JSS Academy of Higher Education & Research, Mysuru
(Deemed to be University – Accredited 'A+' Grade by NAAC)

JSS College of Pharmacy, Ooty
(An ISO 9001:2015 Certified Institution)

Department of Pharmacy Practice

A Brief Report on Invited Impact Pharmacy Lecture Series 2023 – Lecture 05
(New connections and New learning)

Date: 10.03.2023

Name of the presenter:
Dr Thiyagu Rajakannan
Senior Researcher and Lead
Drug Coverage and Payment Practice Hub
Health Division of the American Institutes For Research
USA

Title of the presentation:
Prescription Drug Cost and Prices of Biosimilars in USA

Program Organized by:
Dept. of Pharmacy Practice & Pharmacy Education Unit
JSS College of Pharmacy, Ooty

New Connections and New Learning: Pharmacy Practice- "Learning in the flow of work"

Making learning is a part of everyday work – and everyone's experience at work differs of course and it multiplies at different places. Internship training for Pharm D students is an opportunity to learn new and provide service to the needy patient population. To enhance their learning experience, the institute has created new connections and learning opportunity at various practice settings. Our students are very excited to be at new practice site(s) to learn and demonstrate/shape their competencies.

Dr Thiyagu Rajakannan is alumnus of JSS College of Pharmacy, Ooty and he completed his Master of Pharmacy (Pharmacy Practice) and completed hid PhD from Manipal College of Pharmaceutical Sciences. He is a Senior Researcher and Lead for the Drug Coverage and Payment Practice Hub at the Health Division of the American Institutes for Research (AIR). With over 18 years of experience in clinical pharmacy, he is skilled in designing and conducting both quantitative and qualitative analyses for health policy, pharmacoepidemiology, and clinical research. He has worked with a range of databases, including large administrative claim databases, clinical trial registries, electronic medical records, and healthcare survey data. Dr. Rajakannan is a proficient project manager and has expertise in digital healthcare equity. He has received the 'Andrew McAfee Award' from the International Society for Pharmacoepidemiology (ISPE) and the 'Young Investigator Award' from the PhRMA Foundation for his research work. Dr. Rajakannan's commitment to promoting healthcare through innovative analysis and research is evidenced by the fact that his work has been presented and published in more than 50 papers.

Dr Thiyagu started his presentation with a note that world-wide the revenue of prescription drugs, Data Bridge Market Research analyses that the prescription drugs market was valued at USD 1,015.63 billion in 2021 and is expected to reach USD 1,482.35 billion by 2029, registering a CAGR of 4.84% during the forecast period of 2022 to 2029. Further, he also introduced the concept of the functionality of insurance system in US with the specific examples to Medicaid, Medicare, Obama care etc. Market share of private insurance and US Pharmaceutical policy environment were discussed.

Pharmaceutical Pricing Regulation: The federal government does not regulate drug pricing. However, it encourages the development of generic drugs through an abbreviated approval process. For example, the brand Lipitor (a statin) was priced at about $230 for a 30-day supply. The generic, atorvastatin, is priced under $25—nearly a 90 percent savings. Federal law currently prevents the government from negotiating, regulating, or limiting Medicare prescription drug prices. As a result, drug companies often set excessive prices, knowing that the largest payer for these drugs—taxpayers—will pay the full cost regardless of price.

National Average Drug Acquisition Cost (NADAC): is based on the retail price survey and focuses on the retail community pharmacy acquisition costs. CMS has mandated that Medicaid pharmacy programs reimburse the actual acquisition cost (AAC) of drugs plus a professional dispensing fee.

A pharmacy benefit manager (PBM) is a third-party administrator of a prescription drug program that is primarily responsible for processing and paying prescription drug claims. In addition, they typically negotiate discounts and rebates with drug manufacturers, contract with pharmacies and develop and maintain the drug formulary.

