LECTURE 27

Dr. Ariel Pakes

- Fellow of Econometric Society in 1988
- Fellow of the American Academy of Arts and Sciences in 2002
- Member of the National Academy of Sciences in 2017

- Jean-Jacques Laffont Prize in 2017
- BBVA Frontiers of Knowledge Award in 2018
- Global Competition Review's Annual Award in 2021
- Northwestern University's Nemmers Prize in 2022

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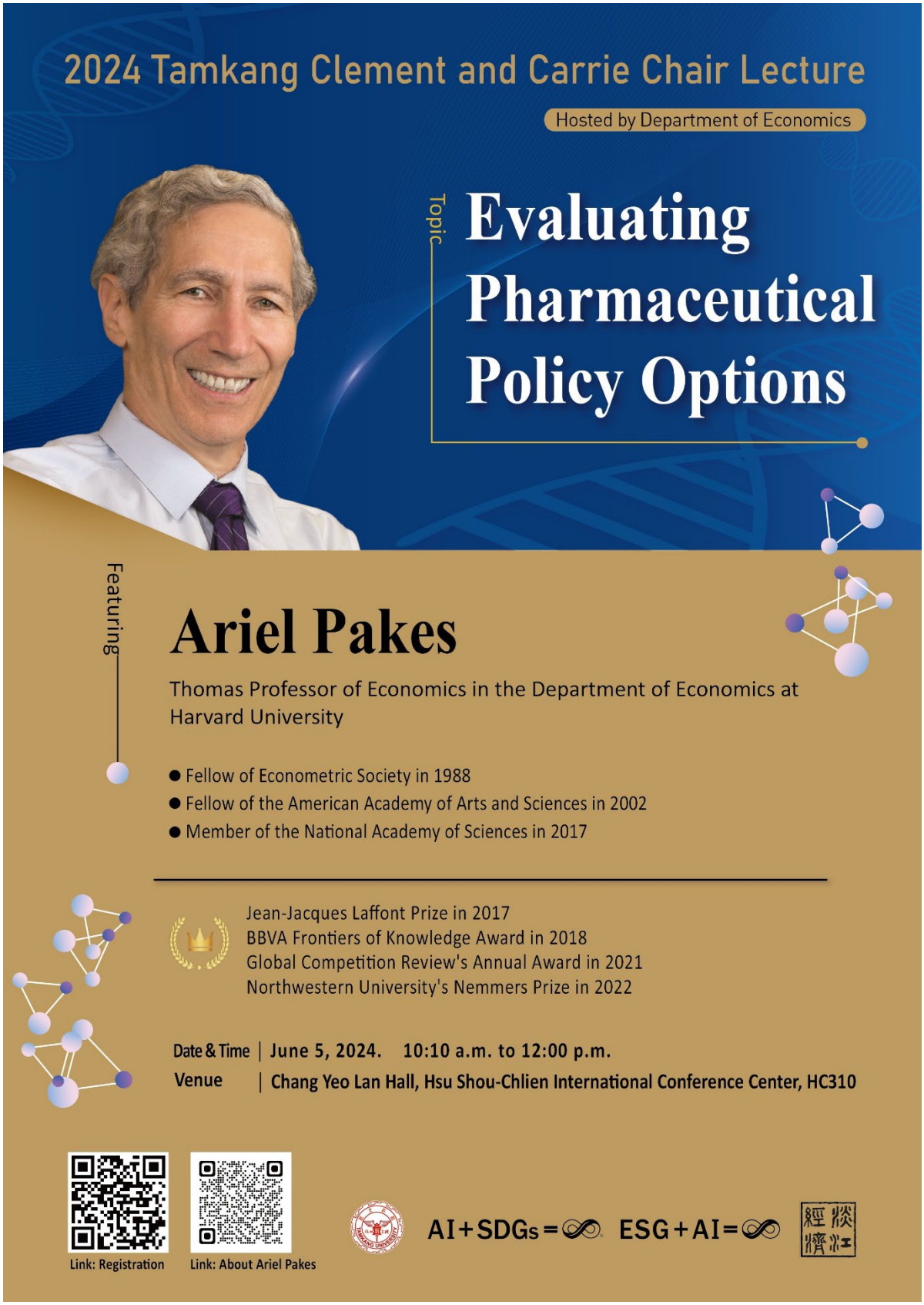
2024 Tamkang Clement and Carrie Chair Lecture
Hosted by Department of Economics
Topic
Evaluating Pharmaceutical Policy Options
Featuring
Ariel Pakes
Thomas Professor of Economics in the Department of Economics at Harvard University
● Fellow of Econometric Society in 1988
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Date & Time | June 5, 2024. 10:10 a.m. to 12:00 p.m.
Venue | Chang Yeo Lan Hall, Hsu Shou-Chlien International Conference Center, HC310
Link: Registration
Link: About Ariel Pakes
AI+SDGs=∞ ESG+AI=∞

