Towards a more effective healthcare regulation system in China

China Health System Study Group

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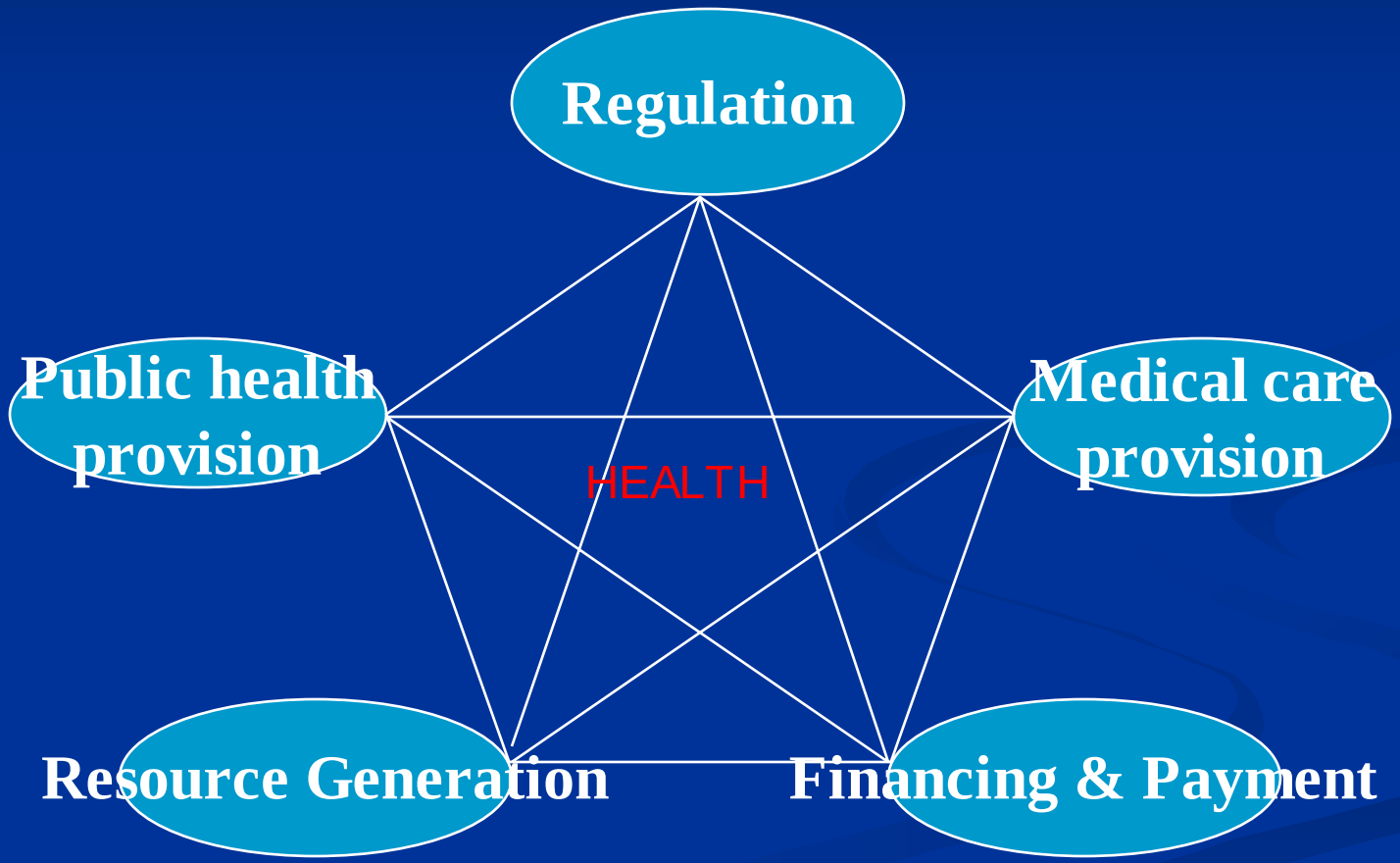
Outline

- Background
- Current situation
- Fundamental Challenges
- Recommendations for healthcare regulation improvement in China