Biologics: A substance that is made from a living organism or its products and is used in the prevention, diagnosis, or treatment of cancer and other diseases. Biological drugs include antibodies, interleukins, and vaccines. Also called biologic agent and biological agent. Biologics can treat a variety of conditions, such as cancer, psoriasis, rheumatoid arthritis (RA), and inflammatory bowel diseases like Crohn's disease. These medicines are given as a shot or through an infusion into a vein.

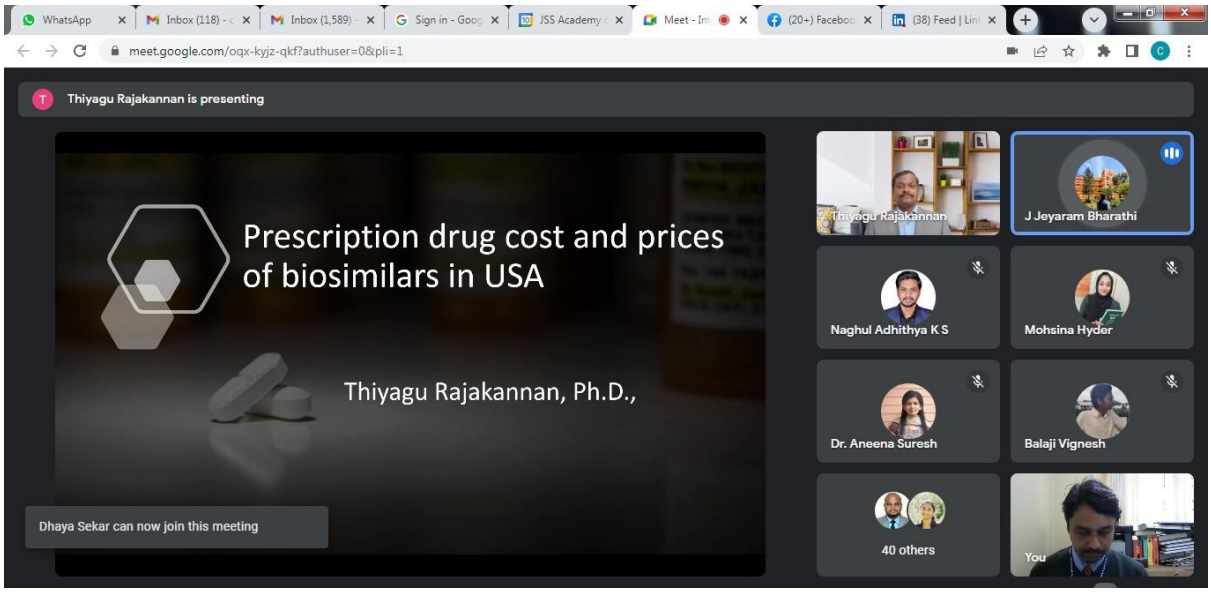
A biosimilars is a biologic that is highly similar to, and has no clinically meaningful differences from, another biologic that's already FDA-approved (referred to as the reference product or original biologic). This means biosimilars: Are given the same way (same route of administration). Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

An interchangeable biological product is a biosimilar that meets additional requirements and may be substituted for the reference product at the pharmacy, depending on state pharmacy laws. Interchangeable biologics are biosimilars that are approved by the FDA to be substituted by a third party for the reference biologic. An interchangeable biosimilar product may be substituted without the intervention of the health care professional who prescribed the reference product, much like how generic drugs are routinely substituted for brand name drugs.

Drug cost pricing of the biologics, biosimilars and interchangeable biological products were discussed in detail by the presenter.

The session was then concluded by Dr Thiyagu Rajakannan by taking questions from staff and students. More than 79 students and staff were fruitfully benefited with this invited virtual guest lecture.

