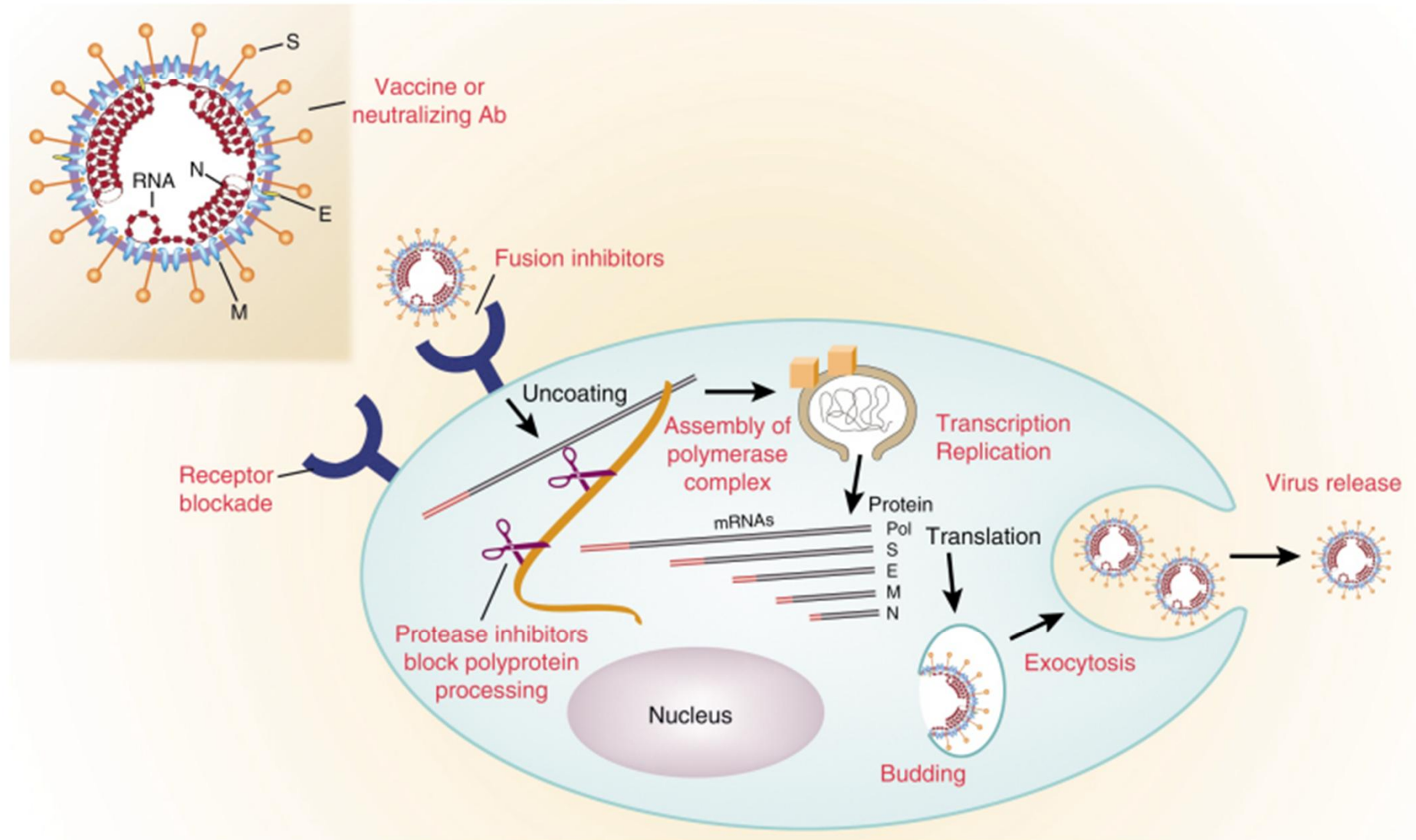
Key features of the technologies used in metabolomics for herbal medicine research. 35

嚴重急性呼吸道症候群(飛沫感染) (Severe Acute Respiratory Syndrome, SARS)

- 全球8,096例SARS病例，
774例死亡(2002-2003)
- 直徑80-140nm，飛沫傳染
- 致死率9.56% (約10 %)



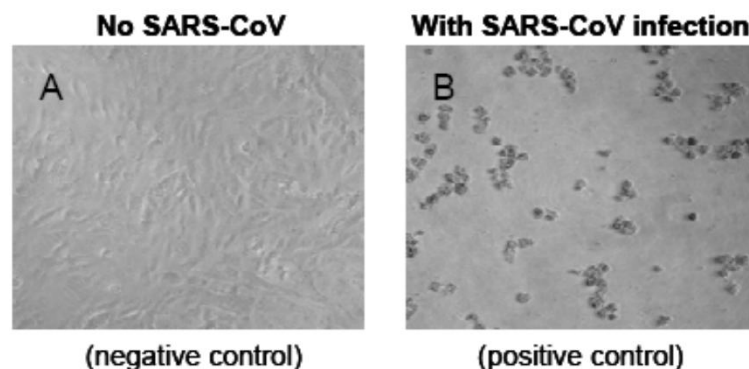
Steps in coronavirus replication that are potential targets for antiviral drugs and vaccines.



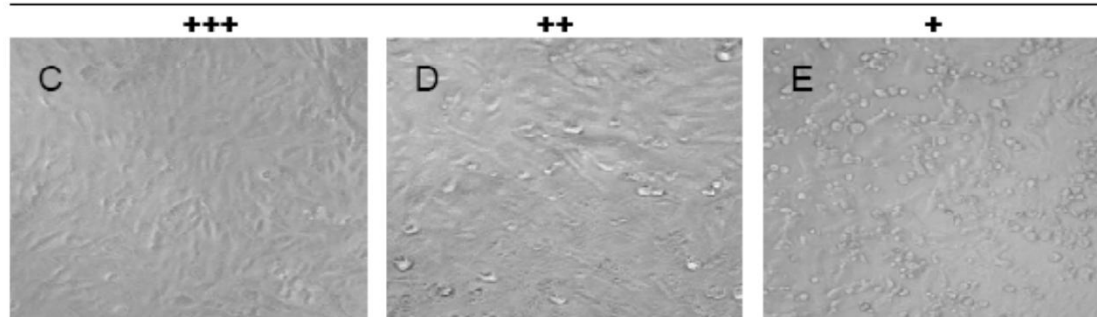
Specific Plant Terpenoids and Lignoids Possess Potent Antiviral Activities against Severe Acute Respiratory Syndrome Coronavirus

Chih-Chun Wen,^{†,‡,×} Yueh-Hsiung Kuo,^{§,#,×} Jia-Tsong Jan,^{∇,×} Po-Huang Liang,[@] Sheng-Yang Wang,^{||} Hong-Gi Liu,[@] Ching-Kuo Lee,[⊗] Shang-Tzen Chang,[⊥] Chih-Jung Kuo,[@] Shoei-Sheng Lee,[∞] Chia-Chung Hou,[†] Pei-Wen Hsiao,[†] Shih-Chang Chien,[†] Lie-Fen Shyur,^{*,†} and Ning-Sun Yang^{*,†}

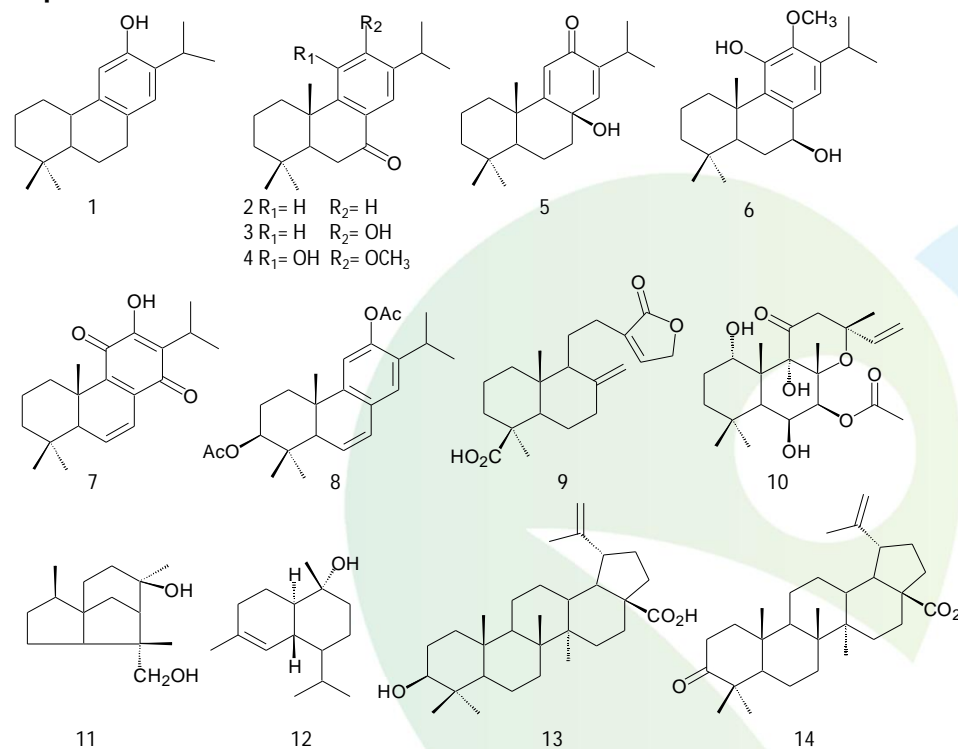
Vero E6 cells



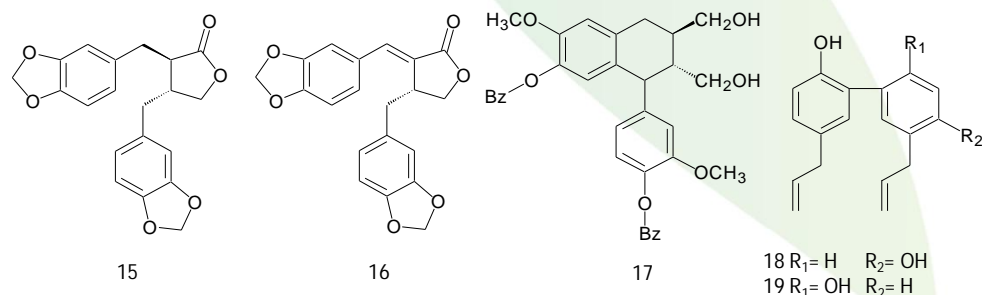
Vero E6 cells + SARS-CoV (100 TCID₅₀/well) + test Compounds