Framework of Health System Analysis

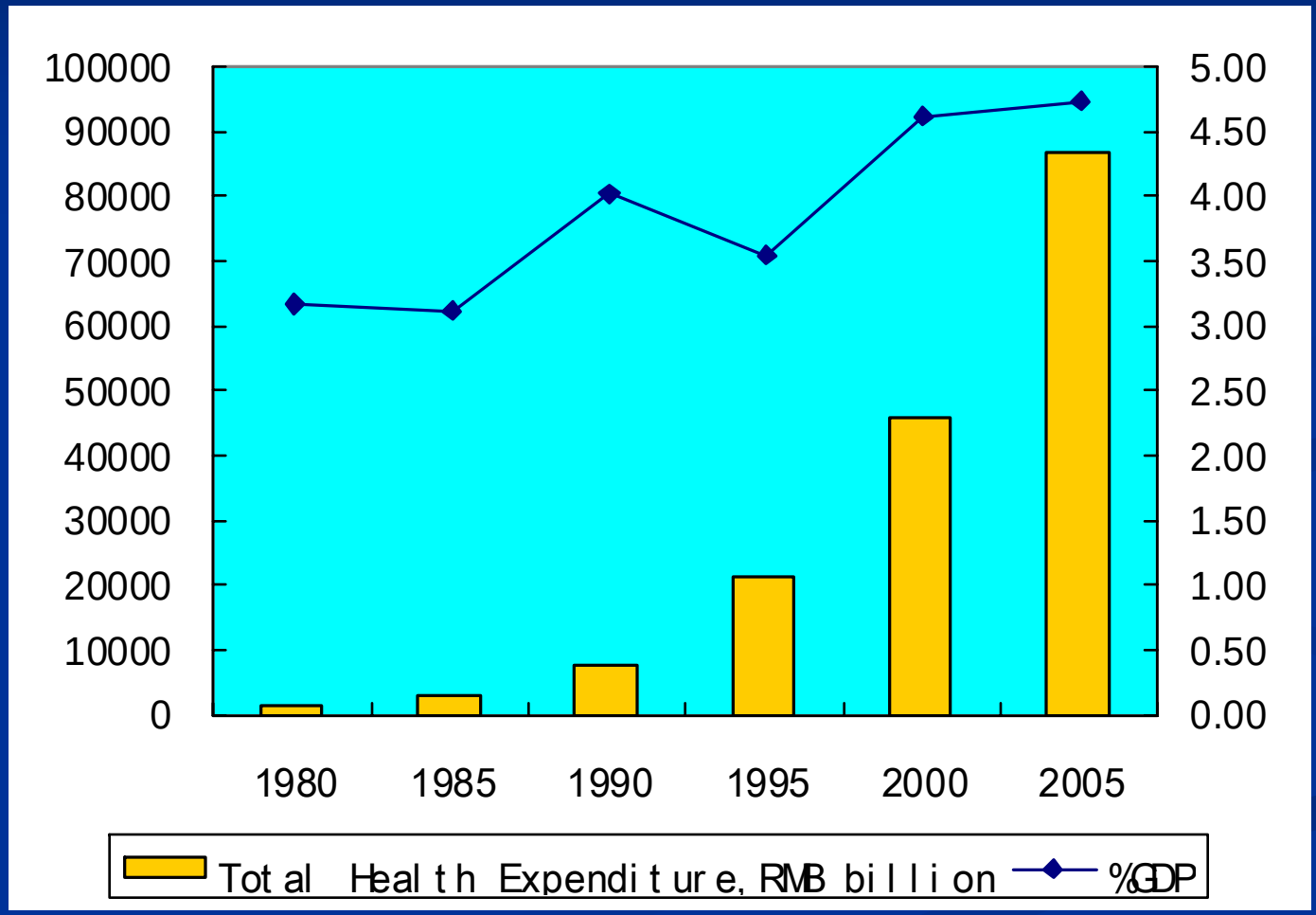


Background: needs to regulate health care system in China

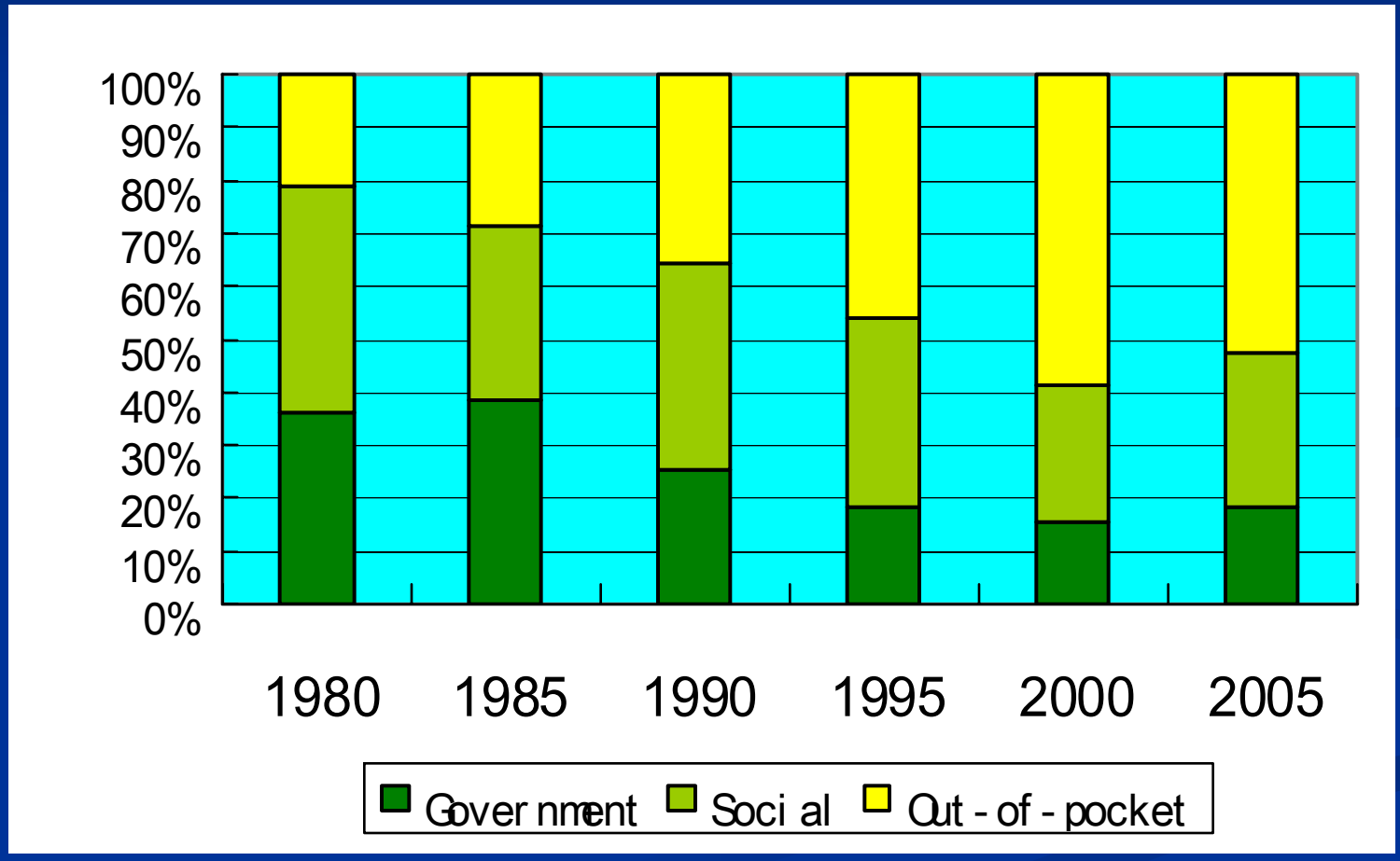
Two major pressing issues facing China's healthcare system

- Cost escalation
- Medical quality & safety

Cost escalation



The majority portion of cost escalation is borne by the patients' OOP



Why cost escalation?

- Market-oriented reform of the health care system has changed the incentives of health facilities
  - ✓ Health facilities rely more on users' fee-for-service payments to raise revenue with much less government subsidies.
  - ✓ Prescription drugs and diagnostic/treatment technologies are allowed a markup beyond cost which creates incentives for providers to provide more services or use more expensive services.
- The incentives & behaviors of providers are not well regulated by proper mechanisms