Dr S Ponnusankar
Co-ordinator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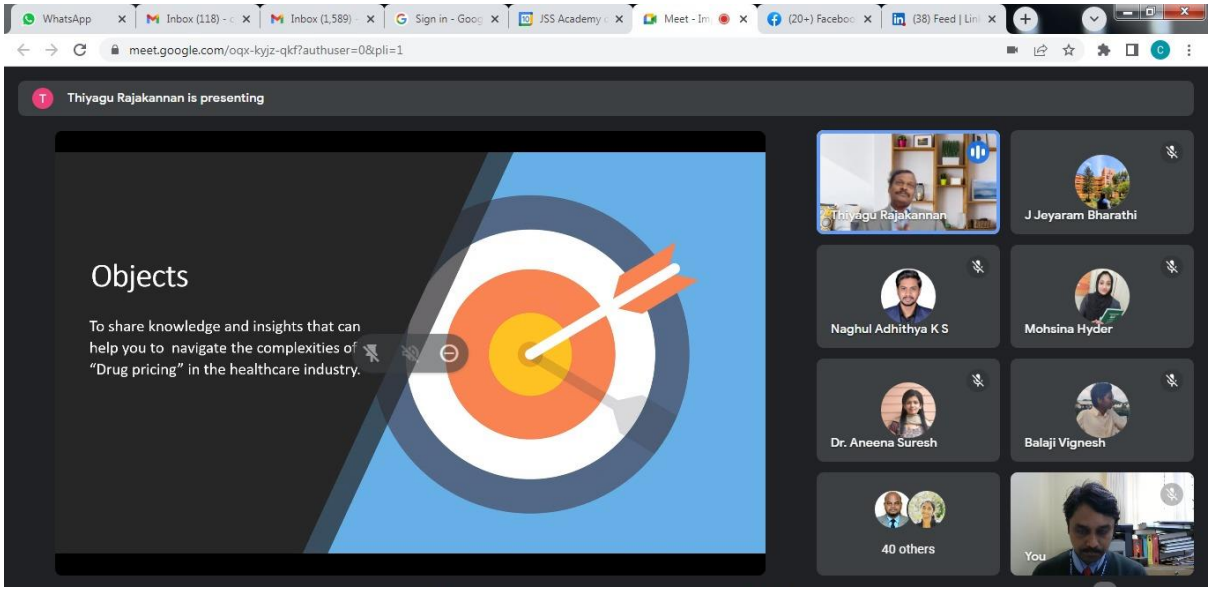
Thiyagu Rajakannan is presenting
Prescription drug cost and prices of biosimilars in USA
Thiyagu Rajakannan, Ph.D.,
Dhaya Sekar can now join this meeting
Thiyagu Rajakannan
J Jeyaram Bharathi
Naghul Adhithya K S
Mohsina Hyder
Dr. Aneena Suresh
Balaji Vignesh
40 others
You


