



TEXAS A&M UNIVERSITY

Irma Lerma Rangel  
College of Pharmacy

# PH.D. DEGREE IN PHARMACEUTICAL SCIENCES

**Mansoor A. Khan, Ph.D.**

Professor and Vice Dean

Texas Higher Education Coordination Board Site Visit

May 7, 2019

# OUTLINE

- RCOP – By the Numbers
- Why Ph.D. in Pharmaceutical Sciences?
- Program Elements
- Research Preparedness and Infrastructure
- Q&A



# BY THE NUMBERS: RCOP

- Campuses: 2
- Current students: 461
- Former Students: 759
- Faculty: 52
- Staff: 36
- Research Associates: 21
- Preceptors: >1260



# BIG IDEAS FROM SPRING 2016 FACULTY RETREAT

| Transformational Idea  | Green | Orange | Pink |
|--|-------|--------|------|
| Develop strong graduate (PhD) and residency programs                         | 24    | 3      | 1    |
| Product development center (convergence integration with TAMU)               | 13    | 11     | 1    |
| State of the art teaching/learning center                                    | 11    | 5      | 4    |
| College run mini-pharmacy/clinics  | 11    | 3      | 3    |
| Collaborate with community health centers & pharmacy services                | 10    | 8      | 3    |
| International scholars program - faculty recruitment                         | 10    | 7      | 5    |
| Establish pediatric and geriatric centers of excellence                      | 5     | 6      | 6    |
| Work with Clinicians/Pharmacist for solutions to adverse product evaluations | 2     | 12     | 6    |
| Personalized medicine kiosk  | 1     | 6      | 7    |
|  |       |        |      |
| Change curriculum to a 2 + 2 program   | 13    | 4      | 4    |
| Internationally collaborative pharmacy graduate program                      | 9     | 7      | 0    |
| Increase student quality   | 8     | 4      | 2    |
| Move college closer to a teaching hospital                                   | 5     | 2      | 9    |
| World renowned through global pharmacy                                       | 5     | 0      | 8    |
| Transition COP into problem based learning curriculum                        | 4     | 6      | 3    |

# MISSION AND OBJECTIVES

The mission of the Ph.D. program in Pharmaceutical Sciences (PHSC) is to provide a comprehensive knowledge base that leads to drug discovery, design, and development of pharmaceutical dosage forms through basic and applied research in pharmaceutical sciences.

**Some objectives of the PHSC program are:**

- To provide a meaningful and important course of study that is currently unavailable in Texas A&M University.
- To train and create pharma and biotech entrepreneurs who will know how to leverage the vast knowledge and infrastructure of Texas A&M programs in engineering, veterinary medicine, Agri-Life, medicine, dentistry, biomedical sciences, physical and life sciences, business, and how to help advance drug and medication policies.
- To provide students with specific experiences in conceptual and technical research areas in the pharmaceutical sciences, e.g., pharmaceuticals, medicinal chemistry, pharmacology, pharmacy administration, and basic sciences.



### Five Year Ph.D. Pharmaceutical Sciences Enrolment in National and Texas Universities

| Year           | 2014 | 2013 | 2012 | 2011 | 2010 |
|----------------|------|------|------|------|------|
| Nation         | 3086 | 3094 | 3266 | 3109 | 3051 |
| UT Austin      | 124  | 91   | 125  | 119  | 106  |
| U of Houston   | 65   | 63   | 65   | 58   | 57   |
| Texas Tech     | 38   | 38   | 37   | 38   | 43   |
| Texas Southern | 16   | 18   | 19   | 18   | 18   |

- Less than 10% of qualified applicants accepted in these programs
- Employment is almost 100% within 3 months of graduation (details provided in proposal)

### Five Year Ph.D. Pharmaceutical Sciences Graduations in National and Texas Universities

| Year           | 2014 | 2013 | 2012 | 2011 | 2010 |
|----------------|------|------|------|------|------|
| Nation         | 565  | 589  | 497  | 471  | 450  |
| UT Austin      | 19   | 12   | 21   | 13   | 13   |
| U of Houston   | 7    | 13   | 7    | 14   | 1    |
| Texas Tech     | 7    | 5    | 5    | 13   | 4    |
| Texas Southern | 6    | 1    | 3    | 0    | 0    |

**Please note that Texas A&M University System does not have ANY ENROLMENT or GRADUATION since we don't have the PhD program in pharmaceutical sciences. More than 60 institutions of higher education in US have PHD degrees in pharmaceutical sciences already**



# INTERNAL SUPPORT

- *“We anticipate that the proposed degree (Ph.D. in PharmSci) would be complementary to the Ph.D. in Biomedical Sciences offered by CVM” --Dean Eleanor Green, Vet Medicine*
- *“A graduate program in pharmaceutical science in Rangel College has the potential to unite enterprise and education, making the State of Texas an epicenter for pharmaceutical development”. “I firmly believe the formation of a graduate program in pharmaceutical science will be a game changer...” Dean Katherine Banks – Engineering*
- *“The area of pharmaceutical sciences is clearly the missing puzzle for formulations development at Texas A&M” – Dean Mark Hussey – Agri-Life, Now President of TAMUK*
- *“I am writing to offer my highest support and best wishes for this worthy endeavor” – Former Dean Paul Ogden, Interim Senior VP and COO HSC, now Provost in TTUHSC El Paso*
- *“The HSC is fully committed to the success of the new Ph.D. program in pharmaceutical sciences”. “I offer my strongest support for the establishment of this new doctoral program in the Texas A&M Irma Lerma Rangel College of Pharmacy. – Dean Carrie Byington, Exec Vice President and Dean COM*
- *“The letter represents my strongest endorsement for the proposal being submitted by your college to develop a Doctor of Philosophy (PhD) program in pharmaceutical sciences) – Provost Anderson – TAMUK, Now President University of Maryland, Eastern Shore.*



# EXTERNAL SUPPORT

- *“Pharmaceutical product development strategies have dramatically changed after FDA’s call for modernization... I believe that newer programs have a much better opportunity to integrate various disciplines..” – Diane Burgess, AAPS President (2002), CRS President (2010), Editor IJP.*
- *I am very pleased to see a much-needed multidisciplinary approach with concrete plans to connect pharmacy, engineering, basic science, medicine, and veterinary medicine... I support this proposal without reservations – Ajaz Hussain, President NIPTE*