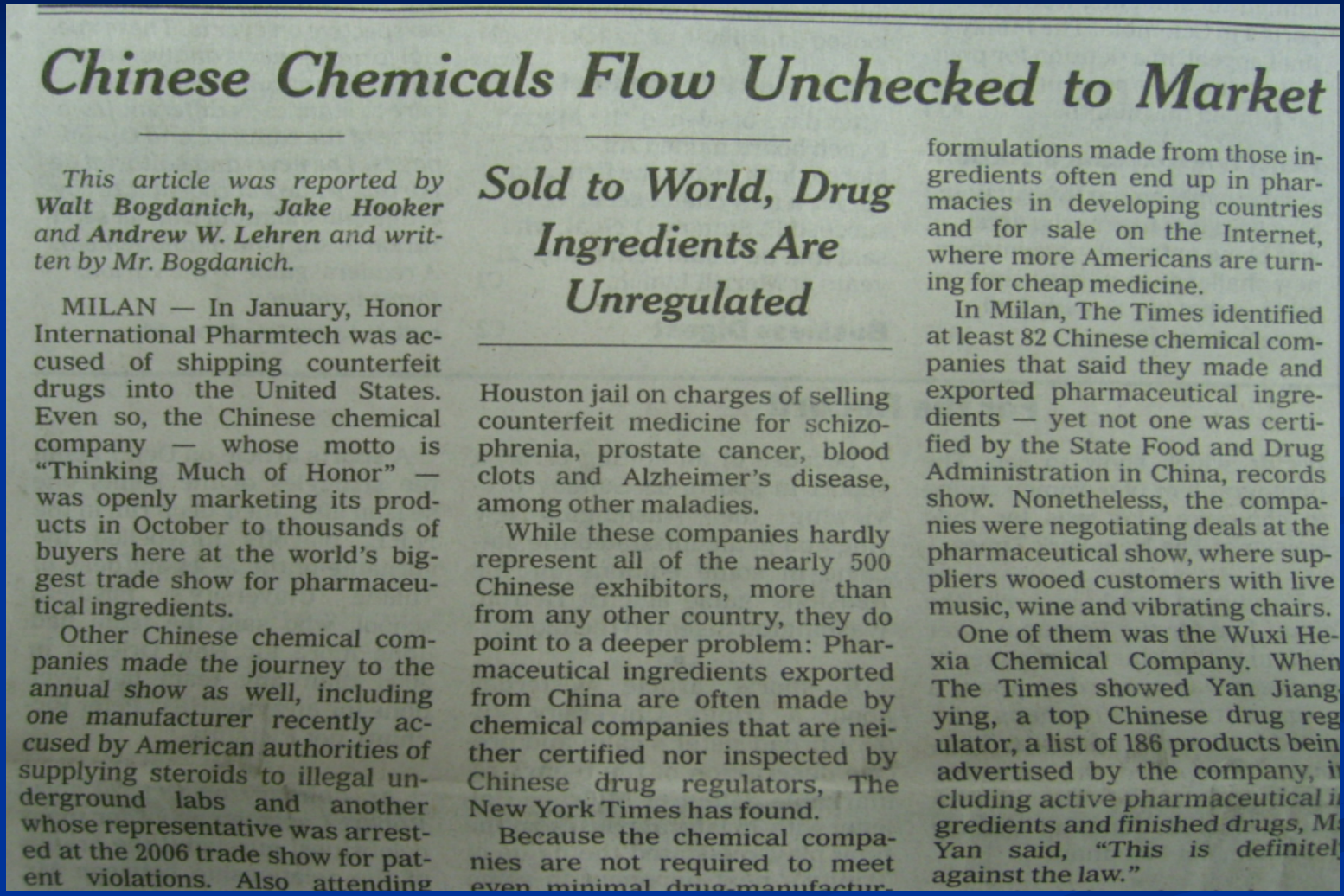
Cost escalation also leads to…

- Lower utilization rate of health care services
- Unequal access to basic health care services
- Public dissatisfaction with the health care system

Medical quality & safety

- Conflicts between doctors and patients due to medical accidents & errors have increased significantly in recent years
- Counterfeit drugs & low quality drugs are still in the market; incidences of adverse drug reaction are happening with greater frequencies
- Inappropriate use of services lowered quality and safety (eg. Misuse of antibiotics)

Drug safety



Chinese Chemicals Flow Unchecked to Market

This article was reported by ***Walt Bogdanich, Jake Hooker*** *and* ***Andrew W. Lehren*** *and written by Mr. Bogdanich.*

MILAN — In January, Honor International Pharmtech was accused of shipping counterfeit drugs into the United States. Even so, the Chinese chemical company — whose motto is "Thinking Much of Honor" — was openly marketing its products in October to thousands of buyers here at the world's biggest trade show for pharmaceutical ingredients.

Other Chinese chemical companies made the journey to the annual show as well, including one manufacturer recently accused by American authorities of supplying steroids to illegal underground labs and another whose representative was arrested at the 2006 trade show for patent violations. Also attending

Sold to World, Drug Ingredients Are Unregulated

Houston jail on charges of selling counterfeit medicine for schizophrenia, prostate cancer, blood clots and Alzheimer's disease, among other maladies.

While these companies hardly represent all of the nearly 500 Chinese exhibitors, more than from any other country, they do point to a deeper problem: Pharmaceutical ingredients exported from China are often made by chemical companies that are neither certified nor inspected by Chinese drug regulators, The New York Times has found.

Because the chemical companies are not required to meet even minimal drug-manufactur-

formulations made from those ingredients often end up in pharmacies in developing countries and for sale on the Internet, where more Americans are turning for cheap medicine.

In Milan, The Times identified at least 82 Chinese chemical companies that said they made and exported pharmaceutical ingredients — yet not one was certified by the State Food and Drug Administration in China, records show. Nonetheless, the companies were negotiating deals at the pharmaceutical show, where suppliers wooed customers with live music, wine and vibrating chairs.

