2017 Taiwan – Asean drug Regulatory Forum

A Health System perspective of pharmaceutical care

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Outline

- UHC as the Ultimate goal
- The Dual role of regulatory authority
- Who's to develop medical products for our region
- Conclusion

My Track Records in Public Health Administration：

— Drug Regulatory Authority (1989-1993)

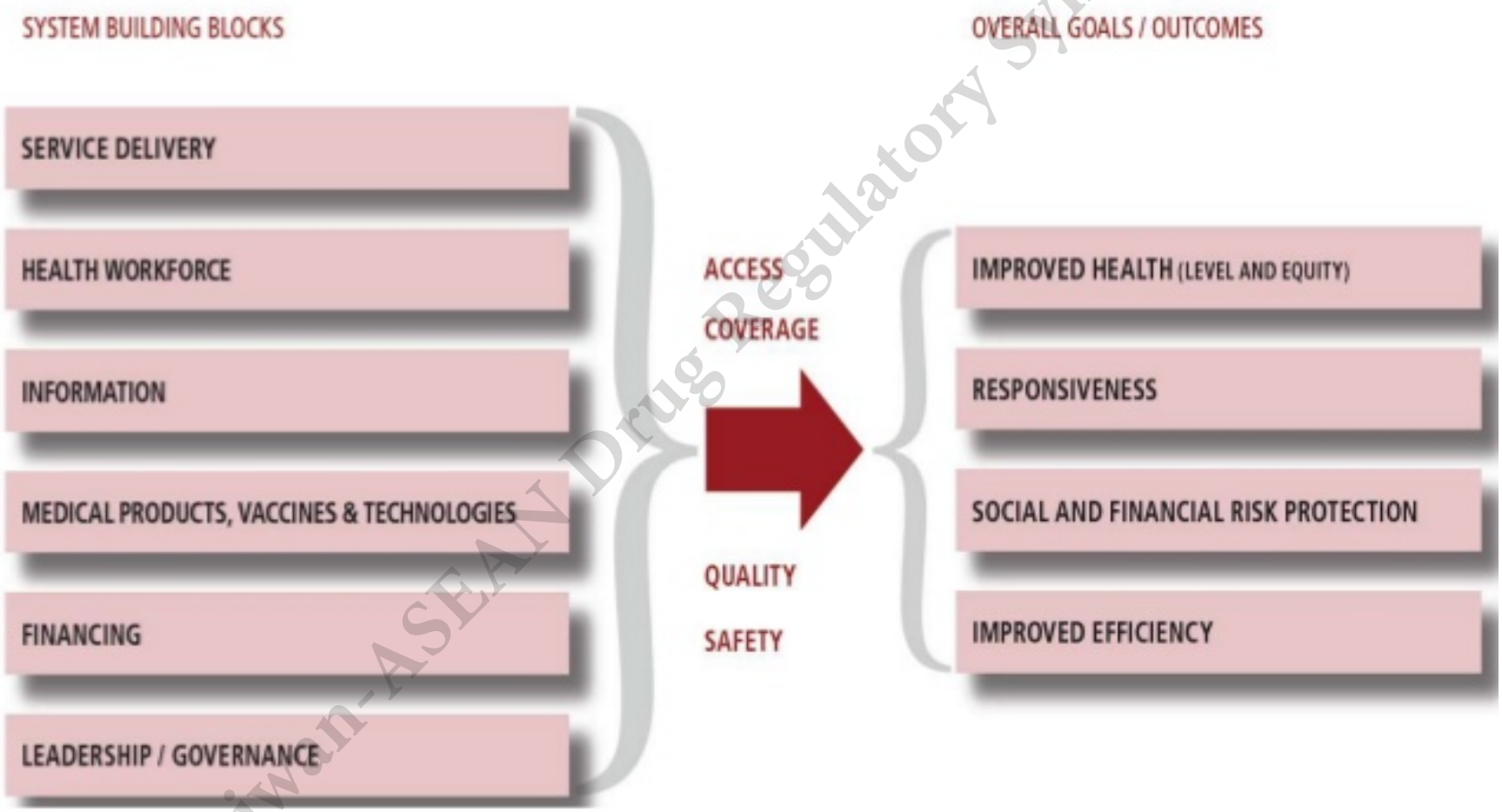
— Chief Science, Technology and information officer (1993-1995)

— Head of Taiwan’s CDC (1999-2000)

— Head of Taiwan’s NHI (2001-2004)

— Deputy Minister(2004)

The WHO Health System Framework



Everybody's Business. Strengthening Health Systems to Improve Health Outcomes. WHO's Framework for Action. WHO, 2007.

https://image.slidesharecdn.com/hsr-smith-beyond-reporting-me-hss-intervention-2012-121107143245-phpapp01/95/beyond-reporting-monitoring-and-evaluation-as-a-health-systems-strengthening-intervention-6-638.jpg?cb=1372175603

How to satisfy the medical needs of our people？

- UHC to provide basic health care : Inpatient /outpatient, Essential drug list, long term care/home care for the chronically ill
- A supplementary risk-pooling system for the better-off for more expensive treatment modalities
- Unmet medical needs

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ATLANTIC CROSSING **Uwe E Reinhardt**

Humbled in Taiwan

Taiwan's highly efficient system of national health insurance should humble and inspire the US

Tagging along with Tsung-Mei Cheng, an expert on Taiwan's health system, on her recent visit to Taiwan's Bureau of National Health Insurance, turned out to be a bit humbling for me as someone who focuses mainly on the US health system.