# EXTERNAL SUPPORT – TEXAS PHARMA INDUSTRY

*“The Mylan research and Development group includes more than 2900 scientists worldwide...”* Often times we face challenges with the lack of availability of talented PhD level scientists..” Mylan Labs, San Antonio

“Please be assured of my full support for the mission of this new Ph.D. program in pharmaceutical sciences. I am confident that Allergan, Santen, Alcon/Novartis, Pfizer and other companies in the region will tremendously benefit with qualified graduates..” [Mike Garrst, Former Senior VP of Allergan.](#)



# Texas A&M Proposal

- Enrolment projections (10 students per year)
- Academics (in proposal)
- Admission standards (in proposal)
- Program degree requirements

**Table 2:** Semester Credit Hour Requirements by Category

| Category   | SCH Entering with a Bachelor's | SCH Entering with a Master's |
|--|--------------------------------|------------------------------|
| Required Courses   | 26                             | 18                           |
| Prescribed Electives   | 14                             | 8                            |
| Electives  | 12                             | 6                            |
| Dissertation   | 38                             | 28                           |
| Other (Specify, e.g., internships, clinical work, residencies) | Lab rotations, seminars (2)    | Lab rotations, seminars (2)  |
| <b>TOTAL</b> <sup>1</sup>                                      | 90                             | 60                           |

<sup>1</sup>Texas Education Code 61.059 (l) limits funding for doctoral students to 99 SCH. Programs may be allowed to require additional SCH, if there is a compelling academic reason.



# REQUIRED COURSES FOR ALL STUDENTS

**Table 4. Required/Core Courses**

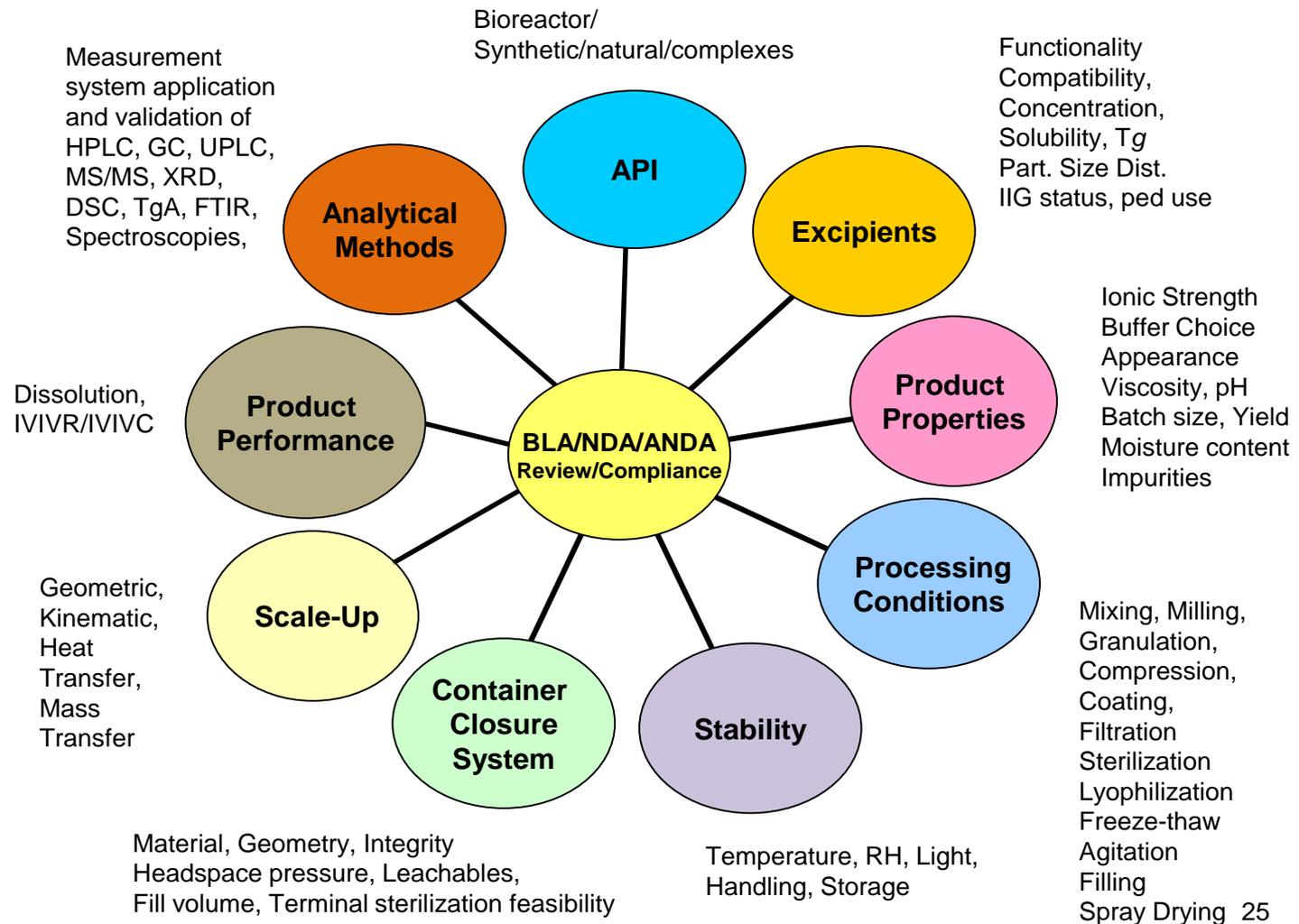
| <b>Prefix and Number</b> | <b>Required/Core Course Title</b>                    | <b>SCH</b> |
|--------------------------|--|------------|
| PHSC 610*                | Biotech drugs and vaccine products                   | 4          |
| PHSC 611*                | Drug delivery and formulations                       | 4          |
| PHSC 612*                | Principles of drug actions                           | 4          |
| PHSC 613*                | Laboratory rotations                                 | 3 + 3      |
| PHSC 621*                | Biostatistics or equivalent                          | 3          |
| PHSC 622*                | Professionalism and ethics in research or equivalent | 3          |
| PHSC 623*                | Seminar  | 1+1        |