One of them was the Wuxi Hexia Chemical Company. When The Times showed Yan Jiangying, a top Chinese drug regulator, a list of 186 products being advertised by the company, including active pharmaceutical ingredients and finished drugs, Ms. Yan said, "This is definitely against the law."

---The New York Times, Oct 31, 2007

Regulation of the health care system in China needs to be strengthened to…

- Contain escalating cost (ensure cost-effectiveness)
- Improve medical quality and safety (assure the legal rights and interests of both patients and medical practitioners)

Current situation of health care regulation in China

Framework for health care regulation analysis

Who regulates?

What to regulate?

Which Variables to regulate?

	Health facilities	Drugs	Healthcare Personnel
Entry			
Quality			
Quantity			
Price			
Competitive Practices			

Regulations related to cost containment

What to regulate	Variables	Regulatory Entities
Health facilities	Price (payment)	SDRC, MOH,SACP,MOLSS
	Competitive Practices	MOH, SAIC
Drugs	Entry	SFDA
	Price	SDRC

SDRC: State Development and Reform Committee
MOH: Ministry of Health
MOLSS: Ministry of Labor and Social Security
SACP: State Administration for Commodity Prices
SAIC: State Administration for Industry & Commerce
SFDA: State Food and Drug Administration

Problems with the above regulations

- Price/payment regulations of health facilities:
- ✓ Central government sets price guidelines and provincial governments set the actual prices of medical services. But a flexible markup is allowed for new equipments & treatments. Since the providers decide which services to use, they choose to use more expensive treatments which causes the government's price regulation to fail.
- ✓ Government subsidy to hospitals is based on the scale of the hospital, not performance
- ✓ Payment from social insurance to hospitals is usually fee for service

Problems with the above regulations (cont.)

- Competitive practice regulations of health facilities:
- ✓ Hospitals compete to attract more patients by getting high-tech equipment, while regulations on purchasing high-tech medical equipment by hospitals is weak. This increases the overuse of high-tech services.
- ✓ Medical advertisements are regulated by different ministries and not well implemented

Problems with the above regulations (cont.)

- Entry regulation of drugs (drug registration) : the standards are too low for new drug registration and serious corruption at SFDA during the process of drug registration
- Price regulation of drugs
  - ✓ SDRC sets price guidelines for a large number of drugs, but new drugs are allowed to set prices above the guideline prices. So pharmaceutical companies choose to register their products as new drugs by making minor changes to take advantage of the price privilege
  - ✓ The policy of Centralized Drug Purchasing Through Bidding failed because of the corruption in the bidding process and bribes by drug companies to medical providers

Regulations related to medical quality & safety

What to regulate	Variables	Regulation Entities
Health facilities	Entry	MOH
	Quality	MOH, NGOs, Juridical System
Healthcare personnel	Entry & Quality	MOH, NGOs
Drugs	Quality	SFDA, MOH

Problems with the above regulations

- Entry regulations on health facilities and healthcare personnel: Loose in suburban & rural areas, uncertified practitioners lead to potential medical risks

- Quality regulations of health facilities:

✓ Current practice guidelines have not become regulations but only provide guidance and not vigorously followed

✓ Accreditation of hospitals is government-driven and become superficial

✓ Current regulations for medical conflict settlements are biased which impair the rights of both patients and medical practitioners in different circumstances

Problems with the above regulations (cont.)

- Quality regulations of drugs

✓ The quality of drug manufacture is inspected by local FDAs, who also take into consideration of the local economic contribution of the drug companies thus could not implement regulations vigorously

✓ The quality issues in drug use are regulated by MOH. The fragmentation of responsibilities leads to coordination and accountability problems

Fundamental Challenges of health care regulation in China

- Fragmented structure of the regulatory system
- Dependency of interests: the regulatory body (MOH) owns and manages the regulated (public hospitals)
- Lack of accountability : corruption and dereliction of duty
- Lack of capacity: non-professional human resources and outdated regulatory mechanisms
- Lack of social participation in the regulation system

Recommendations for health care regulation improvement in China

- Integrate fragmented regulatory functions across ministries with the ultimate goal of forming a "National Health Committee"
- Reform the governance structure of the public hospitals, making the government regulatory entities independent of the hospitals. Then the government could act on behalf of the public to regulate the providers

- Increase accountability by strengthening intra-government regulations and making the regulatory entities accountable for regulation failures
- Improve regulation capacity by enhancing the professional capacity of the regulatory human resources and employing new regulatory methods such as information disclosure and performance assessment
- Involve more social participation in the regulation process, such as the media and professional NGOs

Thank You