INTRODUCTION

Ariel Pakes is the Thomas Professor of Economics in the Department of Economics at Harvard University, where he teaches courses in Industrial Organization and Econometrics. He received the Frisch Medal of the Econometric Society in 1986. He was elected as a fellow of that society in 1988, of the American Academy of Arts and Sciences in 2002, and of the
National Academy of Sciences in 2017. Pakes was the Distinguished Fellow of the Industrial Organization in 2007. In 2017 he received the Jean-Jacques Laffont Prize and in 2018 the BBVA Frontiers of Knowledge Award. In 2019 Pakes was appointed a distinguished fellow of the American Economic Association. In 2020 Pakes was selected to be citation laureate of the Web of Science. In 2021 Pakes received the Global Competition Review's annual award for Prosecution of Collusion and became the American Antitrust Institute's honoree for Outstanding Antitrust Litigation Achievement in Economics. In 2022 he was recipient of Northwestern University's Nemmers Prize in Economics, honored for his "fundamental contributions to the development of the field of empirical industrial organization as it is applied to the study of market power, prices, mergers and productivity."

Pakes's research has focused on developing methods for empirically analyzing market responses to environmental and policy changes. He and his co-authors have applied these tools to the analysis of the auto, electricity, health care, and telecommunications equipment industries. Pakes also developed techniques for analyzing the impacts of privately funded research and development activity, for constructing a more accurate Consumer Price Index, and for analyzing the impact of incentive schemes on the hospital allocations of doctors. Many of Pakes's methodological contributions have been incorporated into the work of government agencies and private firms.

Topic：Evaluating Pharmaceutical Policy Options

ABSTRACT

Evaluating Pharmaceutical Policy Options.

Tamking Clement and Carrie Chair Lecture

Taipei, Taiwan.

Ariel Pakes, Harvard University

June, 2024

Recent U.S. policies.

Allowing Direct to Consumer Advertising ("DTCA") of prescription pharmaceuticals (mostly TV and only allowed since 1997). Only two developed countries allow this (U.S. & New Zealand). None of the countries we compare to below do.

Allowing Medicare (grew to 30% of prescription drug sales in the U.S. in 2017) to bargain prices. Currently ten products (≈ $48 billion in sales). However President Biden's state of the union address states:

"Now it's time to go further and give Medicare the power to negotiate lower prices for 500 drugs over the next decade".

Allowing importation of pharmaceuticals from Canada. Florida has been approved to do so (initially in a limited way). 7 others applying for permission (≈ 20% of U.S. sales). U.S. sales are over 50% of global sales (62.5% of sales in OECD countries studied below).

The European Union's Policies.

_ I will be focused primarily on U.S. policies, but will return to the European Union towards the end of the talk.

_ For now suffice it to say that the European Parliament adopted a Pharmaceutical Reform on April 10, 2024. It still has to be passed by the governments of the member states. It has two main parts One part is directed at centralizing procurement among member states. Similar to Europes' acquisition of COVID vaccines: procurement for the member states was centralized in one body. The second part is designed to increase the incentives for pharmaceutical R&D. It largely consists of insuring minimum levels of regulatory protection for new pharmaceutical products.

Two papers in process on these changes.

_ Kate Ho and I on the likely implications of Bargaining with Medicare and Importation of pharmaceuticals from Canada.
on both pharma company profitability and on consumer welfare.

_ Goal. Provide a comparison of the private and public incentives for company funded R&D.

_ I will provide a summary of where we have gotten to and "back of the envelope" calculations of the likely impact of the policies. They should be thought of as indicative, but not definitive.

_ DTCA. Pierre Dubois and I analyze the impact of DTCA. I will summarize our findings.

Background: Benefits from pharma R&D in the U.S.

_ Buxbaum et. al. (2020) report that between 1990 and 2015 life expectancy in the U.S. increased 1.32 years per decade, and attribute about 35% of this, or .46 years, to pharmaceuticals.

_ I do not have European numbers, but they are likely similar.

_ There were 48.9 million live births in the U.S. between 2005 and 2015. If we value a life year at $100,000, this generates 2.25 trillion dollars in value.

_ Taking the same period, we should:

Value the improvement in life expectancy of immigrants.

Value the decrease in morbidity in the population.

Valuing the improvement in life expectancy of immigrants: net immigration is ≈1.04 million per year; at 1/10th of the decadal life year increment for every year in the U.S.

This adds ≈ .57 trillion.