A Terpenoids



B Lignoids



C Miscellaneous

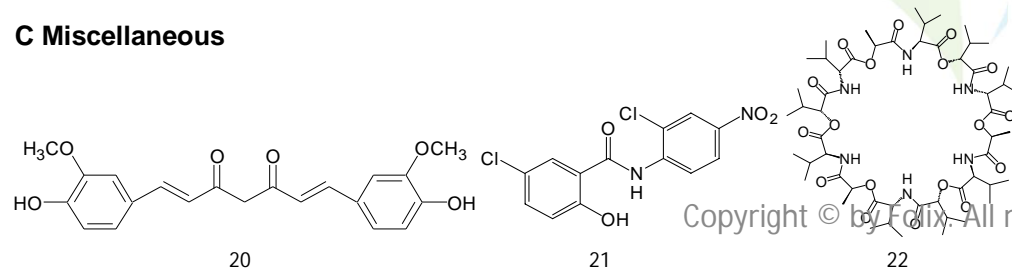


Table 2. Inhibition of Vero E6 Cell Proliferation and SARS-CoV Replication

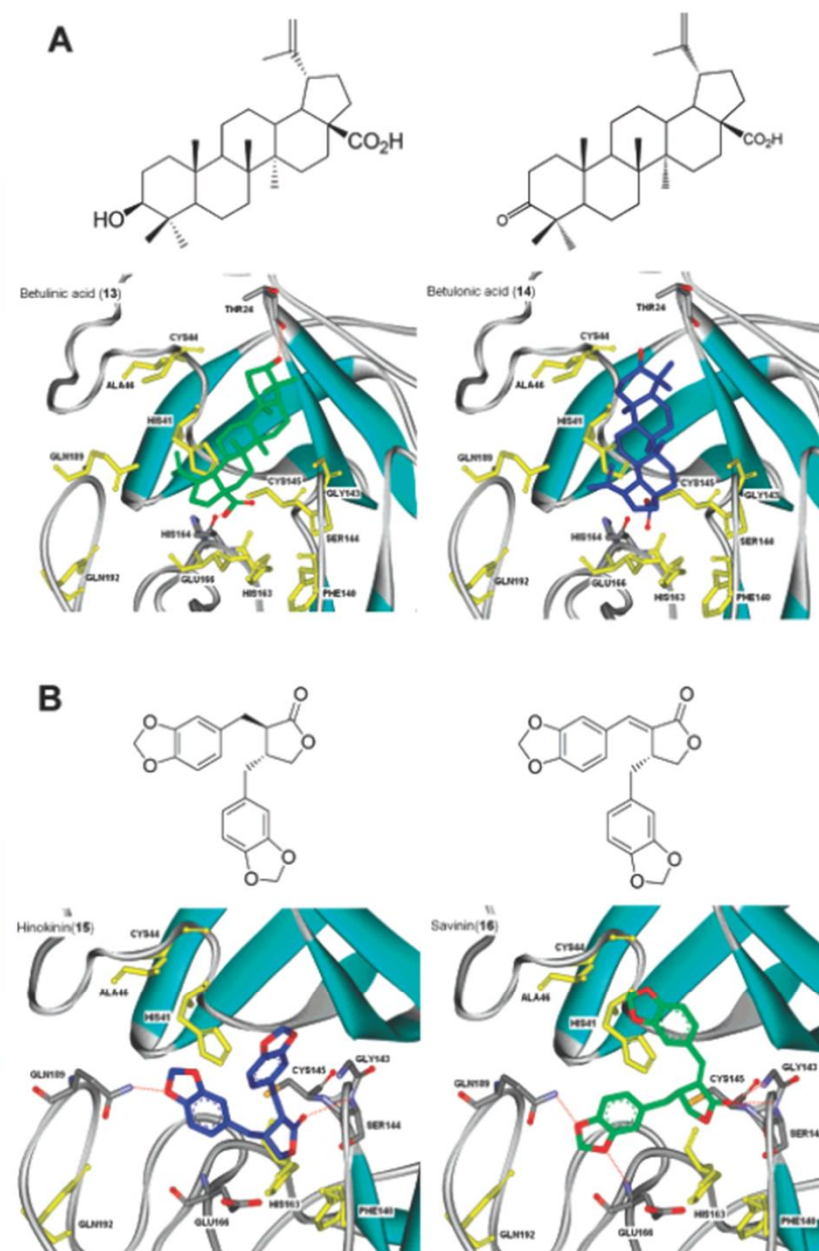
compound	CC ₅₀ (μM) ^a	EC ₅₀ (μM) ^b	selective index ^c
Diterpenoids (Abietane-type)			
1	80.4	1.39	58.0
2	305.1	4.00	76.3
3	N.T. ^d	N.T. ^d	N.C. ^e
4	78.5	>10	<7.9
5	>750	1.47	>510
6	127	1.15	111
7	89.7	5.55	16.2
8	303.3	1.57	193
Diterpenoids (Labdane-type)			
9	>750	4.71	>159
10	674	7.5	89.8
Sesquiterpenoids			
11	>750	>10	N.C. ^e
12	76.8	4.44	17.3
Triterpenoids (Lupane-type)			
13	150	>10	<15
14	112	0.63	180
Lignoids			
15	>750	>10	N.C. ^e
16	>750	1.13	>667
17	N.T. ^d	N.T. ^d	N.C. ^e
18	88.9	6.50	13.7
19	68.3	3.80	18.0
curcumin, 20	>250	>10	N.C. ^e
niclosamide, 21	22.1	<0.1	>221
valinomycin, 22	67.5	1.63	41.4

Table 3. Kinetic Properties of Specific Compounds That Inhibit the Enzymatic Activity of SARS-CoV 3CL Protease

compound	IC ₅₀ (μM)	K _i ^a
betulinic acid (13)	10	8.2 ± 0.7
betulonic acid (14)	>100	N.T. ^b
hinokinin (15)	>100	N.T. ^b
savinin (16)	25	9.1 ± 2.4
curcumin (20)	40	N.T. ^b
niclosamide (21)	40	N.T. ^b

^a K_i value was measured using two fixed compound concentrations and varying substrate concentrations containing 50 nM SARS-CoV protease.

^b N.T.: not tested.



Traditional Chinese medicine herbal extracts of *Cibotium barometz*, *Gentiana scabra*, *Dioscorea batatas*, *Cassia tora*, and *Taxillus chinensis* inhibit SARS-CoV replication

Chih-Chun Wen^{1,2,§}, Lie-Fen Shyur^{2,§}, Jia-Tsong Jan^{3,§}, Po-Huang Liang⁴, Chih-Jung Kuo^{4,5}, Palanisamy Arulselvan², Jin-Bin Wu¹, Sheng-Chu Kuo^{1,*}, Ning-Sun Yang^{2,*}

Table 1. Effect of Traditional Chinese Medicine extracts on cytopathogenic effect (CPE) of SARS-CoV on Vero E6 cells

Sample	Extract code	Concentration (µg/ml)				
		200	100	50	25	0
Rhizoma Cibotii (狗脊 gǒu jǐ)	CBE	+++	++	+	+	—
Rhizoma Cibotii (狗脊 gǒu jǐ)	CBM	+++	+	+	—	—
Gentianae Radix (龍膽 lóng dǎn)	GSH	+++	++	+	+	—
Dioscoreae Rhizoma (山藥 shān yào)	DBM	+++	++	+	+	—
Cassiae Semen (決明子 jué míng zǐ)	CTH	++	++	+	+	—
Loranthi Ramus (桑寄生 sāng jì shēng)	TCH	+++	+++	++	+	—
Valinomycin	VAL	N.T.	N.T.	N.T.	+++	—

^a N.T., not tested

Table 2. Effect of test extracts on Vero E6 cell proliferation and SARS-CoV replication

Sample	CC50 (µg/ml) ^a	EC50 (µg/ml) ^b	Selective Index ^c
CBE	>500	8.42	>59.4
CBM	>500	>10	N.C. ^d
GSH	>500	8.70	>57.5
DBM	>500	8.06	>62.0
CTH	>500	8.43	>59.3
TCH	>500	5.39	>92.8
VAL ^e	75.01	1.81	41.4

^a Determined as the cytotoxic concentration of test extracts that reduced cell viability to 50% of the control (i.e., cells with a treated equal volume of vehicle control). Each value was calculated with data obtained from triplicate samples.

^b Determined as the effective concentration at which inhibition of viral replication was reduced to 50% of the untreated (control) cell cultures. Each value was calculated with data obtained from triplicate samples.

^c Selective index was taken to be the ratio of CC₅₀ to EC₅₀ (CC₅₀/EC₅₀). N.C., not calculable

^e VAL., valinomycin

中東呼吸症候群冠狀病毒(飛沫感染)

(Middle East Respiratory Syndrome Coronavirus [MERS-CoV])

12 Aug, 2015



Health topics Data Media centre Publications Countries Programmes Governance About WHO Search

Middle East respiratory syndrome coronavirus (MERS-CoV)

Summary of Current Situation, Literature Update and Risk Assessment

July 2015 -- This publication brings together all of the latest information on the current MERS-CoV outbreak and reports on WHO's support to countries to help contain the virus. The summary gives guidance and recommendations for WHO best practices for infection, prevention, and control that is specific to the current outbreak. The maps and graphs highlight cases by country, an epicurve of the main countries affected, and a global map that shows concentrated areas affected.



致死率約
36%

Current outbreak situation in the Republic of Korea and China as of 12 August 2015

News on the current situation

The last case of MERS-CoV infection in the Republic of Korea, who was laboratory confirmed on 4 July 2015.

TOTAL CONFIRMED	Republic of Korea	China	DEATHS	GLOBAL TOTAL CONFIRMED	GLOBAL DEATHS
186	185	1	36	1401	500

2012年公布全球第一例MERS感染
2014年5月3日止，WHO公布全球累計163例確診病例，38例死亡。
2015年8月12日止，WHO公布全球累計1401例確診病例，500例死亡。

Integrative Approach to Analyze Biodiversity and Anti-Inflammatory Bioactivity of *Wedelia* Medicinal Plants

Wen-Ching Lin^{1,2*}, Chih-Chun Wen^{1*}, Yung-Hsiang Chen¹, Pei-Wen Hsiao¹, Jiunn-Wang Liao³, Ching-I Peng^{4†}, Ning-Sun Yang^{1†*}



地址：台中市沙鹿區興安路65號
代理商：品冠行銷股份有限公司
地址：台中市沙鹿區錦華街17號2樓
免費服務專線：(0800)461015
委託臺灣第一生化科技股份有限公司
嘉義保健飲料廠 製造
製造地址：嘉義縣民雄鄉興南村工業二路12-1號
電話：(05)2205500
品名：味丹心茶道健康青草茶
內容量：1480 mL
原料：水、蔗糖、青草茶葉(陳橘皮、白鶴靈芝、黃花蜜菜、
橄欖根、車前草、珠仔草)、薄荷香料(含薄荷抽出物、葡萄柚葉)
保存期限：9個月
有效日期：標示於瓶身
食用方法：冰涼後飲用，風味更佳
請保存於陰涼處，避免高溫或陽光直射，開瓶後請立
即飲用。
本產品係屬青草茶葉萃取，若有沉澱現象，請搖勻後
飲用。

Table 2. *Wedelia* species in Taiwan.

Species	Acronym	Additional Varieties	Acronym
<i>Wedelia chinensis</i>	WC		
<i>Wedelia trilobata</i>	WT		
<i>Wedelia biflora</i>	WB	<i>Wedelia biflora</i> var. <i>ryukyuensis</i>	WBR
<i>Wedelia prostrata</i>	WP	<i>Wedelia prostrata</i> var. <i>robusta</i>	WPR

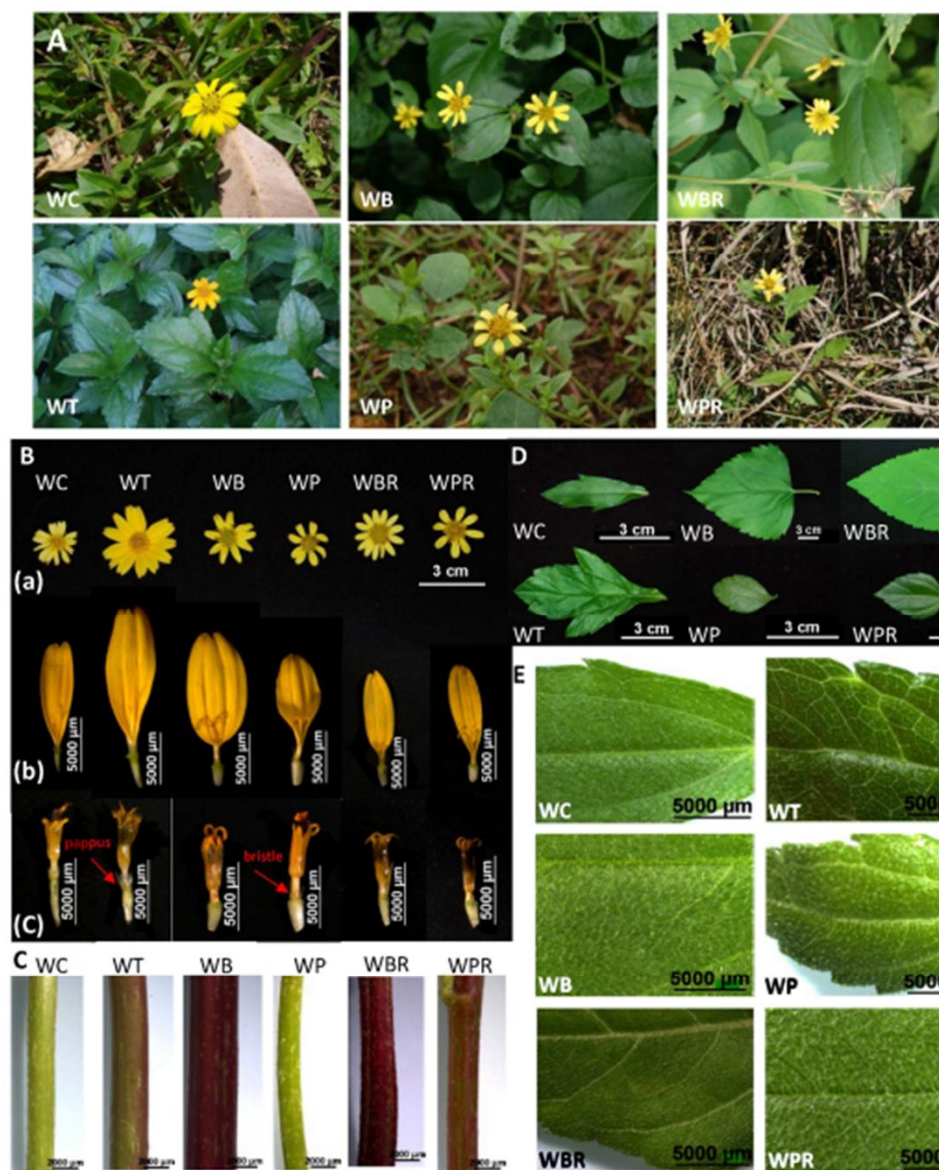


Fig 1. Macroscopic characteristics of *Wedelia* species. A, habitat; B, flower structures: (a) flowers, (b) ray florets.