meet.google.com/oqx-kyjz-qkf?authuser=0&pli=1
Thiyagu Rajakannan is presenting
Objects
To share knowledge and insights that can help you to navigate the complexities of "Drug pricing" in the healthcare industry.
Thiyagu Rajakannan
J Jeyaram Bharathi
Naghul Adhithya K S
Mohsina Hyder
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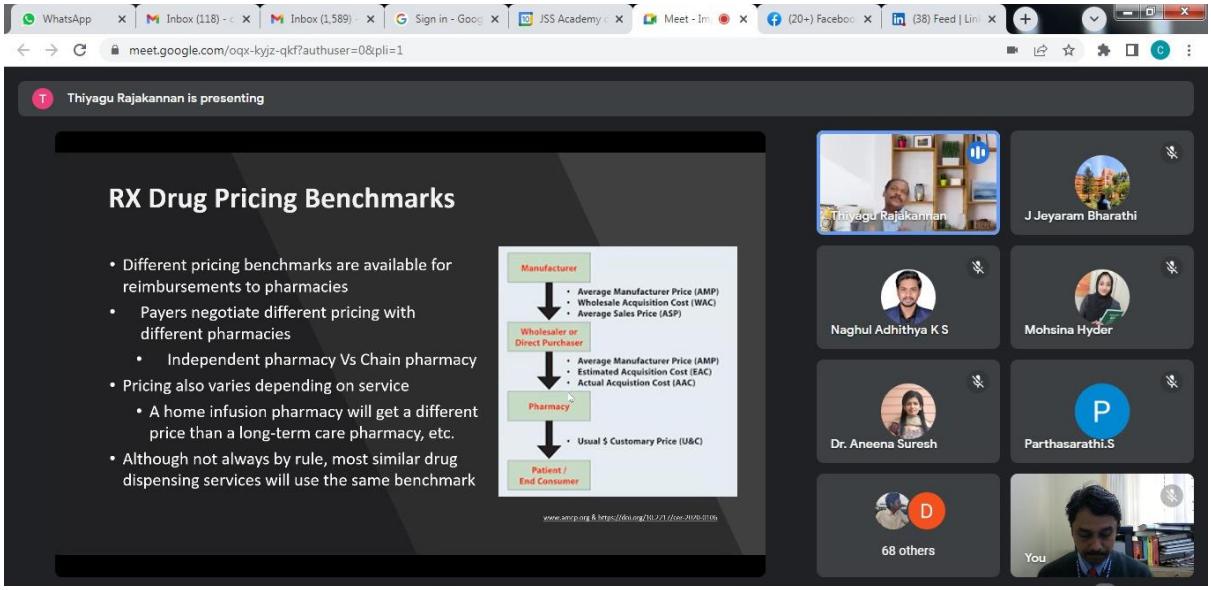
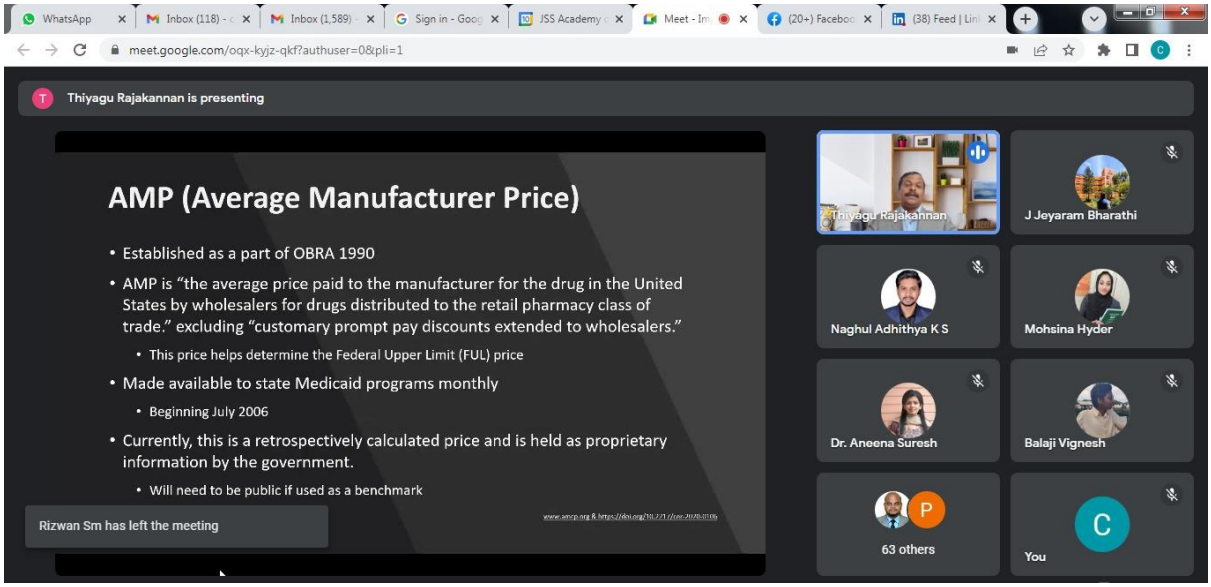
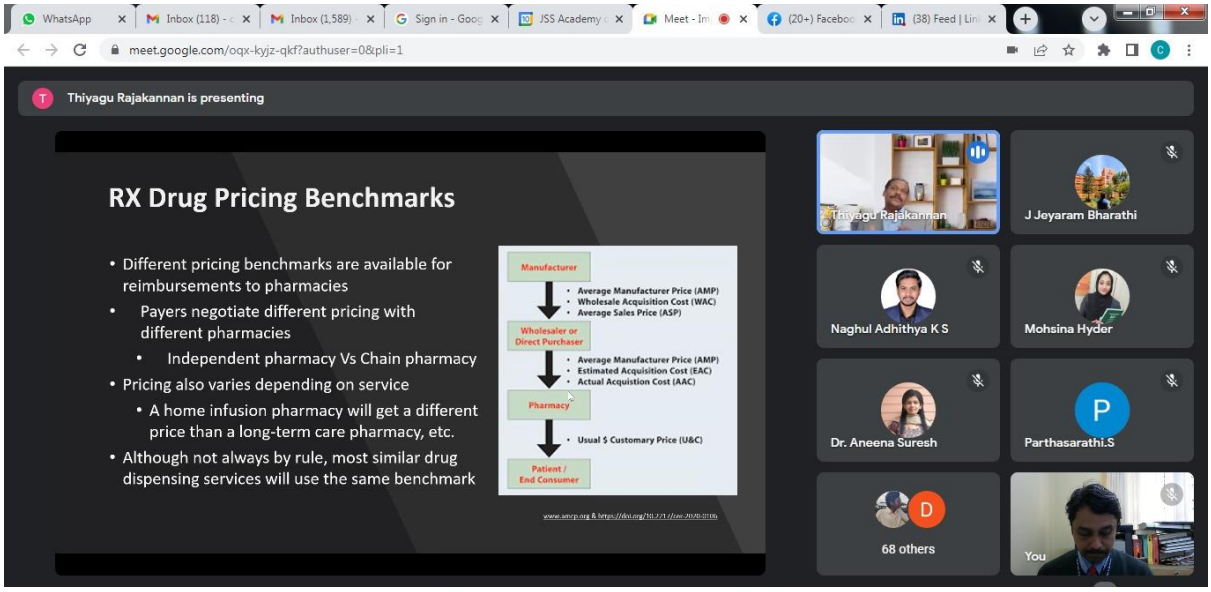