The bureau is the government agency that administers Taiwan's single payer national health insurance system. Its staff members fret when hospitals and walk-in clinics fail to submit completed claims within the required 24 hours after delivery of service. Private health insurance companies in the United States count themselves lucky if high priced actuaries can tell them in the middle of the year what the carrier ultimately will have to pay the providers of health care for services rendered in the previous year. Taiwan's bureau can track almost in real time what goes on in the nation's healthcare system. In the US even a vague idea of what has been going on a year or two ago can be

in Taiwan jumped from roughly 57% of the population before 1 March 1995 to virtually the entire population. For US policy makers and presidential contenders—who for half a century now have engaged in a perpetual "national conversation" on universal health insurance, only to see the number of uninsured people grow apace over the years—the speed of Taiwan's move to a national health insurance system seems downright surreal.

Taiwan's system is financed in roughly equal share by the government, employers, and households in a complex scheme that includes subsidies, payroll taxes, and premiums paid by self employed people. Health care is delivered by a mixed system that includes private clinics, private non-profit hospitals, and public hospitals, among which patients have full freedom of choice. The main tool for cost containment has been sectoral global budgets; while effective in the short run,

> **Loss of health insurance and fear of bankruptcy over medical bills is a growing fear among millions of Americans; it has not been in Taiwan since 1995**

top tier, US style care for the rich funded by private insurance, a social insurance system for the employed middle class with highly variable quality of care, and much less or nothing for millions of uninsured poorer citizens.

Taiwan could much improve its health system by allocating an additional, say, 1-2% of its gross domestic product to health care. Some of the additional funds could be used to reduce patients' own spending, which is still higher than that in most European nations. Furthermore, much more should be allocated to the administrative budget of the Bureau of National Health Insurance, which now accounts for only an inadequate 1.5% of total spending on the health insurance system, compared with the 10% to 12% that premium commercial insurers in the US spend on administration, in addition to another 8% or so for marketing and profits. Recent research indicates that Taiwan's healthcare system devotes

A highly efficient system with low adm cost

The U.S. learned from Taiwan

http://www.pbs.org/wgbh/pages/frontline/sickaroundtheworld/

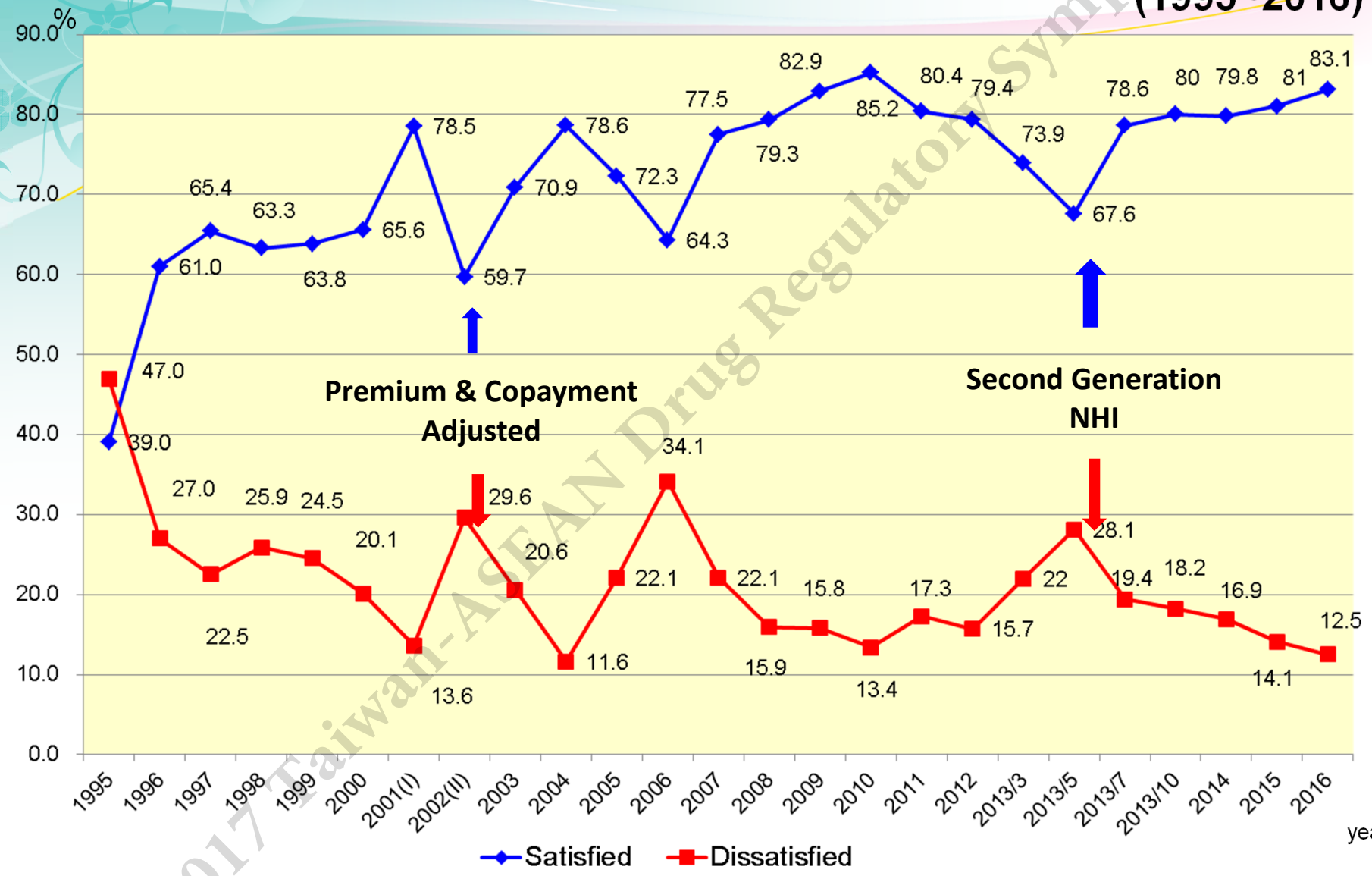
Benefits

Disease | **Injury** | **Maternity care**

- Inpatient care
- Outpatient care
- Prescription drugs
- Dental services (orthodontics, prothodontics excluded)
- Traditional Chinese medicine
- Day care for the mentally ill
- Home nursing care

High Public Satisfaction

(1995~2016)



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How we developed a world class Universal Health Care (UHC)-National Health Insurance(NHI)

- "NHI is like A car, with parts imported from a dozen different countries, but domestically made in Taiwan."