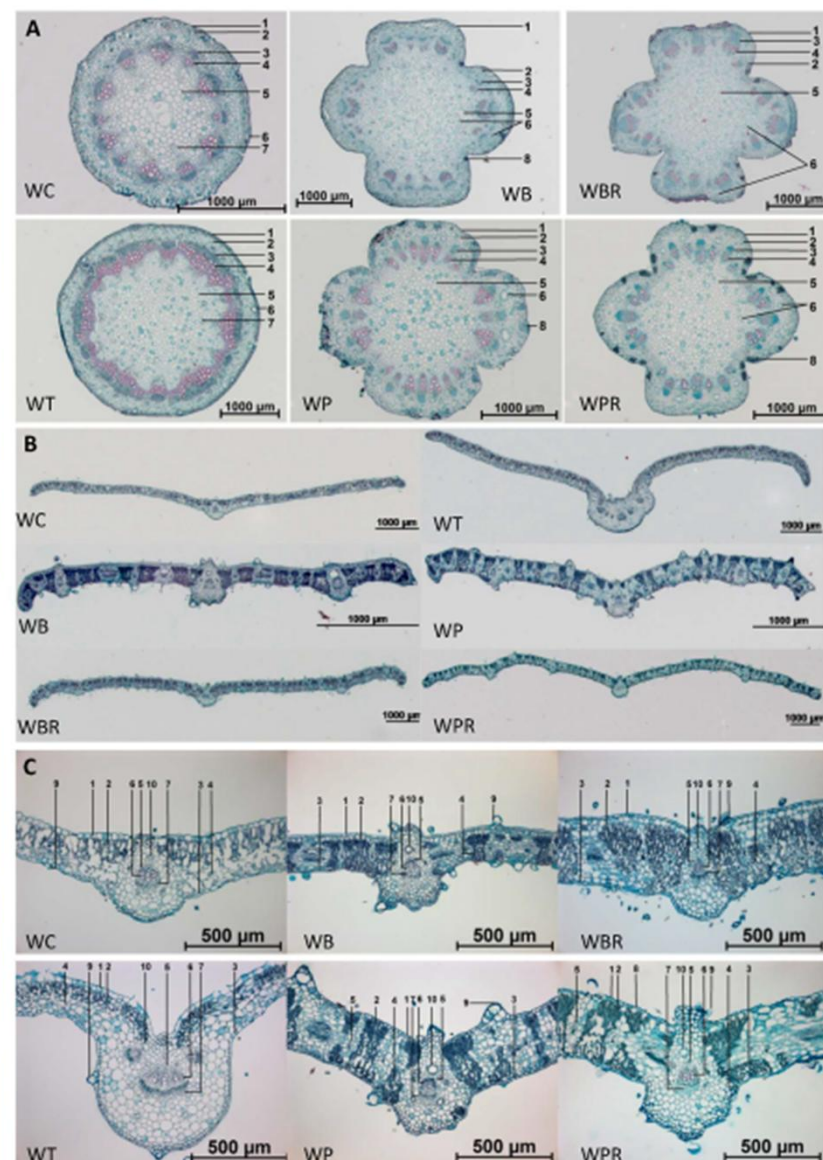


Fig 2. Transverse sections of stems and leaves of *Wedelia* species. A, Tissue sections of stems: 1. Epidermis; 2. Cortex; 3. Phloem; 4. Xylem; 5. Pith; 6. Resin duct; 7. Pro-resin duct; and 8. Secretory cells. B & C, Tissue sections of leaves: 1. Upper epidermis; 2. Palisade tissue; 3. Lower epidermis; 4. Spongy tissue; 5. Bundle sheath; 6. Xylem; 7. Phloem; 8. Stoma; 9. Trichome; 10. Resin duct.

Lin, W. C., C. C. Wen, Y. H. Chen, P. W. Hsiao, J. W. Liao, C. I. Peng and N. S. Yang (2015). "Integrative approach to analyze biodiversity and anti-inflammatory bioactivity of *Wedelia* medicinal plants." *PLoS One* 10(6): e0129067.



Table 4. Nucleotide sequence length of ITS1, 5.8S rRNA and ITS2 genomic DNA fragments of four species and two additional varieties of *Wedelia*.

Species	ITS regions (bp)				Accession number
	ITS1	5.8S	ITS2	Total	NCBI database
<i>W. chinensis</i>	254	164	228	646	AY947415* ¹
<i>W. trilobata</i>	256	162	218	636	AY303442* ²
<i>W. biflora</i>	253	163	225	641	JF934953
<i>W. prostrata</i>	253	167	217	637	AY947412* ¹
<i>W. biflora</i> var. <i>ryukyuensis</i>	253	163	225	641	JF430396
<i>Wedelia prostrata</i> var. <i>robusta</i>	253	167	218	638	JF430395

*¹ The sequences AY947415 and AY947412 were submitted to GenBank by Yuan, C.I., Hsieh, Y.C. and Chiang, M.Y.

*² The sequence AY303442 was submitted to GenBank by Dias de Moraes, M., Panero, J.L. and Semir, J.



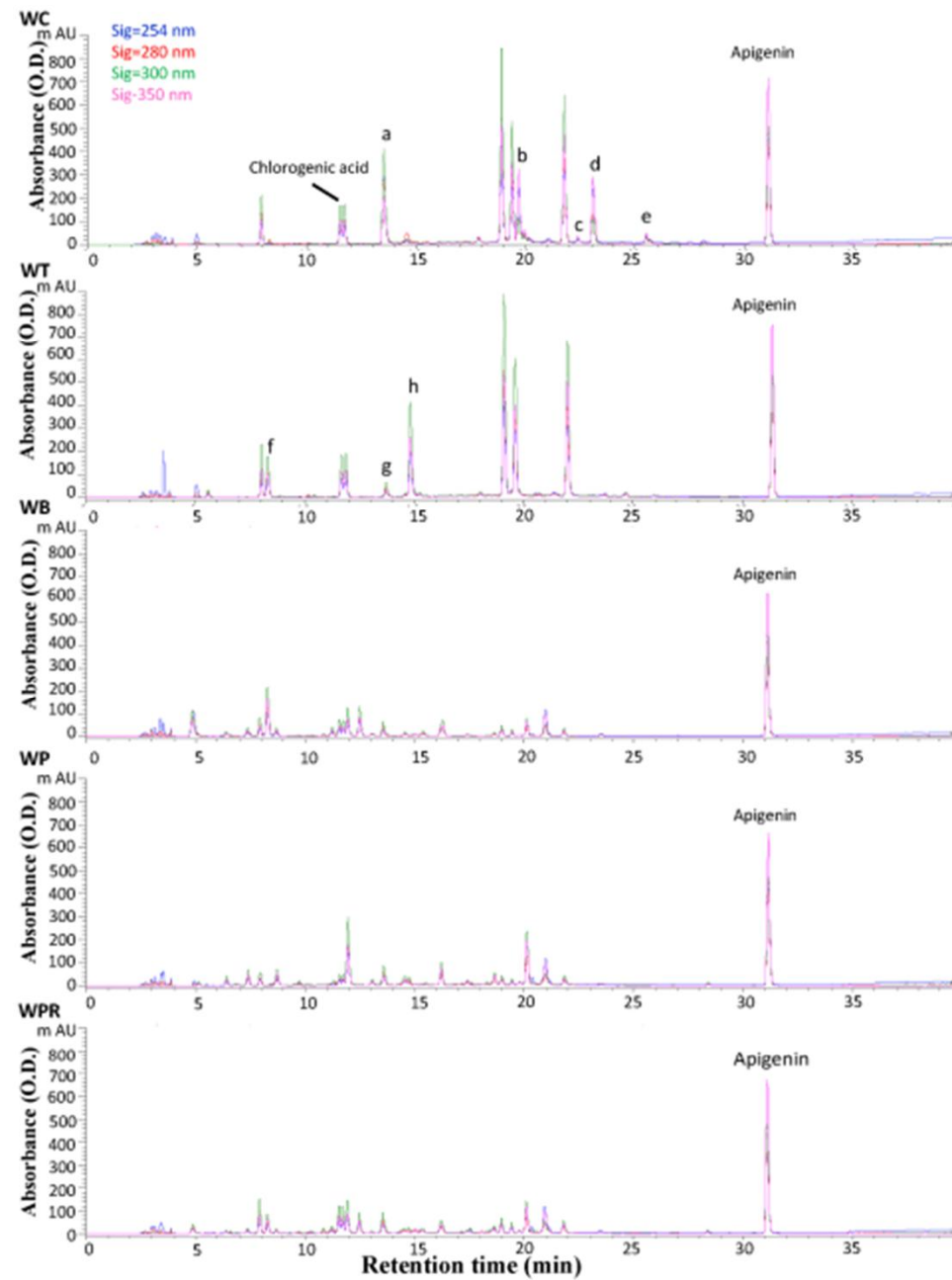


Fig 4. HPLC chromatograms of hot water extracts of five *Wedelia* species. Apigenin was supplemented only as an internal standard to calibrate the HPLC data. The colors of signals, blue, red, green and pink, denote different absorbance levels of 254 nm, 280 nm, 300 nm and 350 nm, respectively. The peaks of a, b, c, d, e, f and g represent the different peaks detected between WC and WT extracts.