**Table 5. Prescribed Elective and Elective Courses**

| <b>Prefix and Number</b> | <b>Prescribed Elective Course Title</b>                   | <b>SCH</b> |
|--------------------------|---|------------|
| PHSC 724*                | Principles of pharmacology and toxicology                 | 3          |
| PHSC 725*                | Biopharmaceutics and pharmacokinetics                     | 3          |
| PHSC 731*                | Process and product development or equivalent             | 2          |
| PHSC 732*                | Controlled and targeted drug delivery                     | 3          |
| PHSC 733*                | Drug degradation and product stability or equivalent      | 3          |
| PHSC 734*                | Vaccine delivery  | 3          |
| PHSC 735*                | Industrial pharmacy                                       | 3          |
| PHSC 736*                | Physical pharmacy   | 3          |
| PHSC 737*                | Transdermal and topical drug delivery                     | 3          |
| PHSC 738*                | Cosmetic development                                      | 2          |
| PHSC 739*                | Pediatric dosage forms                                    | 3          |
| PHSC 741*                | Analytical/Bioanalytical techniques and validation        | 3          |
| PHSC 742*                | High throughput training in drug discovery and screening  | 3          |
| PHSC 743*                | Polymer chemistry or equivalent                           | 3          |
| PHSC 744*                | <u>Chemometrics</u> and big data management or equivalent | 3          |
| PHSC 689*                | Topics in pharmaceutical science                          | 1, 2, 3    |
| PHSC 752*                | Nanotechnology for biomedical applications                | 3          |
| PHSC 753*                | <u>Pk/PD</u> and drug metabolism or equivalent            | 3          |
| PHSC 754*                | <u>Toxicokinetics</u> and predictive toxicology           | 3          |
| PHSC 755*                | In-vitro/in-vivo simulations and modeling                 | 3          |
| PHSC 756*                | Advanced pharmacology                                     | 3          |
| PHSC 757*                | Herbal drugs or equivalent                                | 3          |
| PHSC 758*                | Research in pharmaceutical science                        | 1,2,3      |
| PHSC 691*                | Dissertation research                                     | 3          |





# TEXAS A&M HUMAN CLINICAL RESEARCH FACILITY



[hcrf.tamu.edu](http://hcrf.tamu.edu)



# TEXAS A&M HUMAN CLINICAL RESEARCH FACILITY

HCRF includes:

- Facilities to conduct training and rehabilitation research
- Conference rooms and offices
- 12 beds for overnight research studies
- A metabolic kitchen
- A pharmacy compounding and sterile products room
- 4 procedure and research examination rooms
- DEXA and resting energy expenditure rooms



# TEXAS A&M NATIONAL CENTER FOR THERAPEUTICS MANUFACTURING



[nctm.tamu.edu](http://nctm.tamu.edu)



# TEXAS A&M NATIONAL CENTER FOR THERAPEUTICS MANUFACTURING

NCTM bioprocess labs include:

- Upstream lab
- Downstream lab
- Analytical lab
- Cell culture lab



NCTM offers:

- Workforce development
- Operation-Technician training
- Continuing education courses
- BioFORCE STEM summer academies



# TEXAS A&M INSTITUTE FOR PRECLINICAL STUDIES (TIPS)



[tips.tamu.edu](http://tips.tamu.edu)



# TEXAS A&M INSTITUTE FOR PRECLINICAL STUDIES (TIPS)

TIPS building amenities include:

- GLP compliant clinical pathology laboratory
- Three 600 ft<sup>2</sup> surgical suites, plus a hybrid imaging suite
- Large 150 person auditorium for meetings/training
- Conference rooms and sponsor work rooms w/video feed to labs



# PRODUCT DEVELOPMENT FACILITY IN COLLEGE STATION



[pharmacy.tamhsc.edu](http://pharmacy.tamhsc.edu)

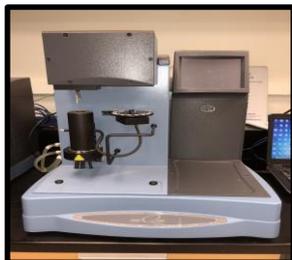


# DR. RAHMAN'S/DR. KHAN'S LAB AT RANGEL COLLEGE OF PHARMACY

Differential Scanning Calorimeter



Thermogravimetric Analyzer



## Analytical Facility

The Analytical Lab and Research Facility incorporates state-of-the-art laboratory equipment for performing chemical analyses, developing methods to aid in research, online-monitoring of process and product development.

High Shear granulator, KG5



10-station tableting machine



Particle Size Analyzer



Texture Analyzer



## Manufacturing Facility

Our Manufacturing facility is a prototype of a pharmaceutical industry equipped with machines for making oral solid dosage forms. Training is provided for faculty and graduate students in equipment operation and research techniques from interdisciplinary departments.

Quadro Co-Mill



V-blender, Model VH2



Thermo Fisher FTIR, NIR and Raman modular systems



Fluid Bed Processor- Strea-1



HCT Mini Tablet Coater

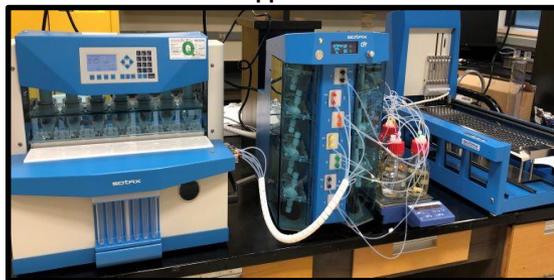


# DR. KHAN'S/DR. RAHMAN'S LAB AT RANGEL COLLEGE OF PHARMACY

Dissolution USP apparatus I and II



USP apparatus IV



XRD, Bruker



UPLC-MS



## Product Characterization Facility

Dosage forms characterization facility incorporates state-of-the-art laboratory equipment's like Agilent Dissolution USP apparatus I and II Model 708-DS with autosampler. Three Agilent HPLC system, Model 1260 Infinity II HPLC's with autosampler and RI and PDA detectors. Waters UPLC-MS, Model Acquity UPLC QSM with Acquity PDA Detector and QDa detector. TA.XTPlus Texture Analyzer (Stable Microsystems Ltd). Laser diffraction particle sizer with solid and liquid samples measuring capability (PSA 1190, Anton Paar)

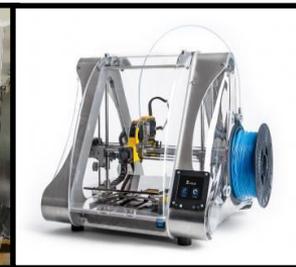
## Additive Manufacturing Facility

In addition to conventional manufacturing our facility is equipped with state of the art 3D printing machines like Selective Laser sintering (SLS) and Fused deposition modelling (FDM) for printing oral solid dosage forms for pediatrics. Training is provided for faculty and graduate students in equipment operation and research techniques from interdisciplinary departments.