Hongjen Chang
President & CEO, BNHI
2003

Possible factors contributing to the success of Taiwan's NHI

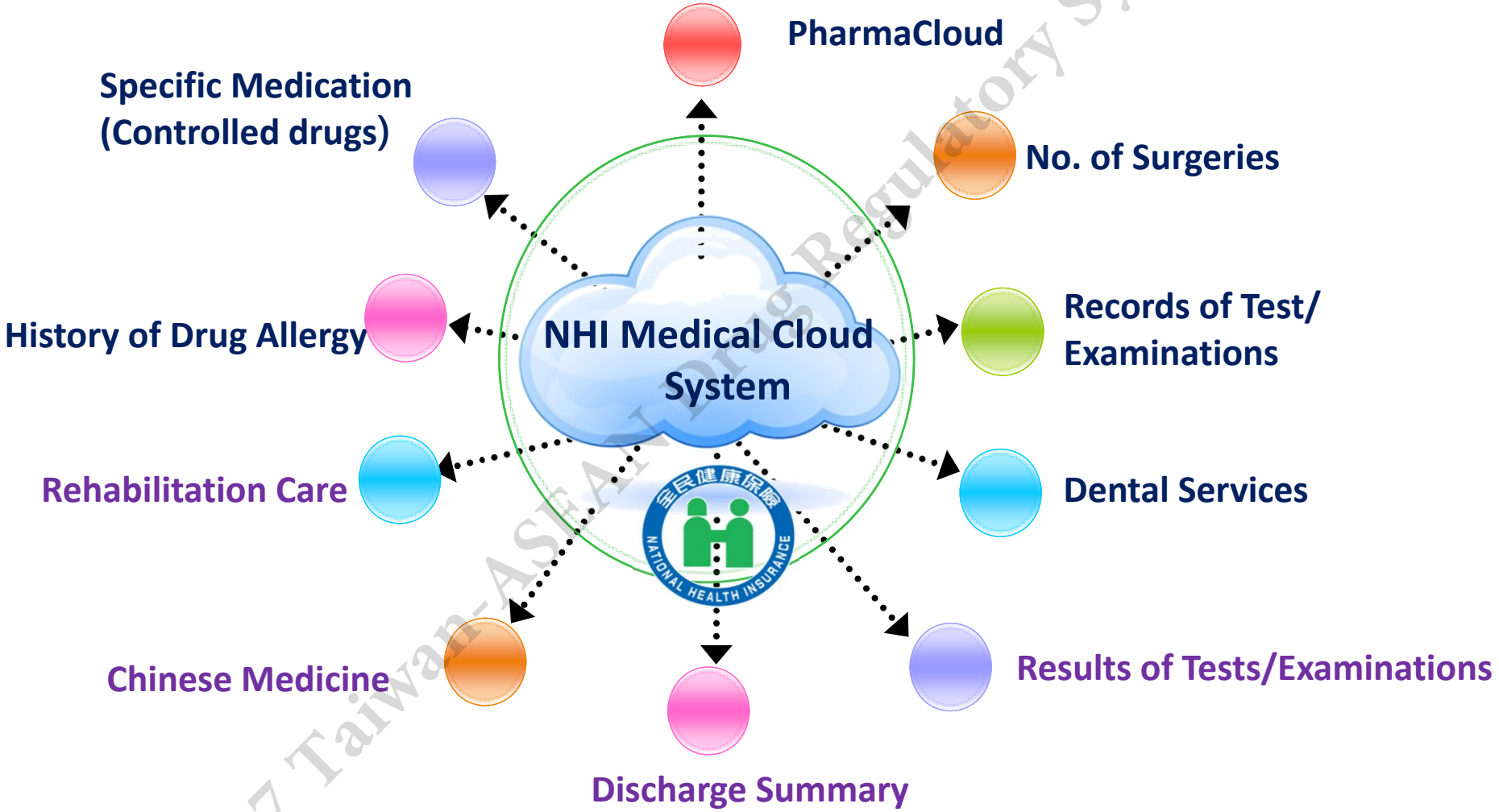
- Single-payer system
- Free market on delivery side
- **IT intensive:**
  - **100% electronic claim processing**
  - **smart card**
- **Strong generic pharmaceutical industry**
- Physicians willing to work very hard at relatively low physician fee
- Tradition of family support

NHI Card

- Simplification of management process
- Daily update of medical visit data
- Infectious disease tracing & monitoring
- Heavy-user detection & management

1. Last Six Medical Visits
2. Drug Prescriptions, Drug Allergies
3. Catastrophic Diseases
4. Organ Donation Consent
5. Palliative Care

NHI Medi-Cloud System



My Health Bank

My Data, My Decision

My Health Bank system was established in 2014 and added newly functions in 2016：

- **3 Years of medical data**
- **Health information is displayed in the form of diagrams to enhance readability**
- **Provide educational guidelines**
- **Simpler access**
- **Certain disease prognosis and evaluation**