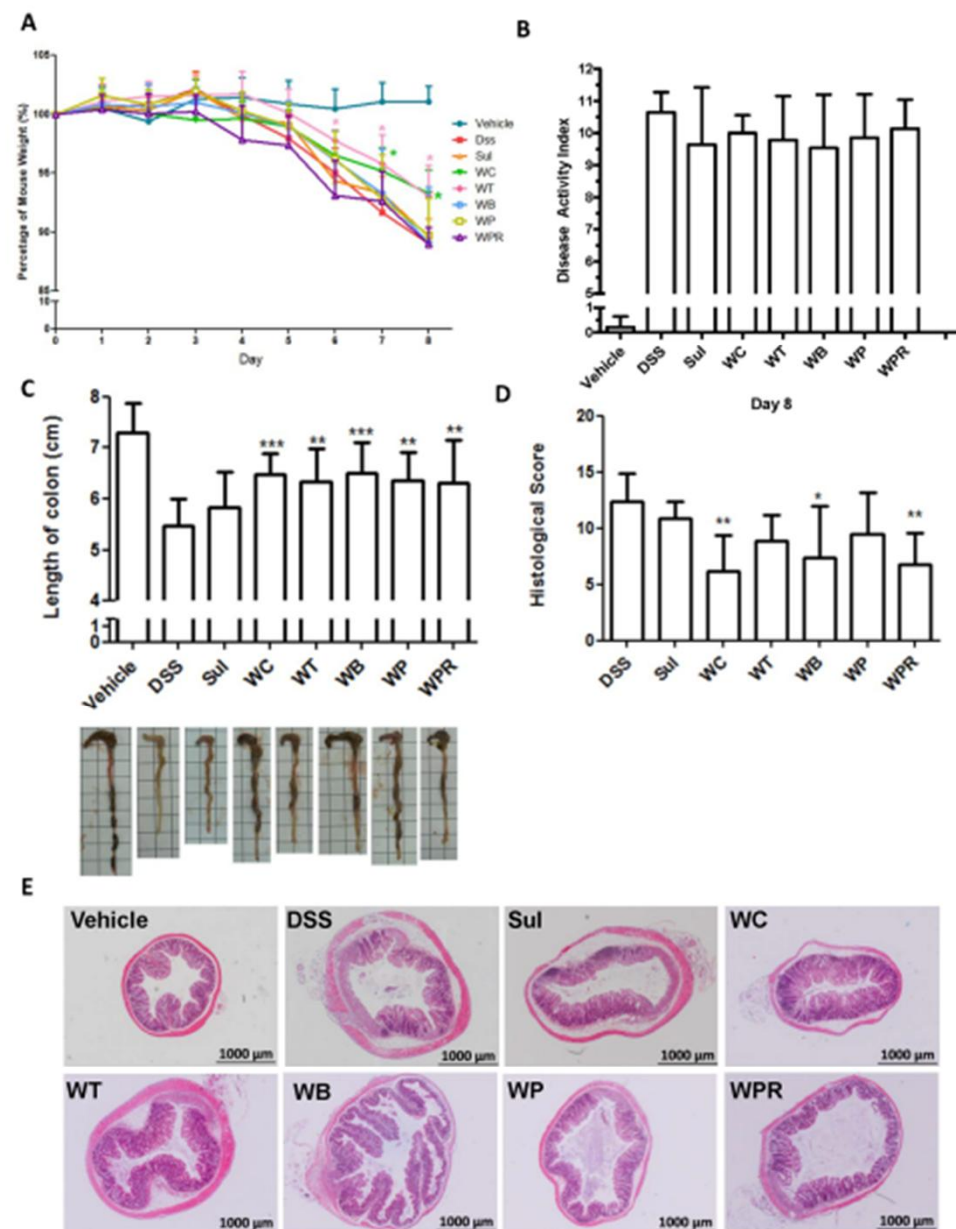


Fig 6. Effect of different extracts of *Wedelia* species in mice with DSS-induced acute colitis. Mice were simultaneously administered orally with vehicle (sterilized water), Sul: sulfasalazine (positive control, 50 mg/kg) or different extracts of *Wedelia* species (50 mg/kg), respectively. **A**, Percentage of murine body weight. **B**, Disease activity index. **C**, Colon length. **D**, Histological score. **E**, Histopathology of mice with DSS-induced acute colitis. Data are expressed as mean \pm SD (n = 10). WC and WT, respectively *P < 0.05, **P < 0.01, ***P < 0.001, significant difference compared with the DSS group.

The Future of Medicine

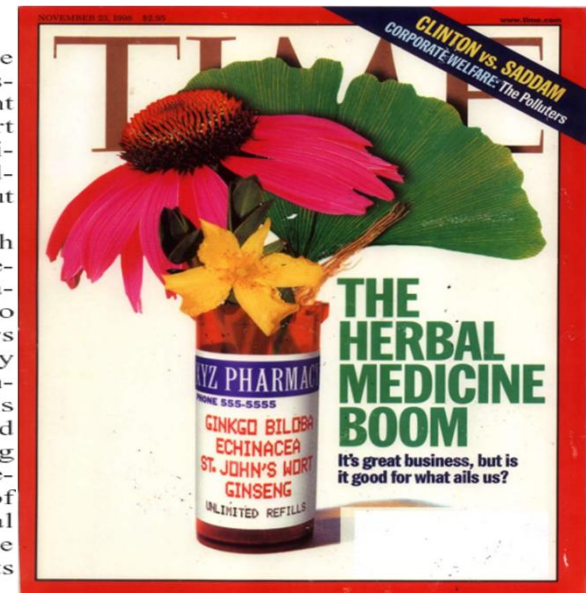
In my 55 years as a physician, I've seen my share of what modern medicine can do. During the 40 years when I was a pediatric surgeon, I saw 95% mortality rates for congenital defects transformed into 95% survival rates because of what surgery can accomplish. As U.S. Surgeon General, I saw effective prevention and treatment techniques beat back the mortality from tobacco use and AIDS. And now, as an 85-year-old, my life has been prolonged and kept active by wonder drugs unknown to my parents. So it's been somewhat surprising in this era of triumph for modern medicine to see the rapid growth of alternative/complementary medicine, which is used by as many as one in three Americans. Although most of those still refrain from informing their regular physicians about that use, there is a growing tendency among physicians to acknowledge and even embrace certain forms of alternative/complementary medicine.

Changes in the use of the terms "alternative" and "complementary" suggest the shape of this shift. At first, it was called simply "alternative medicine," reflecting a dissatisfaction with regular medicine as well as a cultural rebellion against the biomedical community. In more recent years, several studies indicate that there has been a shift from "alternative" therapies to "complementary" therapies, adopted not in opposition to regular medicine but in alliance with it. And increasingly those who use one of the many forms of complementary medicine are not treating a specific medical problem. Rather, they are practicing prevention in ways they find more congruent with their philosophical values or lifestyle.

Now I think we may be seeing another refinement, one that is taking us from "complementary" to "safe and effective." For some people, the appeal of alternative medicine lies in its alternative stance, and as some of these therapies enter the mainstream, some of these individuals may seek other alternative practices. But more and more Americans are demanding greater certainty from alternative or complementary products as an increasing number of press reports document health problems resulting from certain natural products and complementary practices. Thus, the baby-boom health consciousness that led to the resurgence of alternative/complementary medicine now turns toward solutions that rest more heavily on science. We went through a somewhat similar passage a century ago, when dissatisfaction with regular medicine and a growing consumer market in health products led to the widespread use of a variety of nostrums and patent medicines; some no doubt helpful, some merely enjoyable, and some downright dangerous. At that time, journalists and the public pressed for scientific research to support proper branding and safety, culminating in the Pure Food and Drug Act of 1906. Much later, evidence of effectiveness was added to the list. Some among the sellers and buyers of health products objected at first to the intrusion of research-based evaluation into the health market, but soon both came to profit from increased consumer confidence in those health products.

For too long, the natural health products industry has kept its distance from medical research and from clinical medical practice, focusing instead on the short-term marketing advantages derived from keeping herbal and nutritional remedies exempt from any Food and Drug Administration (FDA) review of efficacy. A wiser approach would be for the natural products industry to work with medical research, including the FDA, so that consumers and medical practitioners could be warned about potential harm and assured that the claimed health benefits were really there. Although the growth in the use of alternative/complementary medicine is likely to continue, recent surveys and market data confirm a growing American concern about safety. In this new climate of national wariness and concern for personal safety, those interested in selling and buying natural products associated with complementary medicine will be better off in the long run if reliable research is able to certify their safety and efficacy. As America's baby boomers become senior citizens, the health care system needs the relief provided by effective prevention of disease and disability. There is a potential role for some complementary therapies and natural health products in preparing us to meet the challenges of the 21st century. But it can only be played if that industry and its proponents are prepared to meet real scientific and regulatory tests of safety and effectiveness.

The natural products industry should work with medical research and the FDA.



COMMENTARY

New therapies from old medicines

Shaw T Chen, Jinhui Dou, Robert Temple, Rajiv Agarwal, Kuei-Meng Wu & Susan Walker

Although new botanical drugs pose many challenges for both industry and the FDA, approval of the first botanical prescription drug shows they can be successfully met.

On October 31, 2006, the US Food and Drug Administration (FDA) approved the new drug application (NDA) for marketing of Veregen (sinecatechins), a topical treatment for perianal and genital condyloma. Unlike most small-molecule drugs that comprise a single chemical compound, Veregen, an extract of green tea leaves, contains a mixture of known and possibly active compounds. It is the first new botanical prescription drug approved since the publication of the FDA's industry guidelines for botanical drug products¹ in June 2004. The approval shows that new therapies from natural complex mixtures can be developed to meet current FDA standards of quality control and clinical testing. In recent years, interest in further development of herbal or botanical drug products



Nat Biotechnol. 2008 Oct; 26(10) : 1077-83

Spice Healer

By Gary Stix

Searching for new drugs by milling through ancient folk pharmacopoeia or by just picking a plant while walking in the woods has a decidedly checkered history. Many well-established therapeutic compounds originated in trees, shrubs, mollusks, even dirt. Aspirin came from willow bark, cholesterol-lowering statins from a mold, and the antimalarial artemisinin from a shrub used in traditional Chinese medicine. Yet after raising \$90 million during the 1990s in a much publicized bid to tap indigenous knowledge for new drug leads, Shaman Pharmaceuticals had to lower its sights until it was doing nothing

TURMERIC
(*Curcuma longa*)
grows rhizomes, tuberos underground stems, from which the spice of the same name is produced.



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Sci Am. 2007 Feb;296(2):54-7

Dietary plant agents suggested to confer anti-cancer properties



Artichoke
(Silymarin)



Oleander
(Oleanderin)



Tomato
(Lycopene)



Garlic
(Diallyl sulfide, ajoene,
S-allyl cysteine, allicin)



Carrots
(β -carotenes)



Tea
(Catechins)



Red grapes
(Resveratrol)



Red chilli
(Capsaicin)



Turmeric
(Curcumin)



Cloves
(Eugenol &
isoeugenol)



Honey-bee propolis
(Caffeic acid, CAPE)



**Cruciferous
vegetables**
(Sulforaphane)



Pomegranate
(Ellagic acid)



Ginger
(6-Gingerol)



Basil
(Ursolic acid)



Fennel,
(Anethol)



Soybean
(Genistein)



Aloe
(Emodin)

Fig. 1 – Dietary agents with anti-cancer properties.

(Aggarwal and Shishodia, 2006)

可供食用原料彙整一覽表(TFDA)

https://consumer.fda.gov.tw/Food/Material.aspx?nodeID=160

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https://consumer.fda.gov.tw/Food/Material.aspx?nodeID=160

「可同時提供食品使用之中藥材」品項(中醫藥司)

序號	品名	基原	部位
1	百合	卷丹 <i>Lilium lancifolium</i> Thunb. 百合 <i>Lilium brownii</i> F. E. Brown var. <i>viridulum</i> Baker 細葉百合 <i>Lilium pumilum</i> DC.	乾燥肉質鱗莖
2	荷葉	蓮 <i>Nelumbo nucifera</i> Gaertn.	乾燥葉
3	銀耳 (白木耳)	銀耳 <i>Tremella fuciformis</i> Berk.	乾燥子實體
4	山藥	薯蕷 <i>Dioscorea opposita</i> Thunb. 恆春薯蕷 <i>Dioscorea doryophora</i> Hance 基隆山藥 <i>Dioscorea japonica</i> Thunb. var. <i>pseudojaponica</i> (Hay.) Yamam	乾燥根莖
5	生薑	薑 <i>Zingiber officinale</i> Rosc.	新鮮根莖
6	昆布	海帶 <i>Laminaria japonica</i> Aresch. 昆布 <i>Ecklonia kurome</i> Okam.	乾燥葉狀體
7	薤	小根蒜 <i>Allium macrostemon</i> Bge. 薤 <i>Allium chinense</i> G. Don.	乾燥鱗莖
8	馬齒莧	馬齒莧 <i>Portulaca oleracea</i> L.	乾燥地上部分
9	蒜(小蒜)	小蒜 <i>Allium macrostemon</i> Bunge.	乾燥鱗莖
10	海藻	海蒿子 <i>Sargassum pallidum</i> (Turn.) C. Ag. 羊棲菜 <i>Sargassum fusiforme</i> (Harv.) Setch.	乾燥藻體
11	小茴香 (子)	茴香 <i>Foeniculum vulgare</i> Mill.	乾燥成熟果實
12	八角茴香 (大茴香)	八角茴香 <i>Illicium verum</i> Hook. f.	乾燥成熟果實

<https://dep.mohw.gov.tw/DOCMAP/cp-754-39873-108.html>

「可同時提供食品使用之中藥材」品項(中醫藥司)