SLS 3D Printer



FDM 3D Printer



Chemical/Hyperspectral Imaging



Chewing gum machine



Near-IR, Raman and FTIR Combo



# DR. PALAKURTHI'S LABORATORY

- The Palakurthi Laboratory is interested in applying nanotechnology principles in drug delivery and targeting.
- The lab is working on the design and development of nanoparticle systems using lipids, proteins and polymers for targeting anticancer drugs, and drug combinations, to cancer cells for effective reversal of drug resistance in the cancer cells, particularly breast and ovarian cancers.
- A hybrid plasmid has been developed for Enzyme directed prodrug therapy for breast cancer.
- The lab has developed nanoparticles using zein, a corn protein, for oral delivery of drugs to treat inflammatory bowel disease (IBD).
- A novel in vitro drug release method for testing the bioequivalence of topical ophthalmic products is under investigation.



Advion Expression LC-MS (CMS-L01 model) with Shimadzu HPLC (LC20AB model)



BD Accuri® C6 Flow cytometer

# DR ZHU'S LAB

- Zhu's lab focuses on: (i) design of the stimuli-sensitive nanocarriers/drug conjugates in response to local stimuli, such as pH and matrix metalloproteinases (MMP); (ii) design of the novel nanomaterials to enhance the drug's cellular bioavailability through increasing cellular uptake and inhibiting multidrug resistance (such as drug efflux); and (iii) design of the novel polymers/nanomaterials for intracellular and organelle targeting.



Flow cytometer



Confocal microscope



HPLC



Particle size and zeta potential analyzer

# Dr. Sami Thangavel's Lab

## Neuro-AIDS



**HIV/AIDS and Drugs of Abuse Implicates Neuro-AIDS**

**Research Focuses on:**

- **Metabolic Deficits Impact CNS Dysfunction**
- **Role in Acquit phase proteins and Inflammasome**
- **Epigenetic Modification and Mitochondrial Biogenesis**



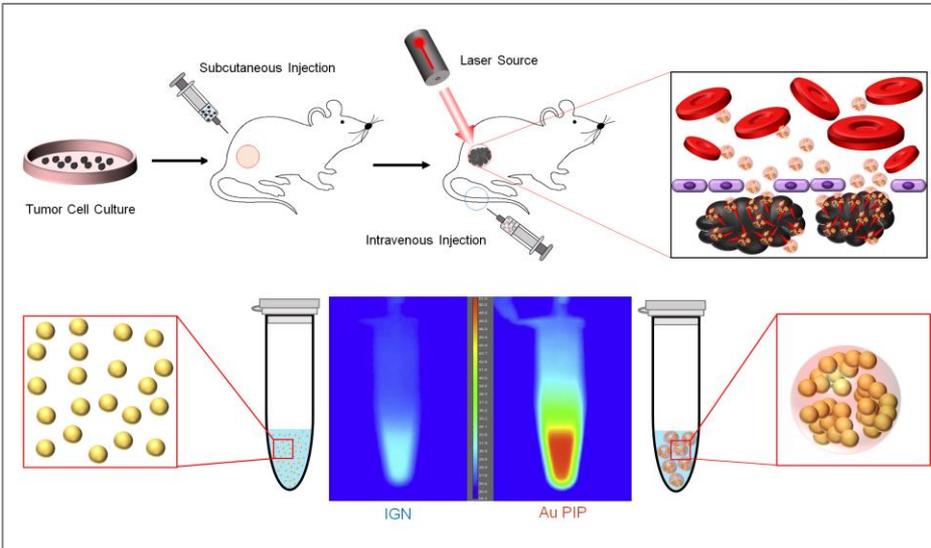
**Central Nervous System  
Dementia & Cognitive Impairments**

**HIV- Associated  
Neurocognitive  
Disorders (HAND)**



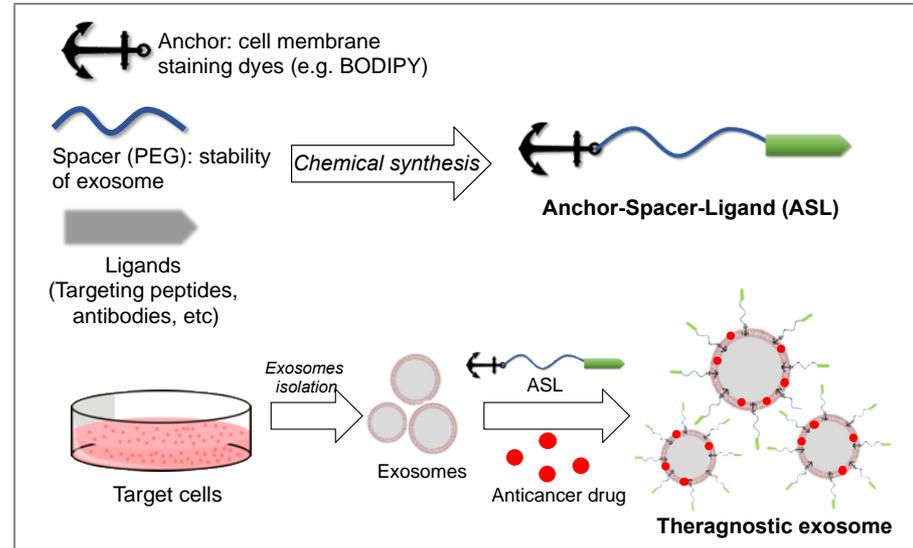
# Dr. Dongjin Kim's lab

## Nanoconfinement Gold mediated Oncothermia



Gold Particle-in-Particle (PIP), in which gold nanoparticles are physically confined within PLGA-PEG nanoparticles, significantly enhances thermal energy production by red-shifting the gold nanoparticle's absorption spectra via a mechanism in which we call Nanoconfinement-Induced Therapeutic Enhancement (NITE). NITE mediated Gold PIPs significantly suppress breast, skin, and multi-drug resistant tumors.