APP of My Health Bank

Download for Android

Download for iOS

Does Universal Health Insurance Make Health Care Unaffordable? Lessons From Taiwan

Evidence from the first half-decade of universal coverage in Taiwan suggests that overall costs do not rise because of increased use of services.

by Jui-Fen Rachel Lu and William C. Hsiao

ABSTRACT: This paper examines the performance of Taiwan's National Health Insurance (NHI), a universal health insurance program, implemented in 1995, that covers comprehensive services. The authors address two key questions: Did the NHI cause Taiwanese health spending to escalate to an "unaffordable" level? What are the benefits of the NHI? They find that Taiwan's single-payer NHI system enabled Taiwan to manage health spending inflation and that the resulting savings largely offset the incremental cost of covering the previously uninsured. Under the NHI, the Taiwanese have more equal access to health care, greater financial risk protection, and equity in health care financing. The NHI consistently receives a 70 percent public satisfaction rate.

Taiwan's New National Health Insurance Program: Genesis And Experience So Far

Taiwan's health policymakers continue to tinker with the country's NHI, which covers almost all citizens with modest cost sharing.

by Tsung-Mei Cheng

ABSTRACT: In 1995, after a planning effort of about half a decade, the Republic of China (Taiwan) replaced a previous patchwork of separate social health insurance funds with one single-payer, national health insurance scheme that is administered by an agency of the central government's Department of Health. Within a year this bold legislative act brought the health care utilization rates of the 41 percent of Taiwan's hitherto uninsured population up to par with those of the previously insured population. This paper describes the achievements of this policy initiative so far, along with the growing pains it has encountered, and seeks to extract lessons from the experience for health policymakers in other countries.

Statement of US FDA Mission

FDA is responsible for **protecting the public health by assuring the safety, efficacy and security** of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

FDA is also responsible **for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable** and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health…

https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/budgetreports/ucm298331.pdf

Regulatory Agency plays critical roles in：

- Essential Drug list
- Promoting the use of Generics.
- Promoting Self medication (OTC)
- Emphasis on prevention n(vaccines)
- Rare diseases (orphan drugs)
- System to prevent /compensate drug injuries.
- Information System to promote rational use of medicine.

Top 10 “suspects” of drug injuries

Rank	Drug	number
1	Allopurinol	242
2	Phenytoin	149
3	Carbamazepine	123
4	Rifampin/Isoniazid/Pyrazinamide	108
5	Diclofenac	70
6	Co-trimoxazole	56
7	Lamotrigine	43
8	Ibuprofen	42
9	Mefenamic acid	40
10	Cefazolin	37

A unique drug-injury relief system in Taiwan: comparing drug-injury compensation in different countries

Angela W.F. On, Lan Hui Chih, Cindy Liu, Kuo Hwa Lin,
Yu Wen Huang Hsueh Yung Tai and Mei Ling Hsiao
Taiwan Drug Relief Foundation, Division of Drugs and New Biotechnology Products, Food and Drug Administration (TFDA) and Department of Health, Executive Yuan, Taiwan

Abstract

Taiwan operates a unique no-fault compensation-based scheme for injuries caused by medication use. This article describes the operation of the Taiwan Drug Relief Foundation and some results since the Taiwan Drug Hazard Relief Act was enacted in 2000. We also briefly review similar no-fault compensation systems in Germany, Japan, New Zealand and Nordic countries. The existence of these schemes provides timely relief and compensation to victims by avoiding the otherwise lengthy court process; however, medication safety education and applied pharmacogenomic and pharmacoepidemiological research are future aspirations to proactively address and prevent drug-induced injuries.

Keywords adverse drug reaction; drug injury; no-fault compensation scheme; pharmacogenomics; Stevens–Johnson syndrome; Taiwan Drug Relief Foundation

Unmet needs of an advanced economy (US. Europe Japan)

- Cancer treatments

  Immune Oncology, Precision medicine

  Liquid Biopsy…etc.
- Minimally invasive surgeries and interventions, interceptions, medical devices
- Unique diseases of the region
- Rare diseases and orphan indications

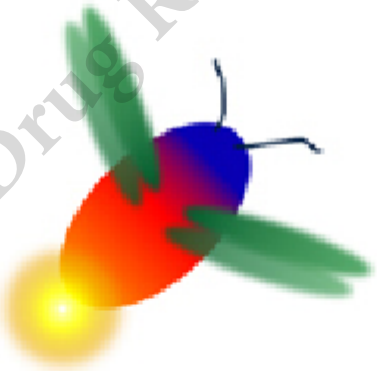
Definition

- Rare disease
  - the prevalence of <1/10,000 with genetic disorder in the population
  - difficult to diagnose and treat
- Orphan medical product*
  - Indications for rare diseases
  - Hard to access
- Special food supplement

* Medical product: medicinal products & medical devices

Spotlight on...

How specific legislation for rare diseases and orphan drugs is changing life for some patients in Taiwan…



財團法人罕見疾病基金會

TAIWAN FOUNDATION FOR RARE DISORDERS

http://www.orpha.net/actor/EuropaNews/2009/doc/Taiwan.pdf

"We can't take care of our children forever, but a well-established system can."

-The Taiwan Foundation for Rare Disorders

Unmet medical needs of our region

- UHC : Provision of “Basic” health services at affordable cost (The 30 Baht scheme of Thailand was a brilliant idea)
- A supplementary system for risk sharing for more expensive treatment modalities
- Diseases unique to the Region

Who is to develop products and vaccines for our region?