107.01.23

公告

13	羅勒	羅勒 <i>Ocimum basilicum</i>	全草
14	龍眼肉	龍眼 <i>Dimocarpus longan</i> Lour. <i>Euphoria longan</i> (Lour.) Steudel (synonym) <i>Nephelium longanum</i> Cambess (synonym)	乾燥之中果皮及果肉
15	枸杞子	枸杞 <i>Lycium chinense</i> Mill. 寧夏枸杞 <i>Lycium barbarum</i> L.	乾燥果實
16	烏梅	梅 <i>Prunus mume</i> (Sieb.) Sieb. et Zucc.	乾燥近成熟果實，經燻製而成
17	大棗(紅棗，黑棗)	棗 <i>Ziziphus jujuba</i> Mill. 紅棗：成熟果實烘乾或曬乾。 黑棗：成熟果實滾水快煮後，撈出放冷燻製而成。	乾燥成熟果實
18	山楂	山楂 <i>Crataegus pinnatifida</i> Bunge. 山里紅 <i>Crataegus pinnatifida</i> Bunge var. <i>major</i> N. E. Br.	乾燥成熟果實
19	秦椒(花椒)	花椒 <i>Zanthoxylum bungeanum</i> Maxim. 青椒 <i>Zanthoxylum schinifolium</i> Sieb. et Zucc.	乾燥成熟果皮
20	胡椒	胡椒 <i>Piper nigrum</i> L.	乾燥成熟果實
21	芡實	芡 <i>Euryale ferox</i> Salisb.	乾燥成熟種仁
22	淡豆豉	大豆 <i>Glycine max</i> (L.) Merr. 成熟種子，加藥汁蒸煮醱酵製成。	成熟種子

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<https://dep.mohw.gov.tw/DOCMAP/cp-754-39873-108.html>

「可同時提供食品使用之中藥材」品項(中醫藥司)

23	蓮子	蓮 <i>Nelumbo nucifera</i> Gaertn.	乾燥成熟果實
24	赤小豆	赤小豆 <i>Vigna calcaratus</i> Roxb. 赤豆 <i>Vigna angularis</i> Ohwi et Ohashi	乾燥成熟種子
25	薏苡仁	薏苡 <i>Coix lacryma-jobi</i> L. var. <i>ma-yuen</i> (Roman.) Stapf	乾燥成熟種仁
26	牡蠣殼	長牡蠣 <i>Ostrea gigas</i> Thunb. 大連灣牡蠣 <i>Ostrea talienwhanensis</i> Crosse 近江牡蠣 <i>Ostrea rivularis</i> Gould 葡萄牙牡蠣 <i>Crassostrea angulata</i>	貝殼
27	菊花	菊花 <i>Chrysanthemum morifolium</i> (Ramat.) Tzvel.	乾燥頭狀花序
28	黃精	多花黃精 <i>Polygonatum cyrtonema</i> Hua. 黃精 <i>Polygonatum sibiricum</i> Delar. ex Redoute 滇黃精 <i>Polygonatum kingianum</i> Coll. et Hemsl.	乾燥根莖
29	薄荷	薄荷 <i>Mentha haplocalyx</i> Briq. 及同屬近緣植物	乾燥地上部分
30	絞股藍 (七葉膽)	絞股藍 <i>Gynostemma pentaphyllum</i> Makino	乾燥全草
31	決明子	決明 <i>Cassia obtusifolia</i> L. 小決明 <i>Cassia tora</i> L.	乾燥種子

「可同時提供食品使用之中藥材」品項(中醫藥司)

32	石斛	石斛 <i>Dendrobium nobile</i> Lindl. 粉花石斛 <i>Dendrobium loddigesii</i> Rolfe. 黃草石斛 <i>Dendrobium chrysanthum</i> Wall. 馬鞭石斛 <i>Dendrobium fimbriatum</i> Hook. var. <i>oculatum</i> Hook. 鐵皮石斛 <i>Dendrobium candidum</i> Wall. ex Lindl 黃花石斛 <i>Dendrobium tosaense</i> Makino	新鮮或乾燥莖
33	陳皮	橘 <i>Citrus reticulata</i> Blanco 及其栽培品種.	乾燥成熟果皮
34	肉豆蔻	肉豆蔻 <i>Myristica fragrans</i> Houtt.	乾燥種仁
35	草豆蔻	草豆蔻 <i>Alpinia katsumadai</i> Hayata	乾燥近成熟種子
36	砂仁	陽春砂 <i>Amomum villosum</i> Lour. 縮砂 <i>Amomum villosum</i> Lour. var. <i>xanthioides</i> (Wall. ex Bak.) T. L. Wu et Senjen 海南砂 <i>Amomum longiligulare</i> T. L. Wu	乾燥成熟果實
37	人參花	人參 <i>Panax ginseng</i> C. A. Meyer	乾燥花序

「可同時提供食品使用之中藥材」品項(中醫藥司)

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「可同時提供食品使用之中藥材」品項(中醫藥司)

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36	砂仁	陽春砂 <i>Amomum villosum</i> Lour. 縮砂 <i>Amomum villosum</i> Lour. var. <i>xanthioides</i> (Wall. ex Bak.) T. L. Wu et Senjen 海南砂 <i>Amomum longiligulare</i> T. L. Wu	乾燥成熟果實
37	人參花	人參 <i>Panax ginseng</i> C. A. Meyer	乾燥花序

得供食品原料使用中藥品項(草案)

107.08.21

(一) 第一類：

1. 具傳統食用文化得供食品原料用途者，共 70 項。
2. 品項：百合、荷葉、銀耳(白木耳)、山藥、乾薑、昆布、薤、蒜(小蒜)、海藻、龍眼肉、枸杞子、烏梅、大棗(紅棗；黑棗)、山楂、芡實、淡豆豉、蓮子、菊花、黃精、薄荷、石斛、陳皮、人參花、羅漢果、橘紅(含青皮)、桑葚(桑椹)、薏苡仁、羅勒、牡蠣殼、紫蘇葉、佛手柑、桑葉、野菊花(油菊)、玉米鬚、苦杏仁、小茴香(懷香)、八角茴香(大茴香)、花椒(秦椒)、胡椒、砂仁、草豆蔻、肉豆蔻、丁香、白豆蔻、番紅花(藏紅花，西紅花)、山柰、甘松(甘松香，香松)、草果、桂子、薑黃、白芥子、靈香、排草、仙鶴草(龍牙草)、雷公根(積雪草)、白茅根(茅根)、伸筋草(石松)、地骨皮、金錢草、廣藿香(左手春)、車前草、小金英(兔仔菜，鵝仔菜)、細本山葡萄、苦蕒(燈籠草，炮仔草)、夏枯草、魚腥草、藿香、貓鬚草、萬點金、白花蛇舌草(百花蛇舌草)。

得供食品原料使用中藥品項(草案)

107.08.21

(二) 第二類：

1. 具有特定效能須注意安全性者，共 64 項。
2. 含本類中藥材之食品，扣除水後應以非中藥材之食品原料為主，並應標示原中藥材含量。
3. 含本類中藥材之產品，其所含第二類中藥材總量大於 10%者，以中藥管理。
4. 品項：馬齒莧、赤小豆、決明子、絞股藍(七葉膽)、五加皮、冬瓜子、枇杷葉、麥門冬、淡竹葉、葛根(葛藤；甘葛)、刺五加、當歸、黃耆、紅耆、白朮、玉竹(萎蕤)、肉桂(桂皮)、桂枝、黨參、桑枝、白扁豆、天麻、人參、西洋參(粉光參，花旗參)、紫蘇子、茯苓、太子參、地黃、元參(玄參)、海螵蛸、天門冬、艾葉、紅花、枸骨葉(功勞葉)、益母草、女貞子、金銀花(含忍冬藤)、桔梗、紅景天、土茯苓、芍藥、白果(銀杏果)、甘草、川芎(芎藭)、膨大海(胖大海)、酸棗仁、冬蟲夏草、鹿茸、鹿角(含鹿角膠)、龜板(含龜板膠)、蒲公英、餘甘子、阿膠、杜仲、葫蘆巴、萊菔子、枳椇、苧麻、川貝母、製何首烏、五味子、丹參、番瀉、苦橙(枳實；枳殼)。

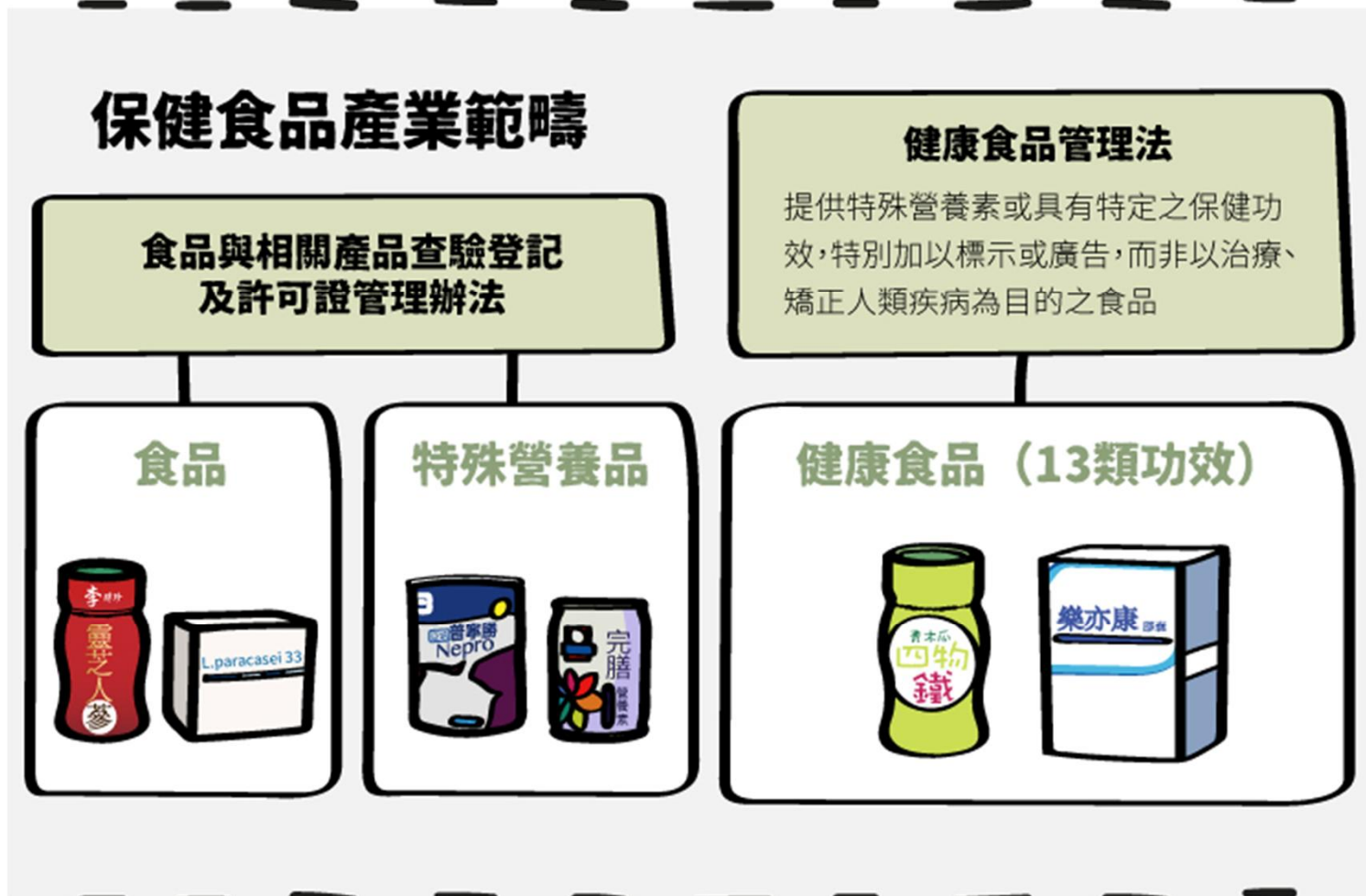
得供食品原料使用中藥品項(草案)