## Active targeting Biological Nanoparticles



An innovative strategy for cancer therapy based on: (i) simple and economic protocol of mass production of pure immune cell exosomes, (ii) synthesis of active targeting moieties, (iii) physical labeling of ligands for active targeting therapy, and (iv) maximum intracellular delivery of exogenous drugs with no or minimum off-targeting side effects.

# MAJETI-LAB DRUG & DISEASE-NO BAR

- Well supported by basic and clinical collaborators
- Large or Small, we deliver ALL! It's all about DELIVERY!

*TBI*  
Epilepsy  
*Gulf War illness*  
Alzheimer's  
Stroke

**b-gal**  
**465 kDa**

**Diabetes**  
Postmenopausal-dyslipidemia  
Hypertension  
Myocardial Ischemia

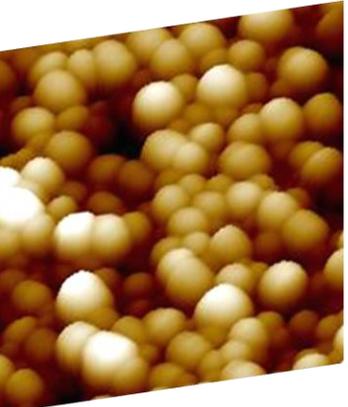
*HIV*  
*IBD*  
*AKI*  
Lupus  
Fungal infection  
*Leishmaniasis*

**Cancer (breast, lung, ovarian)**  
Arthritis

Amphotericin B; Atorvastatin  
Cyclosporine A; Paclitaxel  
Doxorubicin; Insulin  
Tamoxifen etc

Curcumin; Coenzyme Q<sub>10</sub>  
Ellagic acid; EGCG, Urolithin A

**E2**  
**272.4 Da**

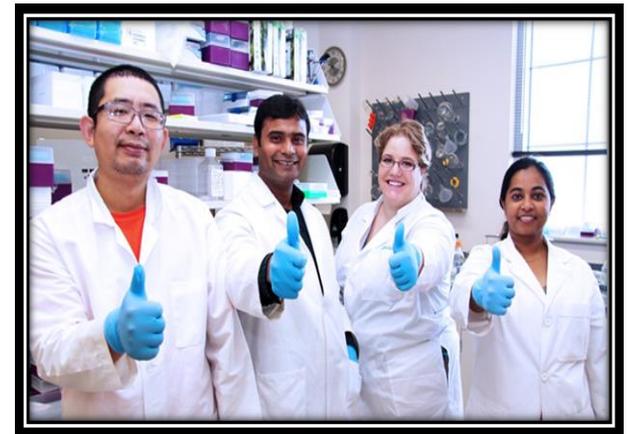


# DR. CHOUDHURY'S RESEARCH



Research includes:

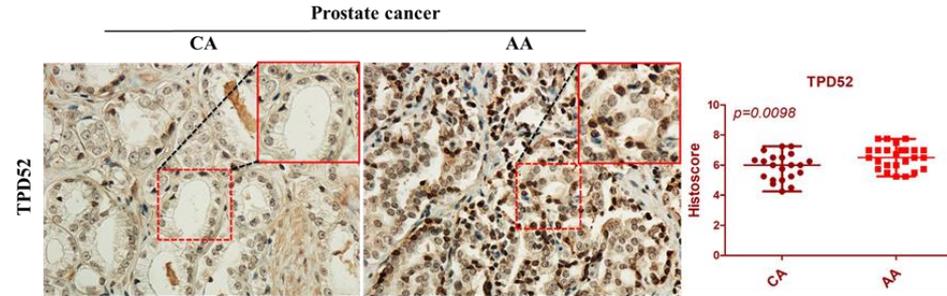
- 1) Early epigenetic biomarkers in preeclampsia and diabetes
- 2) Effect of plastics in pregnancy complications and diabetes and obesity
- 3) Anti-HIV condom material development
- 4) Reversal of metabolic diseases via nutraceuticals
- 5) Epigenetic regulation during exercise
- 6) Epigenetic instrumentation development



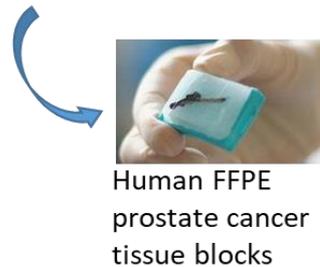
# DR. ELMAGEED'S LABORATORY



Prostate cancer patient received anti-androgen therapy



Immunostaining of tissue sections of PCa with anti-TPD52 antibodies and its IHC score. [Sci Rep.](#) 2018 Nov 5;8(1):16335.



Leica microtome to prepare tissue sections



Leica stainer to perform IHC of selected proteins

- Dr. Elmageed laboratory is focussing on translational research in the field of oncology and therapeutics including prostate, breast cancer and melanoma. This encompasses molecular and cellular biology and therapeutic approaches using in vitro and in vivo mouse model systems as well as human specimens. His laboratory has been actively involved in research training of international graduate students, scholars, postdoctoral fellows and junior faculty members at Texas A&M Health Sciences Center.

# DR. KUMAR'S LAB

Kumar's lab focuses on:

- (i) Understand the mechanism of intestinal restitution during inflammatory bowel disease (IBD) and development of intestinal-specific therapeutics.
- (ii) Understand gut-brain communication during obesity, and develop gut-dysbiosis associated therapeutics for Alzheimer's disease/mental health.
- (iii) Understand gut-liver communication during obesity associated hepatic steatosis.



Clinical pathology: cryostat



Clinical pathology: plate reader



Immunological imaging  
Confocal microscope



Immunological Flow cytometer

# DR. NUTAN'S RESEARCH LAB

- Liposomal delivery system of gene
- Solid lipid nanoparticles of curcumin for antitumor activity
- Biodegradable in situ injectable preparations for extended delivery of various drugs



# THE LU LABORATORY AT COLLEGE OF PHARMACY



- The Lu lab is a medicinal chemistry laboratory working in the interface of organic synthesis and pharmaceutical sciences.
- The lab is engaged in the discovery of potential therapeutics for the treatment of cancer, neurodegenerative diseases and various disorders associated with the endocannabinoid system such as pain, drug-addiction and obesity.
- The lab has filed three patent applications, and one is in the stage of PCT application.
- The lab currently has three senior scientists, one research assistant, several student workers and two consultants. (Profs. K.C. Nicolaou and Apurba Bhattacharya).