meet.google.com/oqx-kyjz-qkf?authuser=0&pli=1
Thiyagu Rajakannan is presenting
RX Drug Pricing Benchmarks
• Different pricing benchmarks are available for reimbursements to pharmacies
• Payers negotiate different pricing with different pharmacies
• Independent pharmacy Vs Chain pharmacy
• Pricing also varies depending on service
• A home infusion pharmacy will get a different price than a long-term care pharmacy, etc.
• Although not always by rule, most similar drug dispensing services will use the same benchmark
Manufacturer
Average Manufacturer Price (AMP)
Wholesale Acquisition Cost (WAC)
Average Sales Price (ASP)
Wholesaler or Direct Purchaser
Average Manufacturer Price (AMP)
Estimated Acquisition Cost (EAC)
Actual Acquisition Cost (AAC)
Pharmacy
Usual $ Customary Price (U&C)
Patient / End Consumer
Thiyagu Rajakannan
J Jeyaram Bharathi
Naghul Adhithya K S
Mohsina Hyder
Dr. Aneena Suresh
Parthasarathi.S
68 others
You


meet.google.com/oqx-kyjz-qkf?authuser=0&pli=1
Thiyagu Rajakannan is presenting
AMP (Average Manufacturer Price)
• Established as a part of OBRA 1990
• AMP is "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." excluding "customary prompt pay discounts extended to wholesalers."
• This price helps determine the Federal Upper Limit (FUL) price