- Dengue vaccine, therapeutics, and diagnostic tests
- Snake venom Anti-serum
- Test for the early diagnosis of Oral Cancer
- Malaria AI screening system

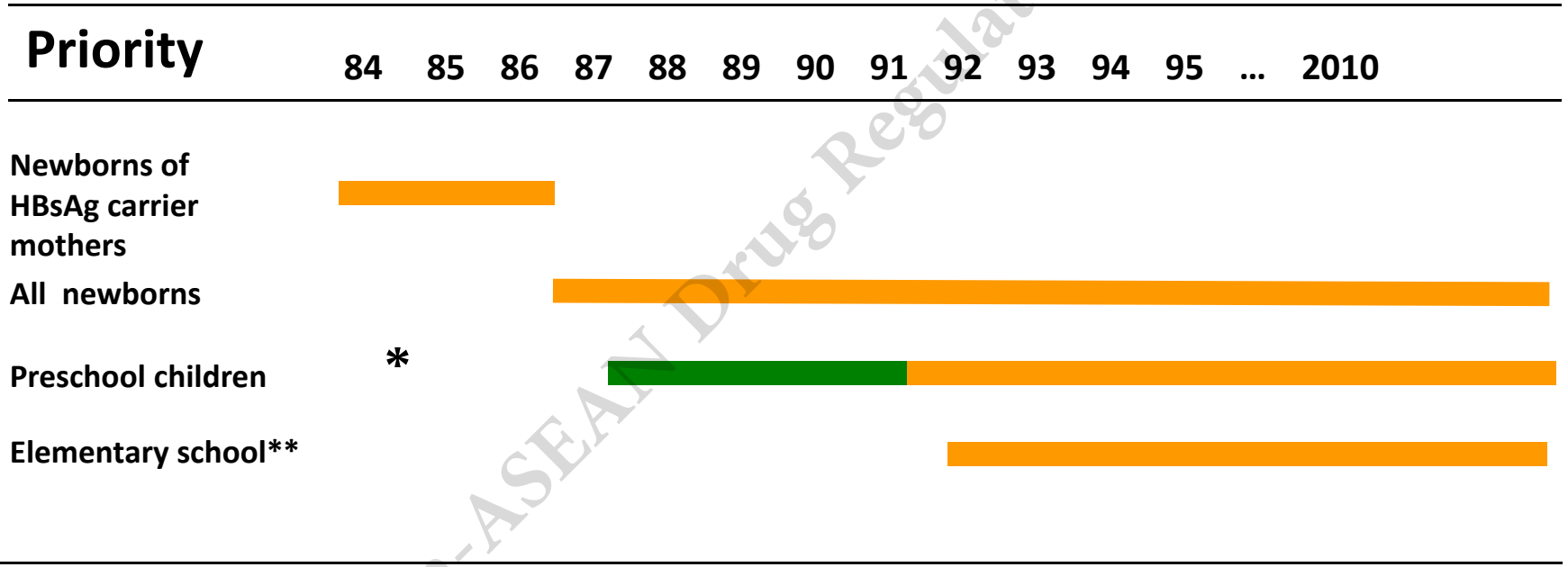
Taiwan's self sufficient in Vaccination

Vaccinia	DPT
Typhoid/ paratyphoid	JBE
Cholera	Plaque
Snake venom antiserum	

1959 Taiwan Serum and Vaccine institute

Taiwan was the first country to implement Universal HBV Vaccination

Priorities and Timetable of Hepatitis B Vaccine Program



* July 1987 ~ Sep. 1990 : Vaccinate preschool on voluntary base with payment.
After Oct. 1990 : Catch-up vaccination without charge for children up to 1st graders.
** After July 1991, all first graders were checked for their vaccination record.
Non- or incompletely vaccinated pupils needed to be vaccinated.

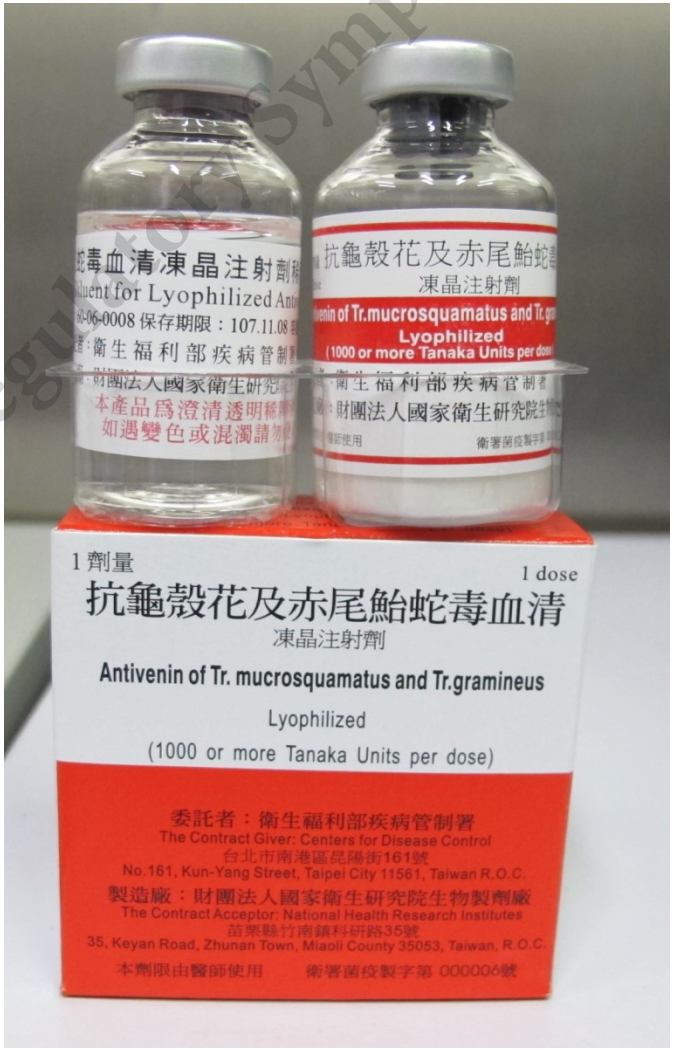
Bungarus multicinctus

Naja atra

Deinagkistrodon acutus

Protobothrops mucrosquamatus

Viridovipera stejnegeri



Daboia russellii siamensis

Dengue Fever (Break-bone Fever)