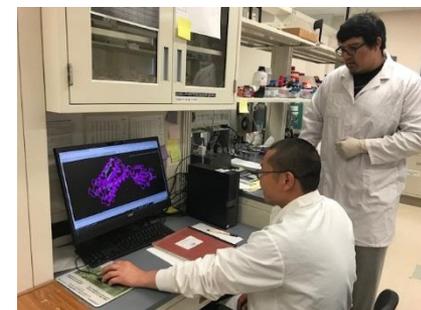
**Fume hoods & Automatic Flash Chromatography**



**Advion Mass Spectrometer**



**Chiral HPLC**



**Computer Modeling Station**





# DR. LIXIAN ZHONG'S LAB

- Dr. Lixian Zhong's lab focuses on Pharmacoeconomics and Outcomes Research in the disease area of oncology, neurological diseases and opioid use disorders.

### Pharmacoeconomic Evaluation of Naloxone Distribution for the Prevention of Opioid Overdose Fatalities: A Systematic Review

Toney Duong, BS, PharmD Candidate; Anh Thu Tran, BS, PharmD Candidate; Joy Alonzo, PharmD; Lixian Zhong, PhD\*  
Texas A&M Irma Lerma Rangel College of Pharmacy, College Station, Texas  
\*Corresponding author's email: zhong@pharmacy.tamuhsc.edu

#### INTRODUCTION

- Drug Overdose mortality became the number cause of accidental deaths in the United States.
- Naloxone is a pure mu receptor antagonist that competes with opioids by having a greater affinity; this pharmacologically reversing opioid overdoses in populations at risk.
- Distribution of naloxones in high risk populations can reduce opioid-related deaths by 65%.
- In 2016, the Surgeon General of the United States Public Health Service issued a statement that addressed the use of naloxone to reverse opioid overdoses.
- The objective of this study is to evaluate pharmacoeconomic of distributing naloxone in community for prevention of opioid overdose fatalities, via a systematic review.

#### METHODS

- The systematic review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.
- Medline® and EMBASE® were searched to identify articles published between January 1986 and June 2018. Two independent reviewers screened and selected the articles based on the criteria listed in Table 1.

| Criteria   | Inclusion   | Exclusion                                  |
|------------|---|--|
| Population | Populations at risk of opioid use disorder/ Naloxone injection or Naloxone intranasal spray                               | None                                       |
| Comparator | No naloxone use or different types of naloxone (e.g. route of administration)   | None                                       |
| Outcomes   | Cost-savings, incremental cost-effectiveness ratio, net benefits, net costs, benefit-cost ratio, cost-benefit ratio, etc. | Other than listed under inclusion criteria |

Study design: Original economic analysis

Case studies, randomized controlled trials, review articles, expert opinions

- The lab is engaged in using large national and statewide healthcare data and economic modeling to study:

### Budget Impact Analysis for Olaparib and Niraparib as Maintenance Therapy in Platinum-Sensitive, Recurrent Ovarian Cancer in the US

Lei Wu, M.S., and Lixian Zhong, Ph.D.\*  
Irma Lerma Rangel College of Pharmacy, Texas A&M University Health Science Center, Kingsville/College Station, Texas, US

#### Background

In US females, ovarian cancer ranks fifth in cancers and causes more deaths than any other reproductive system cancer. In 2017, about 22,440 women will be diagnosed of ovarian cancer and about 14,080 women will die from it.

#### Methods

One million females in a hypothetical health plan  
Ovarian cancer population  
High grade serous ovarian cancer  
Recurrent ovarian cancer  
Platinum-sensitive after first line chemotherapy

With pBRCA mutation  
Without pBRCA mutation

#### Results: Sensitivity Analysis

Market share (70% (95% CI: 60-80%))  
Market share (70% (95% CI: 60-80%))  
Market share (70% (95% CI: 60-80%))  
Market share (70% (95% CI: 60-80%))

#### Discussion

- To our knowledge, this is the first study to evaluate the budget impact of niraparib and olaparib as a maintenance therapy for patients with platinum-sensitive, recurrent ovarian cancer.
- In this BIA model, it assumed that adopting niraparib and olaparib would not affect the utilization of existing medications.
- The estimated clinical parameters such as median PFS and incidences of adverse events were from clinical trials may differ from those in real world settings.

- Cost-effectiveness of novel interventions
- Healthcare costs and resource utilizations
- Comparative outcomes associated with different treatment options

### Opioid Misuse-Related Health Care Resource Utilization and Costs in Texas

Lixian Zhong, PhD<sup>1</sup>; Meri Davila-Sheridze, PhD<sup>2</sup>; Marcia G. Ory, PhD<sup>3</sup>  
<sup>1</sup> Rangel College of Pharmacy, Texas A&M University; <sup>2</sup> Department of Marine Sciences, Texas A&M University at Galveston; <sup>3</sup> School of Public Health, Texas A&M University

#### INTRODUCTION

- The opioid crisis has been declared a public health emergency
- An estimated 2 million Americans live with OUD, with more than 13,000 overdose deaths each day and annual costs over \$200 billion.
- Burden estimates in Texas are underestimated.
- **This study characterizes patient population, health care utilization, and costs related to opioid use disorder (OUD) in Texas.**

#### METHODS

- **Data source:** 2016 Texas Inpatient, Outpatient and Emergency Department Public Use Data Files from all state licensed hospitals.
- **Study population:** Clinical encounters were identified using official ICD-10-DM codes for opioid abuse, adverse effects, dependence, and opioid poisoning. Two definitions were used: (1) high-specificity definition use principal diagnosis codes only; and (2) high-sensitivity definition include both principal and 2nd of secondary diagnoses.
- **Variables:** Available demographic, utilization and charge data were analyzed. Direct health care expenditures (DHE USD) were approximated using claim charges.
- **Data analysis:** Descriptive statistics were calculated for baseline patient characteristics. Bivariate analyses (t-test and Chi-square) were used to identify significant relationships.