107.08.21

新申請為得供食品原料使用之中藥材品項，應檢具基原鑑定、傳統中醫藥固有典籍之出處依據、傳統食用經驗證明及毒理學試驗等文獻資料，送請本部審議。

類似於TFDA
非傳統性食品原料登錄申請

保健食品&健康食品



<https://journal.eyeprophet.com/%E5%81%A5%E5%BA%B7%E7%9A%84%E6%B8%B4%E6%9C%9B->

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健康食品

- 名詞定義
- 「健康食品管理法」於八十八年八月三日施行後，「健康食品」為法律名詞，法律上之定義為「具有保健功效，並標示或廣告其具該功效，且須具有實質科學證據，非屬治療、矯正人類疾病之醫療效能為目的之食品」。



健康食品

- 法律效力
- 未經查驗登記申請並審查通過之產品不得使用「健康食品」之名詞，也不得宣稱與健康食品相關之13項功效內容。
- 專家審核
- 需透過查驗登記之申請流程，經專家學者審查、評估其安全無虞以及科學佐證之功效性等，才能稱之為「健康食品」。



健康食品

- 包裝標示規範
- 取得認證之健康食品須在產品包裝標示上載明核准之保健功效敘述、健康食品標章（綠色橢圓標章）及每日建議攝取量等相關規定之標示。



健康食品

- **第一軌：個案審查**
- 衛部健食字第A00001號-第A00358號
- 目前總計 357件
- 個案審查一般需耗時180個日曆天，審查費用250,000元整(初審80,000元整，複審170,000萬元整，不含領證費及檢驗費)
- **第二軌健康食品認證**
- 衛部健食規字第00001號-第A00066號
- 目前總計 66 件
- 規格標準審查型一般需耗時120個日曆天，審查費用80,000元整(不含領證費及檢驗費)



健康食品一軌-13項功效性試驗

編號	試驗項目	案件數	比例
1	調節血脂功能	97	25%
2	胃腸功能改善	82	21%
3	免疫調節功能	46	12%
4	護肝功能	43	11%
5	不易形成體脂肪	22	6%
6	輔助調整過敏體質功能	21	5%
7	骨質保健功能	21	5%
8	調節血糖功能	19	5%
9	抗疲勞功能	16	4%
10	延緩衰老功能	7	2%
11	牙齒保健功能	6	2%
12	促進鐵吸收功能	5	1%
13	輔助調節血壓功能	3	1%
合計		388	100%



健康食品一軌-安全性試驗

分類原則		基因毒性試驗	28天餵食毒性試驗	90天餵食毒性試驗	致畸試驗	致癌試驗	繁殖試驗
第一類	原料屬傳統食用且以通常加工食品形式供食者	×	×	×	×	×	×
第二類	原料屬傳統食用但非以通常加工食品形式供食者	○	○	×	×	×	×
第三類	原料非屬傳統食用者	○	×	○	○	×	×
第四類	原料非屬傳統食用且含有致癌物之類似物者	○	×	○	○	○	○

食品安全衛生管理法

第 28 條 第一項

食品、食品添加物、食品用洗潔劑及經中央主管機關公告之食品器具、食品容器或包裝，其標示、宣傳或廣告，不得有**不實、誇張或易生誤解之情形**。

第 45 條

違反第二十八條第一項或中央主管機關依第二十八條第三項所定辦法者，處**新臺幣四萬元以上四百萬元以下罰鍰**

罰則：4-400萬
罰鍰

法規

食品安全衛生管理法

第 28 條 第二項

食品**不得為醫療效能之標示、宣傳或廣告。**

第 45 條

違反同條第二項規定者，處新臺幣**六十萬元以上五百萬元以下罰鍰**；再次違反者，並得命其歇業、停業一定期間、廢止其公司、商業、工廠之全部或部分登記事項，或食品業者之登錄；經廢止登錄者，一年內不得再申請重新登錄。

罰則：60-
500萬罰鍰

食品標示宣傳或廣告詞句涉及誇張 易生誤解或醫療效能之認定基準

一、衛生福利部(以下稱本部)為維護國人健康，保障消費者權益，有效執行食品安全衛生管理法第二十八條，禁止食品標示、宣傳或廣告誇張、易生誤解或宣稱醫療效能，特訂定本基準。

二、食品標示、宣傳或廣告如有誇張、易生誤解或宣稱醫療效能之情形，且涉及違反**健康食品管理法第六條規定**者，應依違反健康食品管理法論處。

<https://www.fda.gov.tw/tc/sitecontent.aspx?sid=1691>

法規

健康食品管理法

第 6 條

食品非依本法之規定，不得標示或廣告為**健康食品**。
食品標示或廣告提供特殊營養素或具有特定保健功效者，應依本法之規定辦理之。

第 21 條

未經核准擅自製造或輸入**健康食品**或違反第六條第一項規定者，處**三年以下有期徒刑**，得併科新臺幣**一百萬元以下罰金**。

明知為前項之食品而販賣、供出、輸入、輸出、轉讓、標示、廣告或意圖販賣而處罰之。

**3年以下有期徒刑
刑，併科100萬
以下罰金**

食品標示宣傳或廣告詞句涉及誇張 易生誤解或醫療效能之認定基準

(一) 使用下列詞句者，應認定為涉及醫療效能：

1. 宣稱預防、改善、減輕、診斷或治療疾病或特定生理情形：

例句：治療近視。恢復視力。防止便秘。利尿。改善過敏體質。壯陽。強精。減輕過敏性皮膚病。治失眠。防止貧血。降血壓。改善血濁。清血。調整內分泌。防止更年期的提早。

2. 宣稱減輕或降低導致疾病有關之體內成分：

例句：解肝毒。降肝脂。

3. 宣稱產品對疾病及疾病症候群或症狀有效：

例句：消滯。降肝火。改善喉嚨發炎。祛痰止喘。消腫止痛。消除心律不整。解毒。

食品標示宣傳或廣告詞句涉及誇張 易生誤解或醫療效能之認定基準

4. 涉及中藥材之效能者：

例句：補腎。溫腎（化氣）。滋腎。固腎。健脾。補脾。益脾。溫脾。和胃。養胃。補胃。益胃。溫胃（建中）。翻胃。養心。清心火。補心。寧心。瀉心。鎮心。強心。清肺。宣肺。潤肺。傷肺。溫肺（化痰）。補肺。瀉肺。疏肝。養肝。瀉肝。鎮肝（熄風）。潤腸。潤腸。活血。化瘀。

5. 引用或摘錄出版品、典籍或以他人名義並述及醫藥效能：

例句：「本草備要」記載：冬蟲夏草可止血化痰。「本草綱目」記載：黑豆可止痛。散五臟結積內寒。

食品標示宣傳或廣告詞句涉及誇張 易生誤解或醫療效能之認定基準

使用下列詞句者，應認定為未涉及誇張、易生誤解或醫療效能：

(一) 通常可使用之例句(正面表列)

幫助牙齒骨骼正常發育。幫助消化。幫助維持消化道機能。改變細菌叢生態。使排便順暢。調整體質。調節生理機能。滋補強身。增強體力。精神旺盛。養顏美容。幫助入睡。營養補給。健康維持。青春美麗。產前產後或病後之補養。促進新陳代謝。清涼解渴。生津止渴。促進食慾。開胃。退火。降火氣。使口氣芬芳。促進唾液分泌。潤喉。「本草綱目」記載梅子氣味甘酸，可生津解渴（未述及醫藥效能）。

(二) 一般營養素可敘述之生理功能例句（須明敘係營養素之生理功能，例如：膳食纖維可促進腸道蠕動；維生素A有助於維持在暗處的視覺；維生素D可增進鈣吸收）：

法規

健康食品管理法

第 6 條

食品非依本法之規定，不得標示或廣告為**健康食品**。
食品標示或廣告提供特殊營養素或具有特定保健功效者，應依本法之規定辦理之。

第 21 條

未經核准擅自製造或輸入健康食品或違反第六條第一項規定者，處三年以下有期徒刑，得併科新臺幣一百萬元以下罰金。

明知為前項之食品而販賣、供出、轉讓、標示、廣告或意圖販賣而處罰之。

3年以下有期徒刑，併科100萬以下罰金

食品安全衛生管理法

第 28 條 第一項

食品、食品添加物、食品用洗潔劑及經中央主管機關公告之食品器具、食品容器或包裝，其標示、宣傳或廣告，不得有**不實、誇張或易生誤解之情形**。

第 45 條

違反第二十八條第一項或中央主管機關依第二十八條第三項所定辦法者，處**新臺幣四萬元以上四百萬元以下罰鍰**

罰則：4-400萬
罰鍰

法規

食品安全衛生管理法

第 28 條 第二項

食品**不得為醫療效能之標示、宣傳或廣告。**

第 45 條

違反同條第二項規定者，處新臺幣**六十萬元以上五百萬元以下罰鍰**；再次違反者，並得命其歇業、停業一定期間、廢止其公司、商業、工廠之全部或部分登記事項，或食品業者之登錄；經廢止登錄者，一年內不得再申請重新登錄。

罰則：60-
500萬罰鍰

法規

食品安全衛生管理法

第 28 條 第三項

中央主管機關對於**特殊營養食品**、易導致慢性病或不適合兒童及特殊需求者長期食用之食品，得限制其促銷或廣告；其食品之項目、促銷或廣告之限制與停止刊播及其他應遵行事項之辦法，由中央主管機關定之。。

第 45 條

違反第二十八條第一項或中央主管機關依第二十八條第三項所定辦法者，處**新臺幣四萬元以上四百萬元以下罰鍰**

罰則：4-400
萬罰鍰

法規

食品安全衛生管理法



第 15 條

食品或食品添加物有下列情形之一者，不得製造、加工、調配、包裝、運送、貯存、販賣、輸入、輸出、作為贈品或公開陳列：

- 一、變質或腐敗。
- 二、未成熟而有害人體健康。
- 三、有毒或含有害人體健康之物質或異物。
- 四、染有病原性生物，或經流行病學調查認定屬造成食品中毒之病因。
- 五、殘留農藥或動物用藥含量超過安全容許量。
- 六、受原子塵或放射能污染，其含量超過安全容許量。
- 七、攙偽或假冒。
- 八、逾有效日期。
- 九、從未於國內供作飲食且未經證明為無害人體健康。
- 十、添加未經中央主管機關許可之添加物。

法規

食品安全衛生管理法



罰則：6萬-2
億元罰鍰

第 44 條

有下列行為之一者，處新臺幣六萬元以上二億元以下罰鍰；情節重大者，並得命其歇業、停業一定期間、廢止其公司、商業、工廠之全部或部分登記事項，或食品業者之登錄；經廢止登錄者，一年內不得再申請重新登錄：

- 一、違反第八條第一項或第二項規定，經命其限期改正，屆期不改正。
- 二、違反第十五條第一項、第四項或第十六條規定。
- 三、經主管機關依第五十二條第二項規定，命其回收、銷毀而不遵行。
- 四、違反中央主管機關依第五十四條第一項所為禁止其製造、販賣、輸入或輸出之公告。

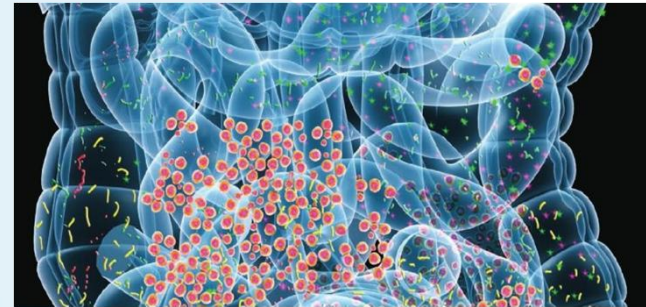


下一波的產品趨勢？

Microbiome

Human Gut Microbiome

- What is it?
- What role does it play in health and in disease.
- Modification of the microbiome to maintain health or treat disease.