• Made available to state Medicaid programs monthly
• Beginning July 2006
• Currently, this is a retrospectively calculated price and is held as proprietary information by the government.
• Will need to be public if used as a benchmark
Rizwan Sm has left the meeting
Thiyagu Rajakannan
J Jeyaram Bharathi
Naghul Adhithya K S
Mohsina Hyder
Dr. Aneena Suresh
Balaji Vignesh
63 others
You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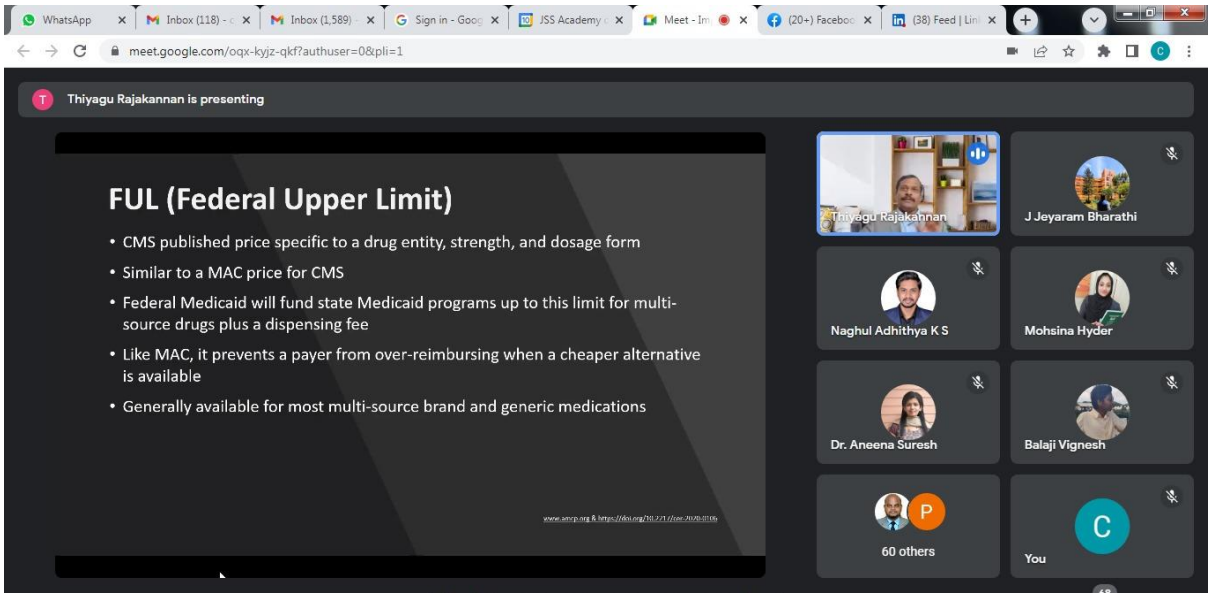
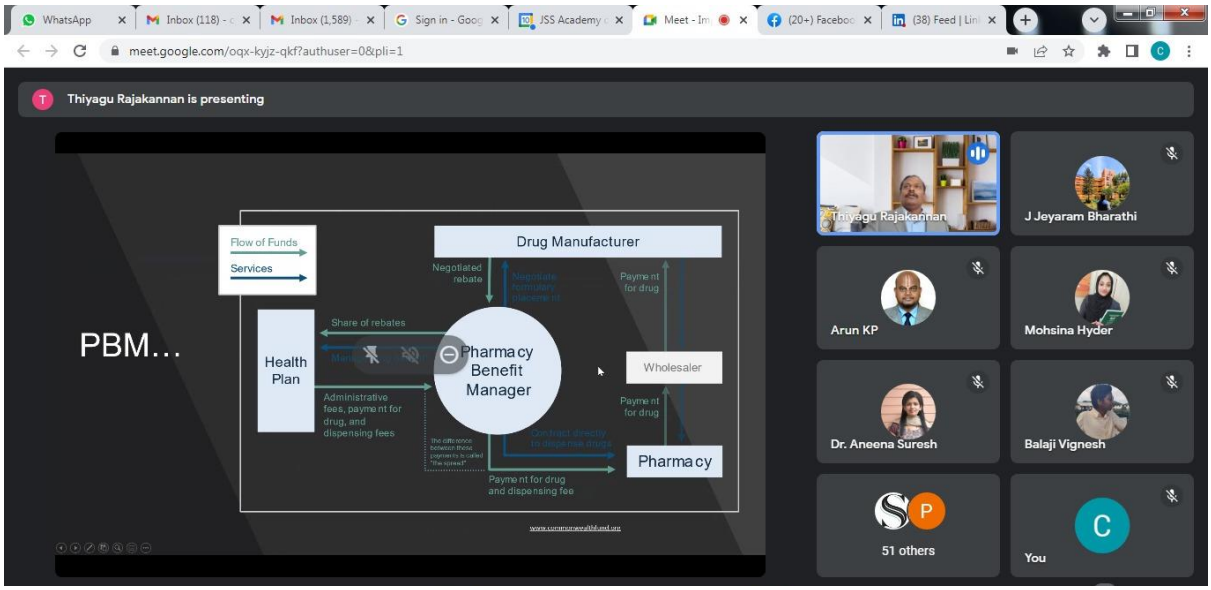
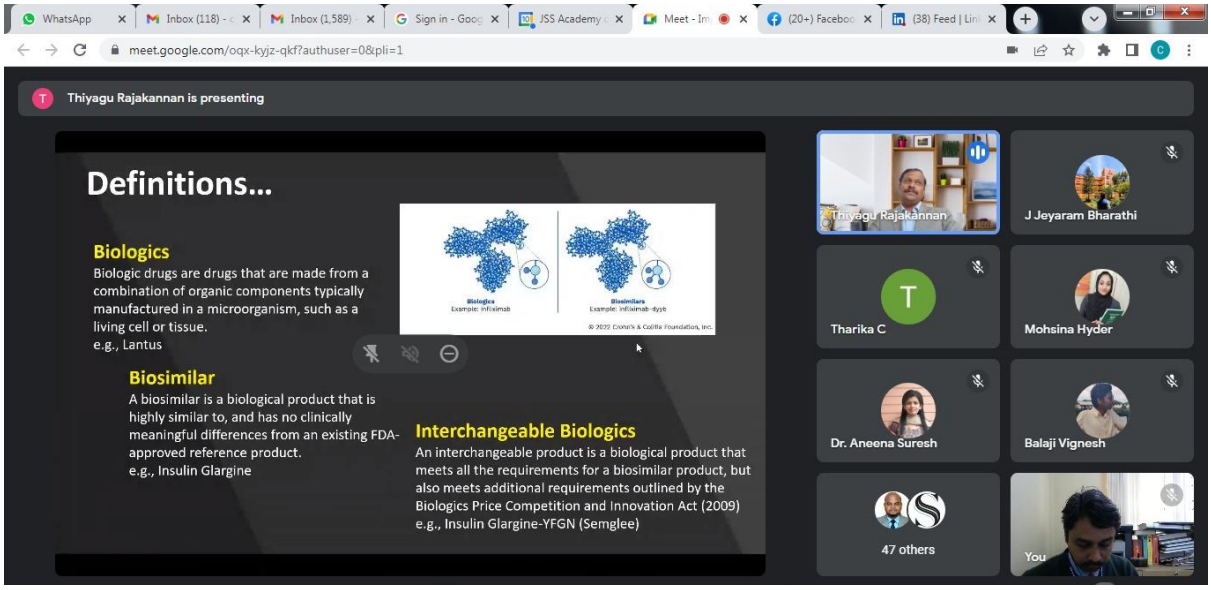
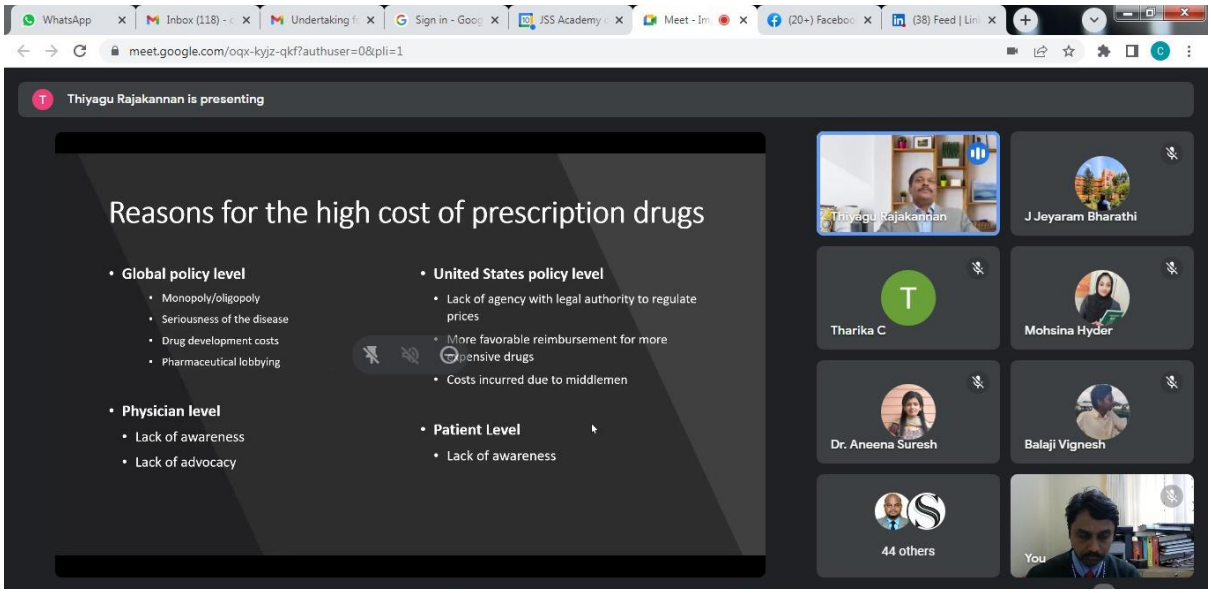