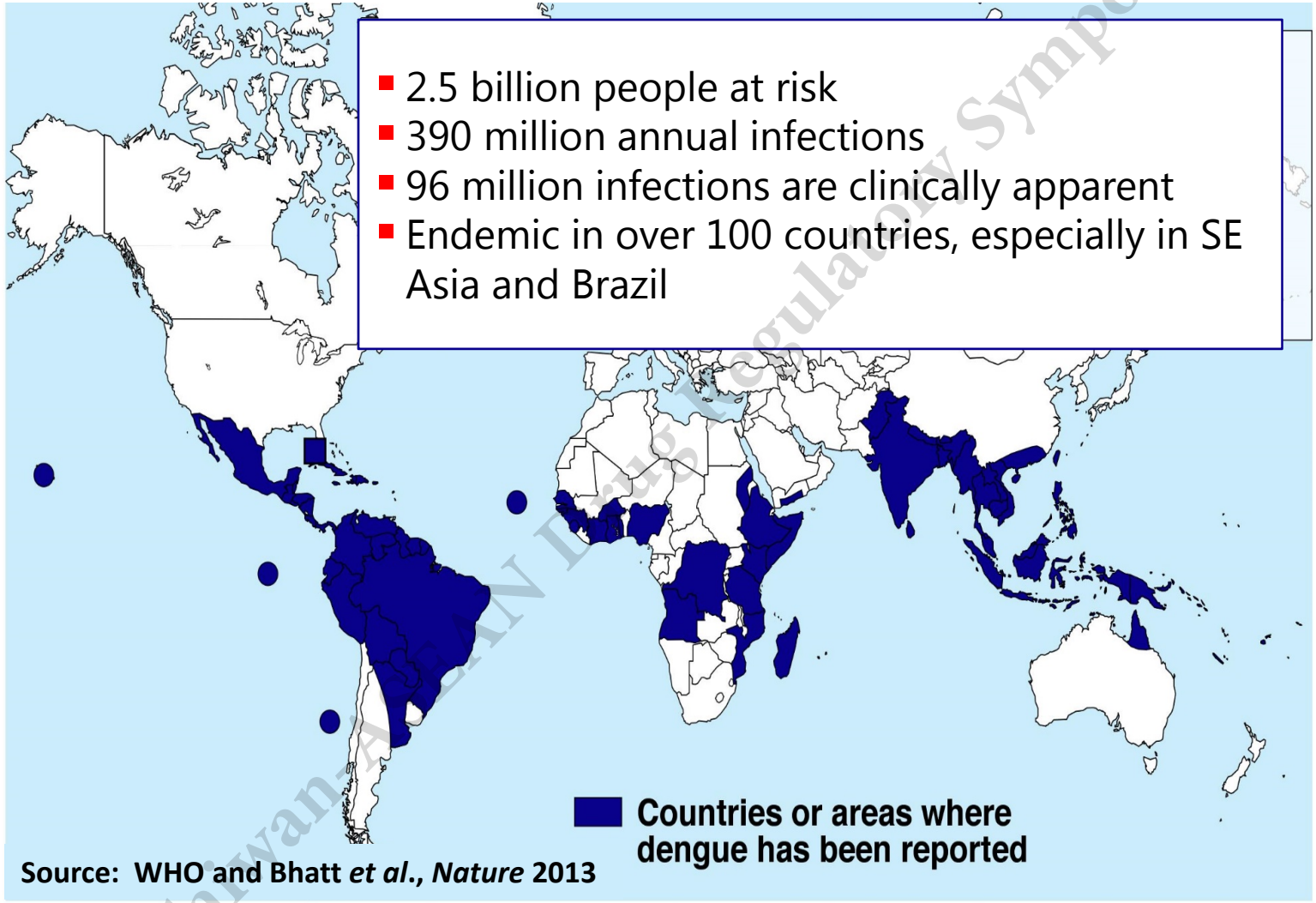
Characteristics

- As painful as it sounds….
- Skin-rash (*as demonstrated in the photo inserts*)
- Caused by 1 of 4 virus serotypes (DENV 1-4)
- Prevails in tropical and sub-tropical areas
- Global warming expands mosquitos habitat
- Transmitted by infected *Aedes aegypti mosquitos*

Wild type dengue fever

Courtesy by Dr. Whitehead, NIAID

Fighting Dengue



Dengue is both an established disease and an emerging/re-emerging disease.

Dengue Development

Medigen Vaccine Biologics Corp.

Dengvaxia®: First Marketed Dengue Vaccine Yet Fails to Fulfill Medical Need?

- Sanofi's Dengvaxia® is the world's first marketed dengue vaccine (2015/12). However, **its clinical trial data showed lower efficacy in preventing DENV2 (only 47%).**
- Dengvaxia® requires 3 doses to complete the series, with unit price ranges from 20 EUR/ dose (Philippines)~38 EUR/ dose (Brazil), the complete vaccination costs 60 EUR~114 EUR/ person.
- From 2016 Q1~Q3, Dengvaxia generated 50 million EUR, 75% lower compared to what Sanofi's CEO, Dr. Bradicourt had predicted in early 2016 that the annual sale would have reached 200 million EUR in first year.