Microbiome

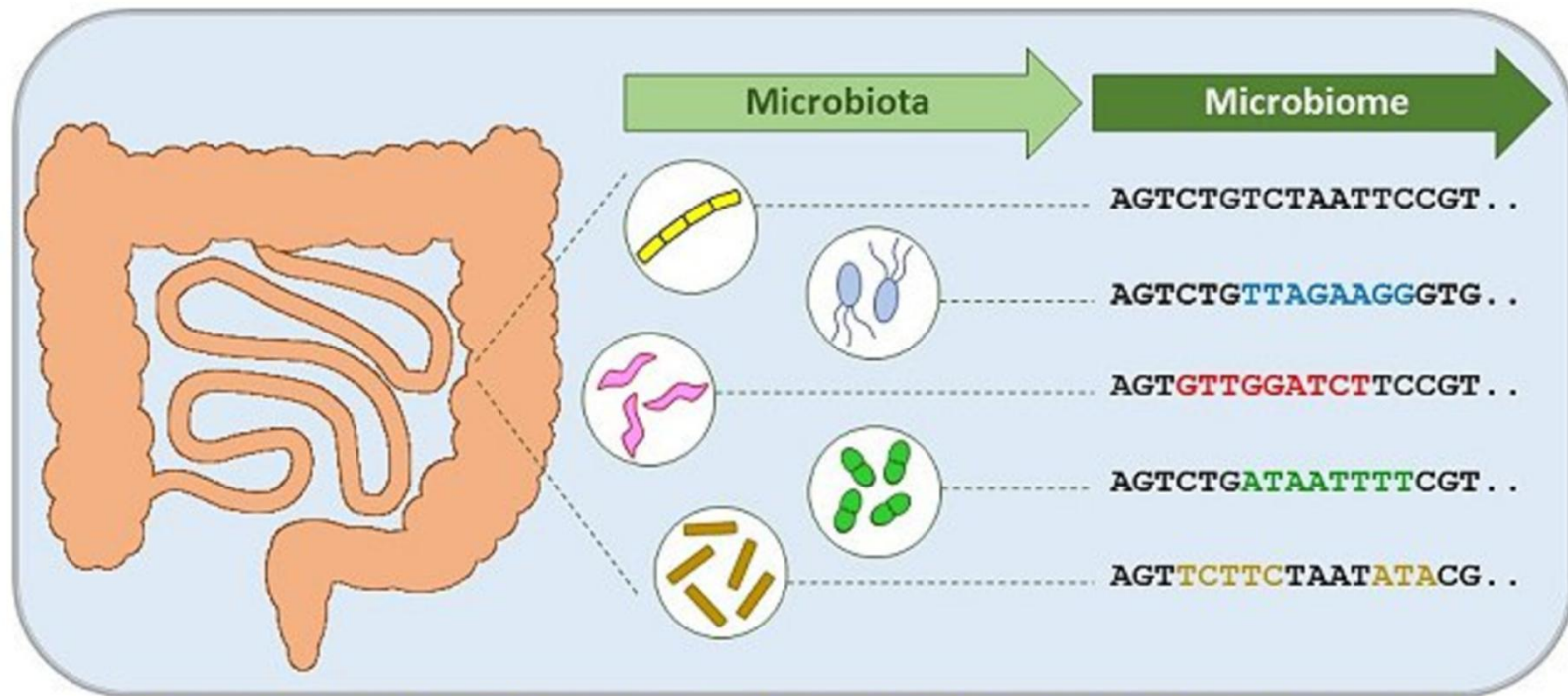
Microbiota

- The microorganisms that live in an established environment.

Microbiome (microbe+genome)

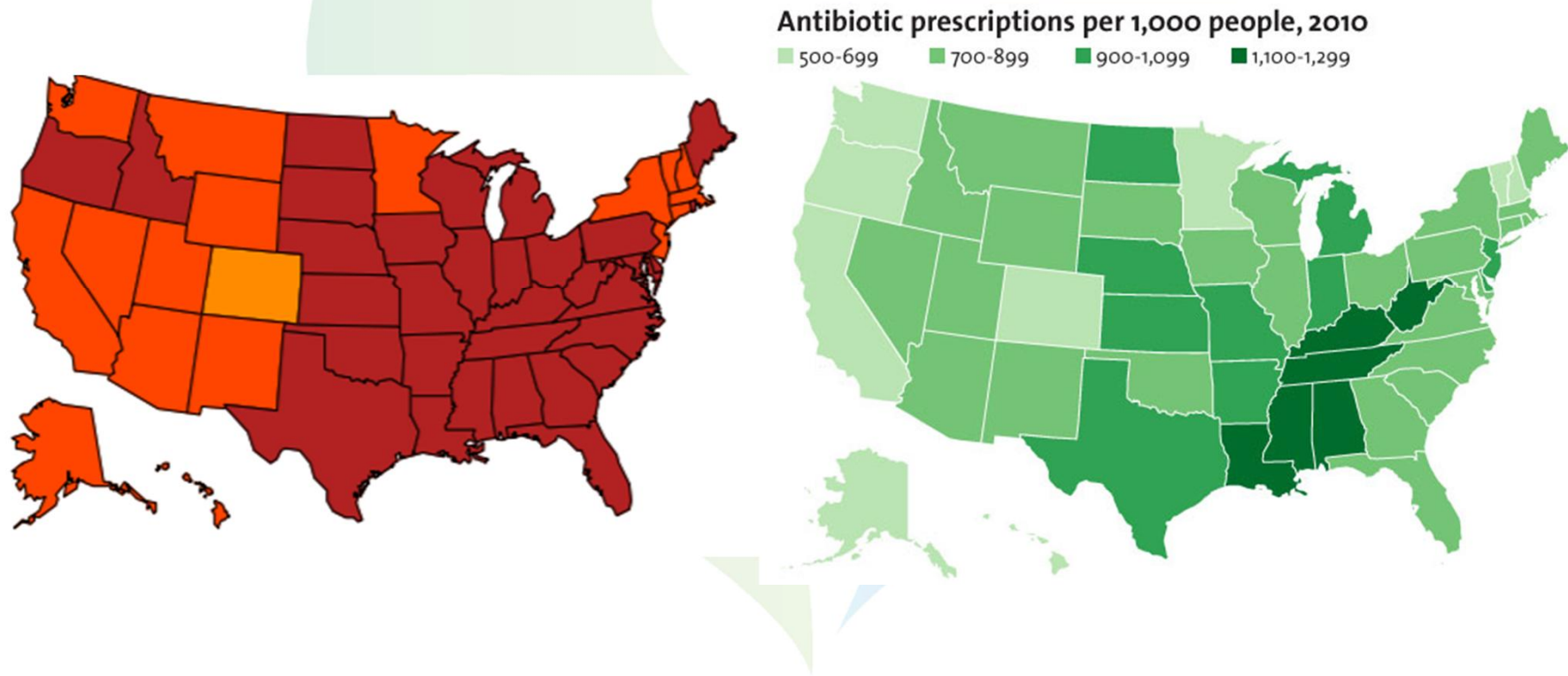
- The full complement of microbes, their genes, and genomes in a particular environment.

Microbiome





Comparison between the geography of obesity and antibiotic use



Comparison between the geography of obesity and antibiotic use



	許可證字號	有效日期	中文品名	英文品名	申請商	製造廠
1	衛署藥製字第033458號	已註銷 88/06/04	金黴素（鹽酸氯 四環素）粉劑	AUREOMYCIN (CHLORTETRACYCL INE HYDROCHLORIDE) POWDER "CYANAMID"	臺灣氰胺股份有 限公司新竹新廠	臺灣氰胺股份有 限公司新竹廠
2	衛署藥製字第042105號	112/04/16	金黴素外用軟膏 30 毫克/公克 （氯四環素）	AUREOMYCIN OINTMENT 30MG/G (CHLORTETRACYCL INE)	輝瑞生技股份有 限公司	聯亞藥業股份有 限公司新竹廠
3	內衛藥製字第004102號	已註銷 97/06/04	金黴素眼用藥膏	AUREOMYCIN OINTMENT	臺灣惠氏股份有 限公司新竹廠	臺灣惠氏股份有 限公司新竹廠
4	內衛藥製字第004148號	已註銷 81/06/04	金黴素粉劑	AUREOMYCIN POWDER	臺灣氰胺股份有 限公司新竹新廠	臺灣氰胺股份有 限公司新竹廠
5	內衛藥製字第004599號	已註銷 97/06/17	金黴素膠囊 25 0 公絲	AUREOMYCIN CAPSULES 250MG	臺灣惠氏股份有 限公司新竹廠	臺灣惠氏股份有 限公司新竹廠