Valuing the decrease morbidity.

Only have a study of the over 65 (≈ 16% of pop).

Chernew et al (2023); disability free life expectancy increased by 1.125 years per decade with ≈ 1/2 due to treatment improvements & "most of the treatment improvements are pharmaceutical";

This adds ≈.25 trillion (50,000$ per morbidity free year), and this does not count decreases in morbidity for the under 65 population.

_ Conclude: The welfare benefit of pharma research to the U.S. population per decade was considerably more than 3 trillion dollars (using a conservative values for a life-year; see Neumann et al, NEFM, 2014).

Relationship to U.S. Costs (sum private and public).

_ U.S. resident companies spent 747 billion dollars on pharma research in the U.S. between 2011-2021. US.

pharmaceutical firms funded 87% of these expenditures.

Companies whose parents were foreign funded 7%, other U.S. companies funded 3%, and 3% came from a mix of governments and other (primarily U.S.) institutions.

_ "Funding from the NIH contributed to 354 of 356 drugs approved from 2010 to 2019 totaling $187 billion ..." (JAMA Health Forum. 2023 Apr)

Social Welfare and Social Costs in the U.S.

So NIH grants are involved in some way in the development of most pharmaceuticals that receive FDA approval, but they spend much less than the pharmaceutical firms do on drug development. Even if we allocate all the NIH funds that "contributed to" new drugs to the R&D of drug development, the U.S. population's welfare benefit to cost ratio from pharma research is well above four.

_ Of course there is a difference between average and marginal welfare benefits, and it has been difficult to empirically establish the connection between company funded pharma research and its

benefits (explain).

_ Still the numbers suggests that it would be socially beneficial to increase pharmaceutical research, not decrease it.

Policies, Incentives, and Company Profitability.

_ As long as the vast majority of the funds for research keeps being supplied by firms, an increase in pharma research likely requires increased private incentives to do that research.

_ Pharmaceutical companies supply their products to all countries. So when calculating returns we compute returns from world-wide sales.

_ U.S. sales are over 50% of world wide sales. They are 62.5% of the sales of the OECD countries.

_ Now a "back of the envelope" calculation of the impact of the proposed U.S. policies on the profitability of pharma companies.

_ I come back to the proposed European policies and their interaction with the U.S. policies below.

Calculating the impact of Medicare bargaining requires "bargained prices".

Medicare pricing would be similar to pricing procedures in other countries (a quasi-governmental institution would represent the buyer).

Canada has the second highest pharma prices of OECD countries. So moving to Canadian prices would incur the smallest loss in profits. If we also allowed importation from Canada at Canadian prices for the eight states who have applied for permission assumed that demand was inelastic (else we would need to adjust benefits; see Alston and Harris, 2020) and no other mitigating developments, There would be a $\approx$ 16% fall in pharmaceutical revenue.

_ We have SEC reports on the 16 largest research based pharma firms (by capitalization). 10 are U.S. firms & 6 are European.

_ The SEC reports provides net profits and net margins.

Net profit is computed as pharmaceutical global revenue after rebates minus operating expenses, taxes, interests, and other expenses.

Net margins = net profits/ global revenue after rebates.

_ The weighted average of the net margin, the weights being net profit shares, is 32%.

_ A 16% fall in U.S. revenue with no change in costs or demand would imply net margins fall from 32% to 25%.

This would cut margins in the pharmaceutical industry by $\approx$ 20%:

_ Of course a cut in margins by 20% does not necessarily imply a cut in research expenditures of 20%.

_ Still it is hard to believe a cut in the returns to research of this magnitude would not negatively impact research investments.

_ All of this despite the fact that our welfare calculations suggest we want to increase pharmaceutical research, not decrease it.

_ On the other hand, rejecting these policy options would increase the cost of pharmaceuticals to the American economy, likely hurting poor and elderly consumers disproportionately.

_ If one believes both in the contractarian view that certain basic goods, including a minimal amount of health care, are a right of consumers who abide by society's rules, and that this requires less costly access to the drugs that are subject to these policies, and that pharmaceutical R&D is as welfare enhancing as it seems to be, then we need to change how the pharmaceutical market works.

_ There has been many proposals on ways to mitigate the tradeoff between incentives for R&D and the costs of pharmaceuticals to society. The U.S. mostly focuses on subsidies (to consumers and/or firms).

_ We want to draw attention to a characteristic of the market that, though often mentioned, is seldom discussed with detailed magnitudes.

The global dimension of the pharmaceutical market.

_ Pharmaceuticals, like climate change, are "international products": once a new drug is developed all countries can benefit from it.

_ Yet unlike the attempts to mitigate the impacts of climate change there are no international agreements on either pharmaceutical pricing, or public funds that facilitate pharmaceutical research.