- **Sanofi's product cannot fulfill market needs, providing entry opportunities for new products.**

Competitive Edge of the NIAID Dengue Vaccine*

- Tetravalent (DENV-1, DENV-2, DENV-3 and DENV-4)
- Single dose
- Tested in 1600+ subjects (Phase 1 & 2) in 3 countries
- Phase III efficacy study has begun in Brazil (~17,000 subjects, Feb., 2016)
- 100% Protection in human challenge study
- Economical to produce: Administer 3 logs, produce bulk at > 7 logs
- Cell-based vaccine (Vero)

*Courtesy by Dr. Whitehead, NIAID

MVC's 2nd Generation of Dengue Vaccine: VLP*

- Tetravalent VLP vaccine against dengue fever
- Transferred from the US CDC
- Progress: early stage development

CDC of United States

*VLP: Virus-Like-Particle

iXensor.

PixoTest Dengue / Zika/ Chikunguya Control System

- Test Results (Positive/Negative)
- Location (GPS)
- Temperature
- Humidity
- Fever
- Sickness
- Pregnant or not
- Travel history
- Other

Dashboards that visualize the spread of disease in real time

EpiGene
iStat Biomedical Co., Ltd.

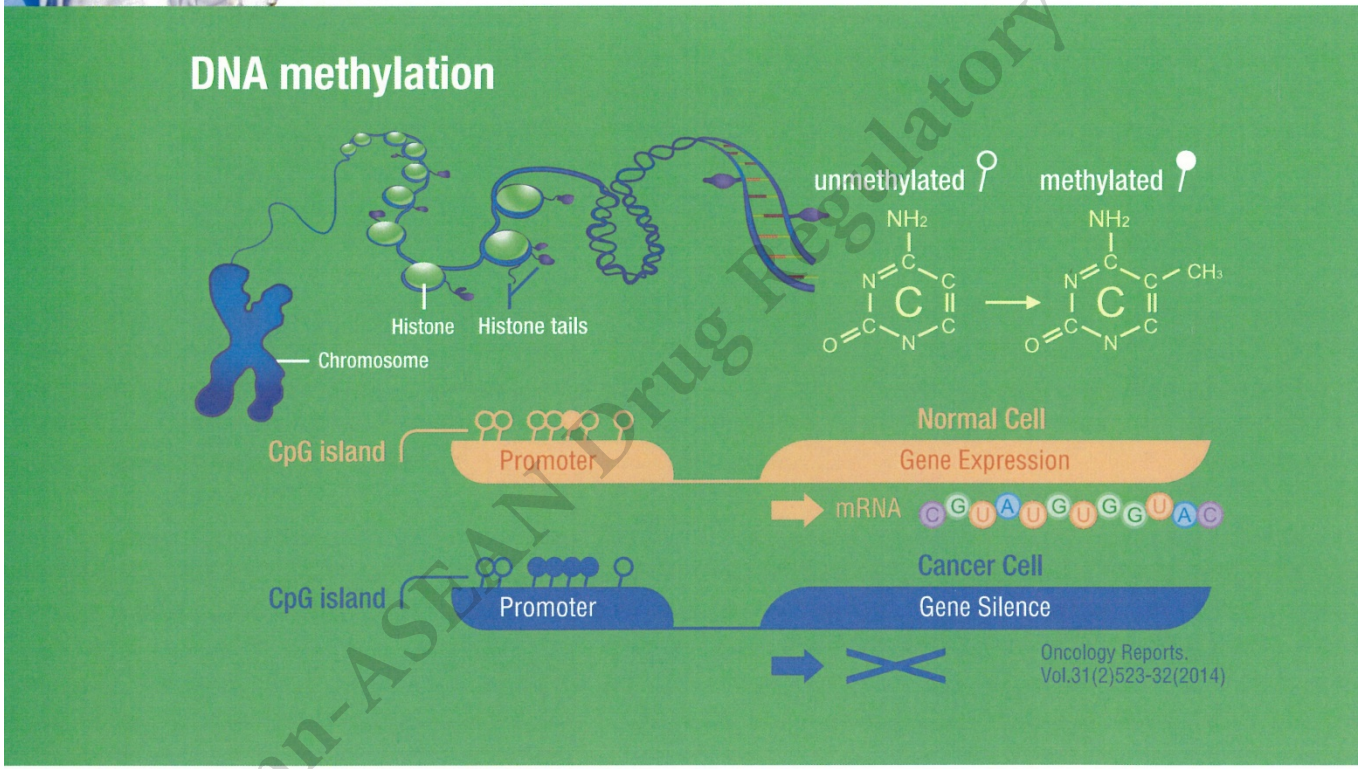
DNA Methylation Assay Platform

Innovation
Sciences
Technology
Affordability
Trusted Partner

CE IVD

The role of DNA methylation in cancer

DNA methylation is an important regulator of gene transcription. However, promoter hypermethylation also plays a major role in tumorigenesis through transcriptional silencing of critical tumor suppressor genes such as PAX1 and ZNF582. These discoveries in the field of DNA methylation in carcinogenesis create new opportunities to identify biomarkers for early detection and personalized treatment of cancer.



Clinical applications

Methylation level of PAX1 and ZNF582 in DNA extract from swab sample.

Screening
Am I at risk?

Diagnosis
What condition do I have?