#### RESULTS

##### Table 1: Number of opioid-related clinical encounters in Texas 2016 by using two different case identification criteria.

| Category   | High specificity definition (N=1,041,241) | High sensitivity definition (N=1,241,241) | Individual patient encounters |
|------------|---|---|-------------------------------|
| Outpatient | 1,041,241                                 | 1,241,241                                 | 1,041,241                     |
| Emergency  | 1,041,241                                 | 1,241,241                                 | 1,041,241                     |
| Inpatient  | 1,041,241                                 | 1,241,241                                 | 1,041,241                     |
| Total      | 3,123,723                                 | 3,723,723                                 | 3,123,723                     |

##### Table 2: Patient characteristics of opioid-misuse related clinical encounters in both outpatient and inpatient settings.

| Patient Characteristics | Outpatient Visits |                  | Inpatient Visits |                  |
|-------------------------|-------------------|------------------|------------------|------------------|
|                         | High specificity  | High sensitivity | High specificity | High sensitivity |
| Age (years)             | 488.52            | 470.72           | 526.14           | 517.03           |
| Sex                     | 63.77 (6.2)       | 67.93 (6.6)      | 58.82 (5.8)      | 63.07 (6.2)      |
| Race                    | 4,980 (0.5)       | 5,925 (0.6)      | 4,980 (0.5)      | 5,925 (0.6)      |
| Ethnicity               | 1,775 (0.2)       | 1,775 (0.2)      | 1,775 (0.2)      | 1,775 (0.2)      |
| Region                  | 1,041,241         | 1,241,241        | 1,041,241        | 1,241,241        |
| Insurance payer         | 1,041,241         | 1,241,241        | 1,041,241        | 1,241,241        |

##### Table 3: Costs of opioid-related clinical encounters in Texas 2016 using two different case identification criteria.

| High specificity method | Costs per opioid-related visit |               |           |              |
|-------------------------|--------------------------------|---------------|-----------|--------------|
|                         | Outpatient                     | Outpatient ED | Inpatient | Inpatient ED |
| Average                 | \$1,212                        | \$1,212       | \$1,212   | \$1,212      |
| Median                  | \$1,212                        | \$1,212       | \$1,212   | \$1,212      |
| Range                   | \$1,212                        | \$1,212       | \$1,212   | \$1,212      |
| Total costs (million)   | \$1,212                        | \$1,212       | \$1,212   | \$1,212      |

##### Figure 1: Geographic Distribution of Opioid Misuse Related Clinical Encounters in Texas (2016)



# MICHAEL J. MILLER, RPH, DRPH, FAPHA

- As a researcher, I use both primary and secondary data to study and refine methods to measure and identify those at risk for low health literacy, evaluate the literacy-sensitivity of pharmacy processes and environments, and identify interventions that improve health literacy and ensure optimal medication use and risk communication.

- My primary areas of clinical interest include cardiovascular-related disease, rheumatology, depression, and, most recently, infectious disease.

- From a process perspective, I also have a strong interest in treatment guideline concordance with respect to medication management as well as disparities in healthcare practices.

**Achieving Cross-Cultural Medication Adherence in South Texas**

Michael J. Miller<sup>1</sup>, M. Irene Moyn<sup>2</sup>, Gabriela C. Zapata<sup>2</sup>  
<sup>1</sup>Departments of Pharmaceutical Sciences and <sup>2</sup>Hispanic Studies  
 Texas A&M Rangel College of Pharmacy and College of Liberal Arts

### Background

- Medication Adherence:**
  - Failure of patients to properly adhere to prescribed treatments is common, negatively affects health outcomes, and contributes to increased health-care costs and decreases in overall population health.
  - In developed countries, adherence for chronic conditions ~ 50%.
  - Nonadherence translates to \$300 billion in avoidable costs.
  - Optimal medication use is influenced by sociodemographic, cultural, and behavioral factors.
- Limited English proficiency in the United States:**
  - There are 14 million people in the US for whom lack of English skills is a barrier to health care and quality health outcomes.
  - In Texas, their number is estimated to be over 3 million, mostly non-Hispanic.
  - Lack of linguistic and cultural competence between the health care system and patients negatively affects access to care, their capacity to participate actively in their treatment and recovery, and the persistence of and trust in health care services.
  - Identified negative financial and social consequences include less access to preventive services and screening, lower quality of treatment, worse health outcomes, and higher medication costs.
- Medication adherence in South Texas:**
  - Most validated data collection instruments are routinely developed, tested, and validated in English-speaking populations with limited range for linguistic and cultural differences.
  - As a consequence of the difficulties with and contextual cross-cultural adherence.
  - Many well-validated instruments may fall short of their goals.
- Project goals:**
  - Overarching to identify barriers to successful medication adherence in university outpatients aligned with healthy behaviors.
  - Focus on and beyond language and cultural differences.
  - Investigate how to translate, pilot, and assess the reliability and feasibility of an instrument that is linguistically and culturally sensitive to the target population's medication use behavior as they relate to self-reported medication adherence.

### Conceptual Framework

This inter-professional project uniquely translates data collection instruments into Spanish that can be used to identify and assess health literacy, understand sociodemographic, functional health literacy beliefs, and identify barriers to medication adherence and self-reported behavior as they relate to self-reported medication adherence.

### Methods

**Phase 1:** translate and validate existing data collection instruments from English to Spanish

- Forward translation by translators with varied linguistic and disciplinary profiles.
- Panel of bilingual graduate students (BSPHARM) to back-translate (reverse-translating BSPHARM).
- Assessment of instrument (panel of 15 lay representatives of Hispanic community).
- Pilot testing of data in bilingual and monolingual Spanish-speaking patient samples (n=50).
- Qualitative data collected through video-recorded interviews with senior patients from the same area (n=20).
- Analysis of English and Spanish versions and qualitative thematic analysis.
- Revise instruments as necessary.

**Phase 2:** administer translated instrument to bilingual and monolingual Spanish-speaking patient samples emphasizing the El Centro Valley region (area administration n=400).