_ Price Comparisons. RAND (2023) calculates that the share weighted indices of U.S. to foreign prices (using U.S. revenue shares as weights) 234% for Candian prices,
280% for United Kingdom prices, and 308% for a share weighted average of 33 developed countries.

_ These percentages have been growing (see Danzon, 2018), & the levels underestimate relative prices (as U.S. prices discount rebates but, due to a lack of data, other countries prices do not).

_ Below we quantify the impact of these price differences on the distribution of the costs and benefits of pharma research among developed countries First consider International differences in other government policies.

_ Currently there are at least two sources of differences in public policies that impact the international division of the costs and benefits from pharmaceutical research.
Publicly funded research that contributes to the development of new pharmaceutical products.
Differences in tax/subsidy regimes which impact both the allocation of ownership rights among subsidiaries and the location of production.

Implications from Non Price Policies

_ We ignore the tax & subsidy issues but research indicates that they would increase the inequities in the international distribution of costs & benefits from pharma research (Sester, 2023, Senate Finance Committee).

_ OECD report (2021) on publicly funded health related research (which includes more than pharma) is .21% of GDP in the U.S. .07% of GDP in Europe (which includes the 21 members of the EU member states that are part of the OECD), and .04% of GDP. in the other OECD members countries.

_ Also European (but not U.S.) laws forbid Direct to Consumer advertising. Paper by Pierre Dubois and I indicates DTCA increases profits (and may well increase welfare, especially of poor and less educated consumers).

_ Conclude. The international differences in pharmaceutical prices that imply the costs of research are born disproportionately by the U.S. population are not mitigated, indeed are likely accentuated, by international differences in other government policies.

The Impact of Internationalizing Pharma Prices.

_ We consider the impact of internationalizing drug prices for only those 21 countries with at least $45,000 in per capita GDP.

_ We ask

if there is an international price for each drug that each of these countries abide by, and we assume total revenue is the same as current total revenue (so incentives to perform R&D would be unchanged),

What would be the weighted average markup or markdown in each country's prices, where the weights are country specific revenue shares?

Price Index Results.

_ I focus on the results for branded pharmaceuticals (exclude generics), as they should be most informative w.r.t. R&D incentives (if we include generics the results are similar).

_ Every country except the U.S. has a price increase.

_ U.S. consumers would pay only .46 cents for every dollar we now spend.

_ The country with the lowest price increase would be Canada; index=1.28. I.e. Canadians would pay 28% more for their pharma purchases.

_ Other European indices:

Germany 1.48

France 1.97

United Kingdom 2.00

Italy 2.63

Spain 2.87.

_ Conclude: Internationalizing pharma prices would cut U.S. prices in half, but would cause sharp increases in European prices (50% to almost 300%).

_ Obstacles and benefits to proceeding with international prices Benefits would include not having to worry about either the costs of quasi-governmental committees setting and monitoring prices in different countries, or "parallel trade" in pharmaceuticals; at least among the countries that agree to the single price policy, Obstacles include many countries might have to find alternative ways of providing their citizens the minimal level of health care that they require, and we would need to formulate international prices, hopefully in a way that leads to optimal R&D incentives.

The European Parliament's proposal.

_ First part: concentrates purchases of pharmaceuticals for all Europe in one purchaser. This would

effect administrative procedures, pricing, and R&D incentives.

_ Administratively

It would eliminate free riding problems in setting drug prices and eliminate parallel trade (and associated "monitoring" costs).

It may decrease the cost of negotiations (once for all Europe).

_ The impact of R&D incentives depend on how the new arrangements affect pharmaceutical prices.

_ The price effects of a single agency purchasing for all of Europe would Increase the bargaining power of European negotiators, which would lower European prices further & accentuate current international inequities. It could also facilitate setting single U.S./European prices.

However this would require European agencies seeing the need to increase prices due to their incentive effects on R&D and

Currently we do not know of a pricing institution that ties their pharmaceutical pricing policies to the incentives to perform pharmaceutical research.

_ The European Package also does have policies that are designed to increase R&D incentives. To do so they focus on various ways of extending exclusivity of pharmaceutical products. These could be helpful and include

A minimum period of protection of 7.5 years (impact depends on time from application to approval).

Two years of market exclusivity (regardless of the appearance of a bio-similar product).

Other extensions if the drug meets an "unmet" medical need, research is done in Europe, or if permission is obtained for a second indication.

_ Notice, however, that there is no reference to pharmaceutical price disparities. Without a lessening of these disparities the political pressure on the U.S. government to decrease pharma prices is unlikely to abate, with dire consequences for pharma innovation.