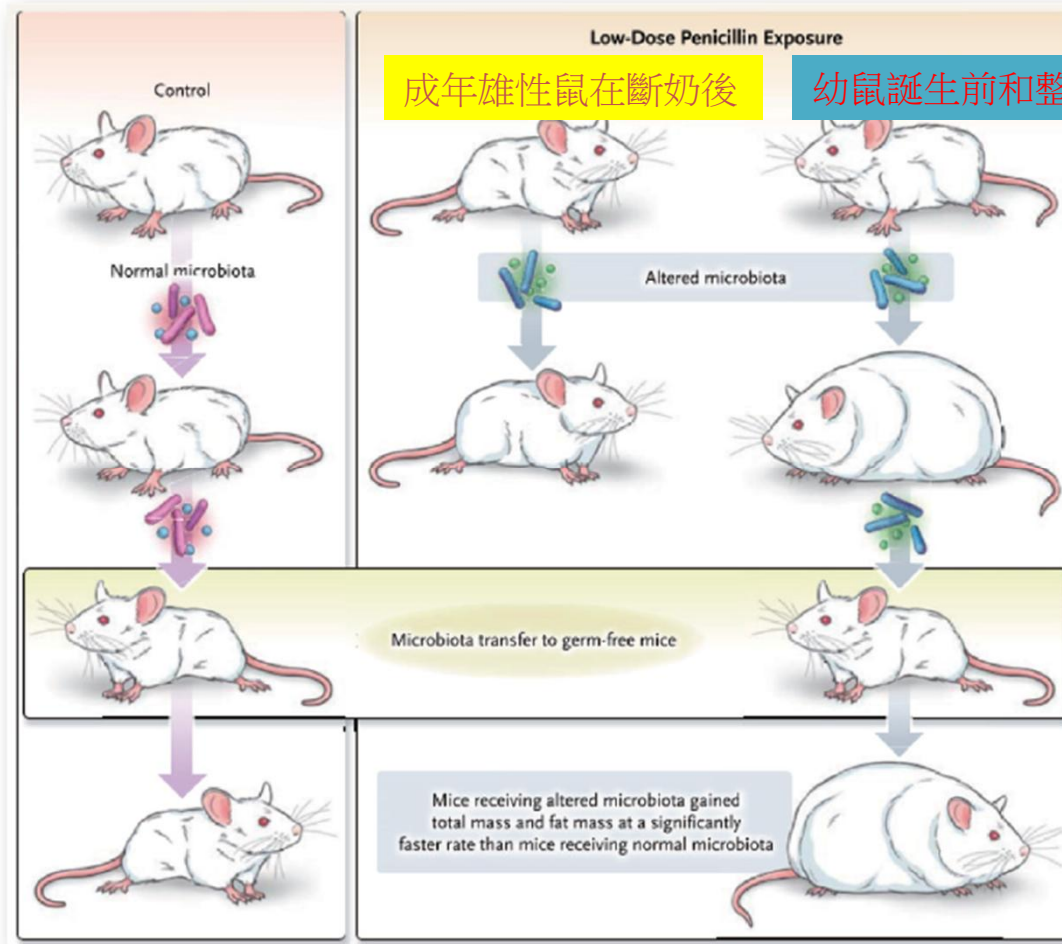


Microbiota, Antibiotics, and Obesity

18 week

low-dose penicillin

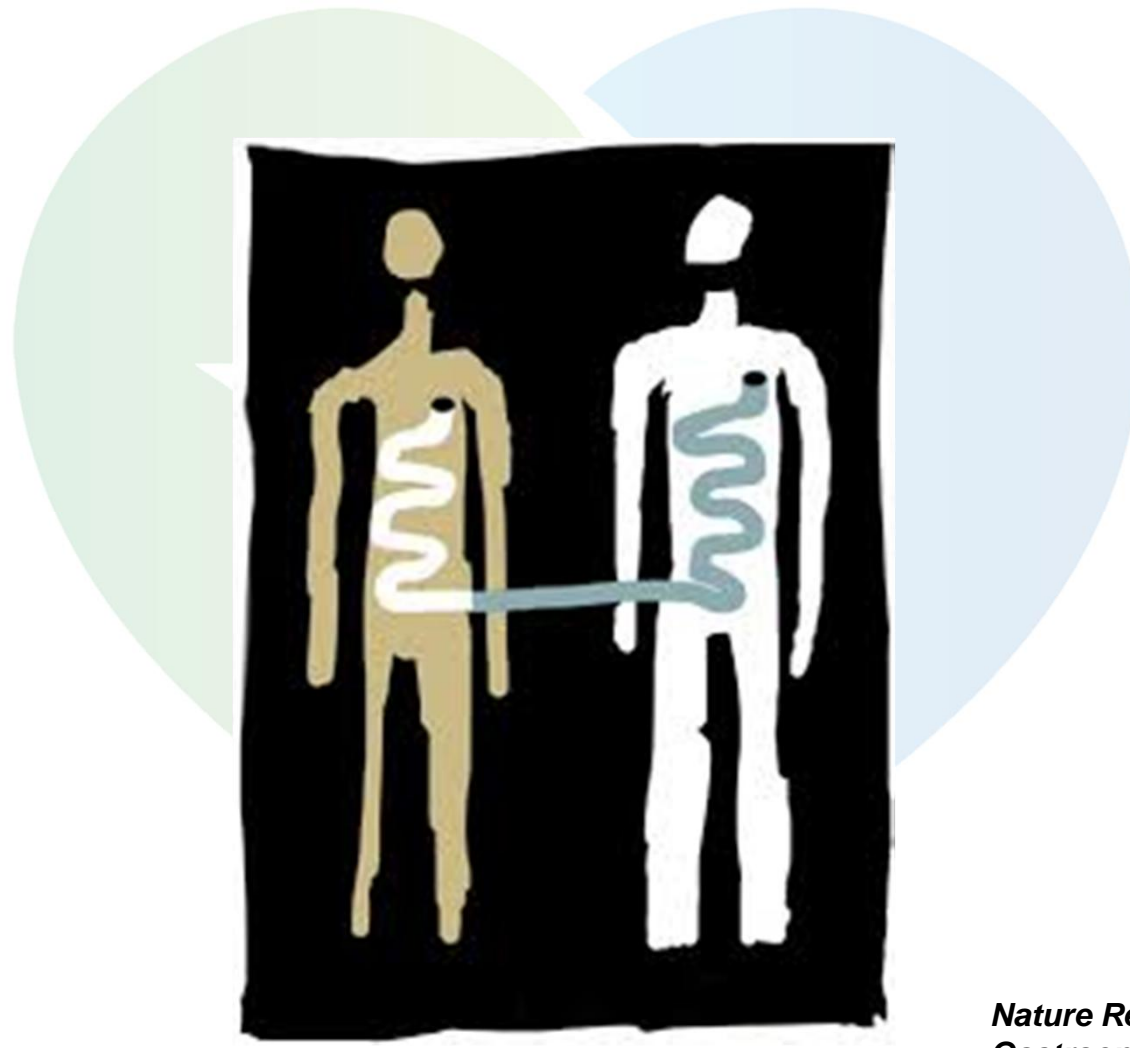
3 week



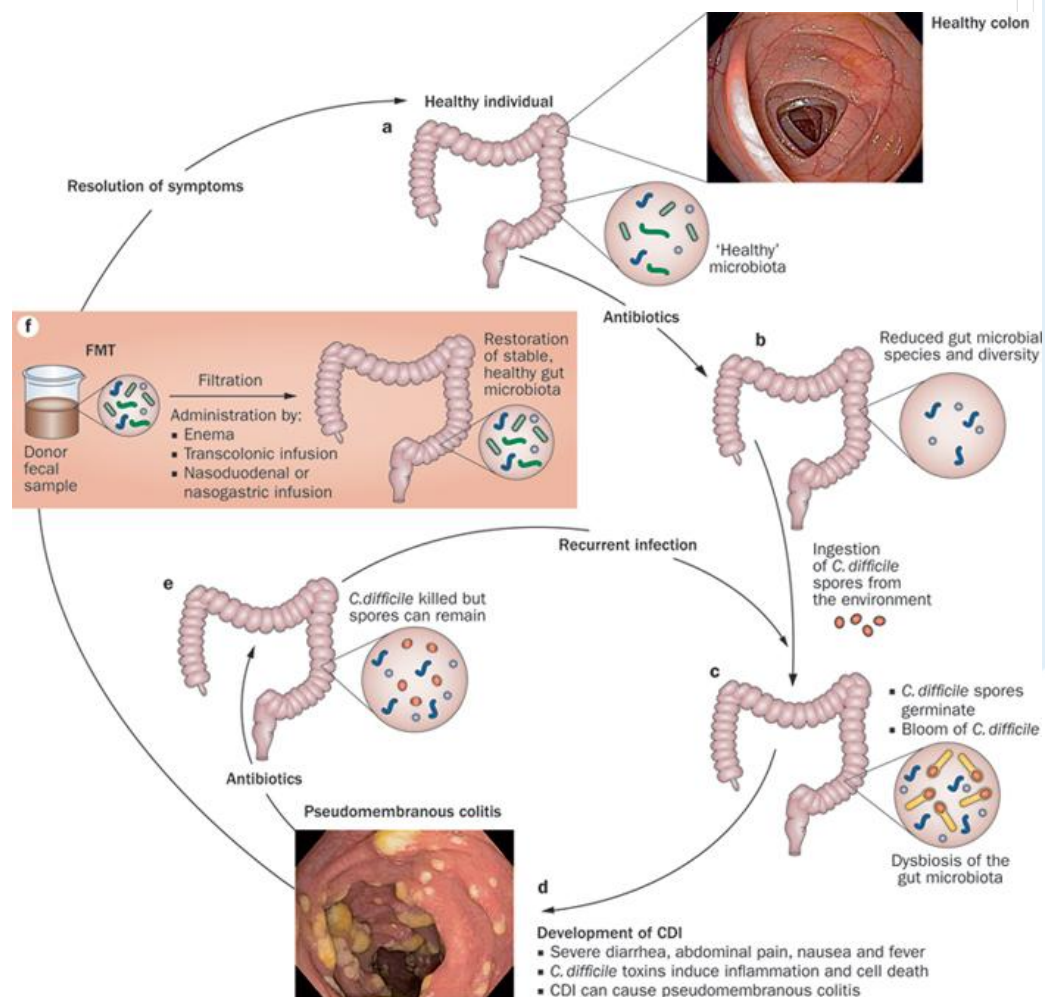
Total mass
Fat mass

N Engl J Med 2014;371:2526-2528

Fecal microbiota transplant



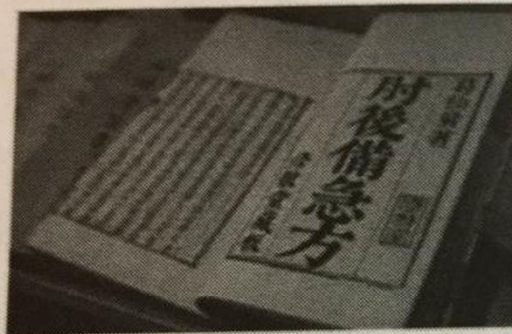
***Nature Reviews
Gastroenterology & Hepatology
Vol 9, 88-96 (2012)***



灌腸
經結腸灌注

Nature Reviews
Gastroenterology & Hepatology
Vol 9, 88-96 (February 2012)

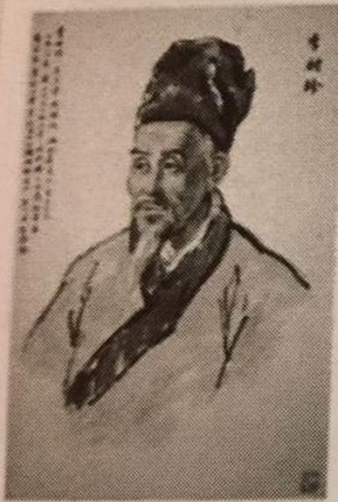
什麼?吃X?



東晉 (A.D. 317 - 420)

「並善，又絞糞汁，
飲數合至一二升，
謂之黃龍湯，陳久者佳。」

明朝 (A.D. 1368 - 1644)



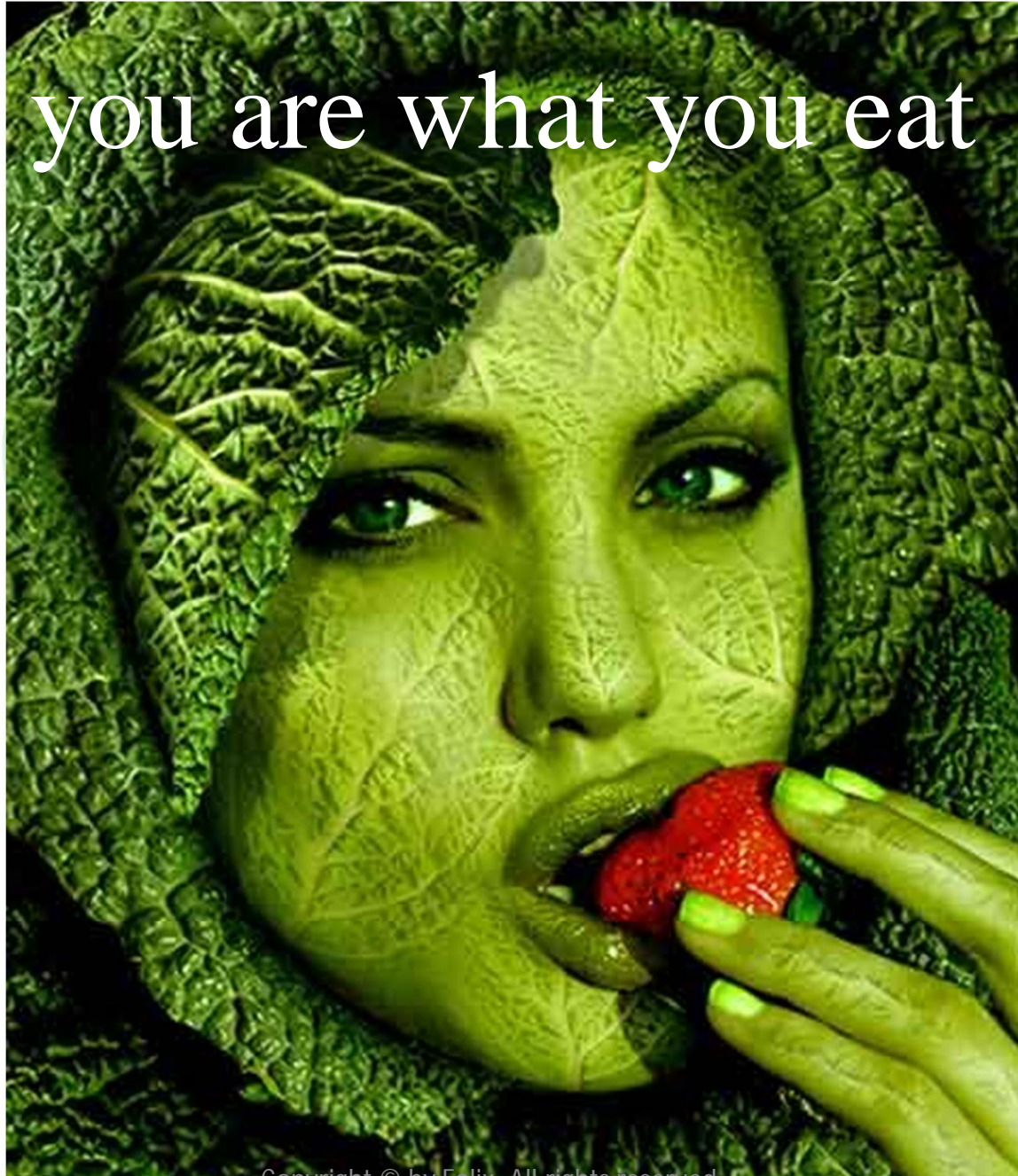
「野葛芋毒、山中毒菌欲死者，並飲糞汁一升，即活。《肘後方》」

「五色丹毒，黃龍湯飲二合」

「諸毒猝惡，熱悶欲死者，
新糞汁，水和服。」

「解藥箭毒，便飲汁並涂之，惟此最妙」

you are what you eat



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