meet.google.com/oqx-kyjz-qkf?authuser=0&pli=1
Thiyagu Rajakannan is presenting
FUL (Federal Upper Limit)
• CMS published price specific to a drug entity, strength, and dosage form
• Similar to a MAC price for CMS
• Federal Medicaid will fund state Medicaid programs up to this limit for multi-source drugs plus a dispensing fee
• Like MAC, it prevents a payer from over-reimbursing when a cheaper alternative is available
• Generally available for most multi-source brand and generic medications
Thiyagu Rajakannan
J Jeyaram Bharathi
Naghul Adhithya K S
Mohsina Hyder
Dr. Aneena Suresh
Balaji Vignesh
60 others
You


Thiyagu Rajakannan is presenting
PBM…
Flow of Funds
Services
Drug Manufacturer
Negotiated rebate
Payment for drug
Share of rebates
Health Plan
Pharmacy Benefit Manager
Wholesaler
Administrative fees, payment for drug, and dispensing fees
Payment for drug
Pharmacy
Payment for drug and dispensing fee
Thiyagu Rajakannan
J Jeyaram Bharathi
Arun KP
Mohsina Hyder
Dr. Aneena Suresh
Balaji Vignesh
51 others
You


Thiyagu Rajakannan is presenting
Definitions…
Biologics
Biologic drugs are drugs that are made from a combination of organic components typically manufactured in a microorganism, such as a living cell or tissue.
e.g., Lantus
Biosimilar
A biosimilar is a biological product that is highly similar to, and has no clinically meaningful differences from an existing FDA-approved reference product.
e.g., Insulin Glargine
Interchangeable Biologics
An interchangeable product is a biological product that meets all the requirements for a biosimilar product, but also meets additional requirements outlined by the Biologics Price Competition and Innovation Act (2009)
e.g., Insulin Glargine-YFGN (Semglee)
Thiyagu Rajakannan
J Jeyaram Bharathi
Tharika C
Mohsina Hyder
Dr. Aneena Suresh
Balaji Vignesh
47 others
You


Thiyagu Rajakannan is presenting
Reasons for the high cost of prescription drugs
Global policy level
Monopoly/oligopoly
Seriousness of the disease
Drug development costs
Pharmaceutical lobbying
Physician level
Lack of awareness
Lack of advocacy
United States policy level
Lack of agency with legal authority to regulate prices
More favorable reimbursement for more expensive drugs
Costs incurred due to middlemen
Patient Level
Lack of awareness
Thiyagu Rajakannan
J Jeyaram Bharathi
Tharika C
Mohsina Hyder
Dr. Aneena Suresh
Balaji Vignesh
44 others
You