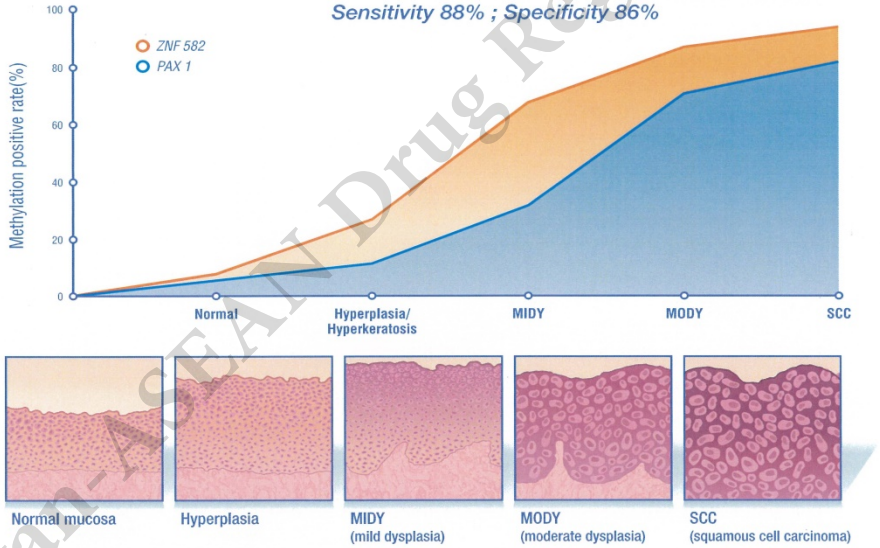
Monitoring
Is the treatment working well for me?

Oral-M®

A novel technology for DNA methylation determination for right treatments of **Oral Cancers.**

— the sooner the better —

Assist in screening, diagnosing, and monitoring treatment of oral premalignant lesion or cancer, for which reliable and affordable screening methods are currently not available.



In a cross sectional clinical study involving 267 subjects (normal, lesions, moderate dysplasia, and worse), sensitivity and specificity of Oral-M® gene methylation kit were 0.88 and 0.86, respectively.

References:

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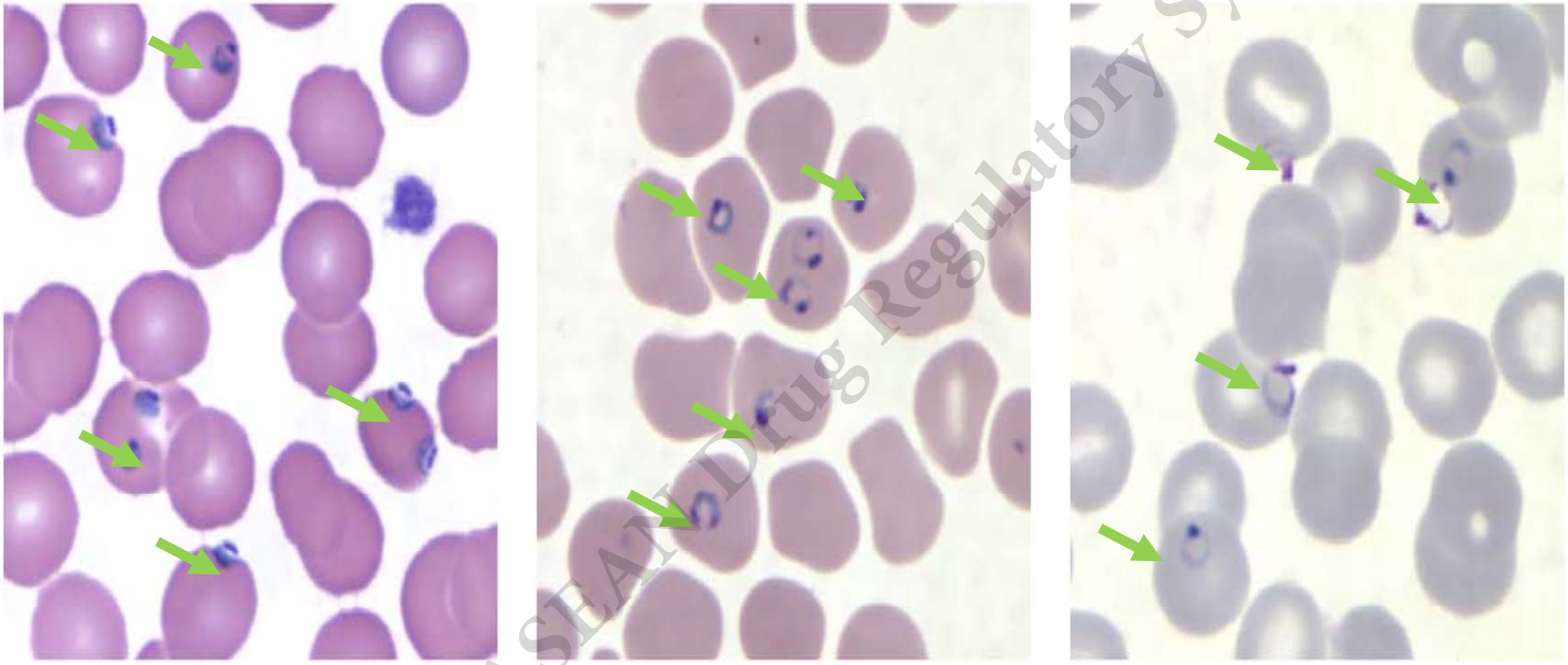
4. Guerrero-Preston R., et. al., Epigenetics. 2014, 9 (7): 1031-46

AI：Image Diagnosis System for Malaria



https://www.cdc.gov/dpdx/malaria/dx.html

How do regulatory bodies play an active roles ?

- Unmet medical needs
- Promoter(facilitator) vs. traditional “regulator”
- Regional Collaboration

  regulatory collaboration to facilitate people’s access to urgently needed medical products.