**New?**

- Participants: 70 years, non-Hispanic/bilingual Spanish speakers, currently prescribed at least one medication for a chronic condition (high blood pressure, high cholesterol, heart disease, diabetes, arthritis, and smoking cessation).
- Qualitative data collected through Qualtrics or paper format using a citizen science, cross-sectional survey design.
- Assess Spanish version psychometric properties from an ethnically-diverse, Spanish-speaking patient population and compare concordance with previously reported English version properties.

**Why?**

- Quantitative data will be used to assess performance of English and Spanish instruments.
- Qualitative interviews will provide greater insight into issues that may be specific to Spanish-speaking patients.

**Preliminary Results**

- Collaborative, inter-professional translation of original documents.
- Collaborative, inter-professional analysis of issues related to the relationship between language and medication adherence.
- Development of draft instruments in Spanish.
- Revisions of English instruments in light of questions and layout.
- Use the content of scanner app on your mobile device to view the instruments using the QR code below.
- Original English Only Instrument → New Bilingual Digital Instrument

### Discussion

- A draft bilingual data collection instrument that incorporates both formal and informal conditions has been developed.
- Create opportunities to support Texas A&M University system-wide.
- Organic nature of collaboration—flexibility of work process and objectives as a result of collaborative discussion and negotiation.
- Development of a community of practice.
- Opportunity for interdisciplinary and inter-professional collaboration.
- Development of participating students: Spanish heritage.
- Pharmacy students → Pharmacy.
- Hispanic students → Pharmacy.
- Development of participating students: Spanish heritage (bilingual English speakers) and English (not) Spanish speakers) proficiency.

### Next Steps

- Complete final form group in Hispanic community.
- Analyze measured instruments between translation to each translation pair (bilingual analysis → critical discourse analysis).
- Distribute Spanish survey among participating community.
- Revise data collection instruments based on additional feedback.
- Revise instrument as necessary.

### Student Translators

| HISPANIC STUDIES     | PHARMACY        |
|----------------------|-----------------|
| Zaini Aguilera       | Joni Aguilera   |
| Carolina Garcia      | Joel Ortega     |
| Leovane Diaz Serrano | Audrey Delatin  |
| Alexandra Ribela     | Lorena Gonzalez |
| Patricia Arreola     | Alexis Leal     |
| Amelia Lila          | Lorena Sanchez  |
|                      | Galvina Villa   |

**Health Literacy and Readiness to Initiate Treatment for Osteoporosis in an At-risk Sample of US Women**

Miller MJ<sup>1</sup>, Danila M<sup>2</sup>, Outman RC<sup>3</sup>, Rahn EJ<sup>2</sup>, Mudano AS<sup>2</sup>, Saag KG<sup>2</sup>  
<sup>1</sup>Texas A&M University Rangel College of Pharmacy, <sup>2</sup>University of Alabama at Birmingham College of Medicine  
 Funding: National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) R01 AR060240

### Background

- Osteoporosis affects 200 million people worldwide.
- ~ 50 million in the US.
- There are approximately 2 million osteoporosis-related fragility fractures annually in the US resulting in \$19 billion in costs.
- Despite medication/recommended treatment, primary and secondary adherence remains a problem.
- Pain, controversy, cost, complex dosing regimens, lack of patient education/understanding, and concerns about side effects, polypharmacy, and medication efficacy contribute to non-adherence.

### Research Question

Is there an association between health literacy and readiness to initiate medication for osteoporosis?

### Methods

Design: Cross-sectional, baseline data (n=2,684 patients) from the Arthritis Patients at Risk for Osteoporosis (ARPOPS) Study

- ARPOPS was a parallel, controlled, randomized clinical trial testing a multi-modal (web-based/SPD), patient-tailored, behavioral intervention.
- Eligibility: self-reported fracture after 45 years of age, not currently using either a bisphosphonate or non-bisphosphonate, and female sex
- Measurements:
  - Age, race, education
  - Perceived Fracture Risk: "Compared to other women your age, how would you rate your own risk of fracturing or breaking a bone?"
  - As little higher to Much higher vs. About the Same/Little Lower/Much Lower
- Health Literacy: "How confident are you filling out medical forms by yourself?"
  - Grade A/B/C to Extremely vs. Somewhat/Little Better/No
- Received Medication Information: "People get information about osteoporosis medicine from different sources. Have you received information about possible osteoporosis medicines in the past year?"
  - Yes vs. No
- Trust/Distrust for Medication
  - 5 to 6-point Likert-type Questions
  - Score: averaged and dichotomized at the median
  - Higher vs. Lower Trust

### Methods

- Readiness to Initiate Osteoporosis Medication
  - "Please choose from your statement that best reflects your feelings about receiving osteoporosis medicines (0-10)"
  - 1 to 10 (with 1=not treatment for osteoporosis)
  - Can you see how there are treatments available for you?
  - Have medication.
  - I am confident using or have previously used osteoporosis medication, but I have not used again because it is too expensive, it is too hard to take, or I do not want to take medication, but I have not made up my mind.
  - I have decided to use osteoporosis medication, but I have not yet started taking it.
  - Not thinking about it / I procrastinate / I am not sure.
  - Collaborative Action
  - Modified version of the Precaution Adoption Process Model

### Results

### Discussion

- A relationship between health literacy and readiness to initiate osteoporosis medication was observed.
- The observed direction of the relationship appears to be to increase rather than the anticipated decrease.
- Age, race, and education are associated with health literacy.
- In turn, their association with readiness to initiate osteoporosis medication may be mediated through health literacy.
- Age and education associations) with readiness to initiate osteoporosis medication may be direct and/or mediated through perceived fracture risk and medication trust.
- The education association with readiness to initiate osteoporosis medication may also be mediated through receipt of medication information.

### Conclusion

- Health literacy may not universally predict anticipated relationships.
- Not a "one size fits all" solution.
- Educational interventions for osteoporosis treatment must be sensitive to age, educational level, and all levels of health literacy.
- At minimum, educational content must...
  - address perceived fracture risk,
  - mitigate medication distrust,
  - focus on enable and boost sources.

### References

1. National Osteoporosis Foundation. (2014). *International Osteoporosis Foundation Global Report 2014*. Washington, DC: International Osteoporosis Foundation.
2. World Health Organization. (2014). *Global Report on Osteoporosis and Osteoporosis-related Fractures*. Geneva: World Health Organization.
3. National Osteoporosis Foundation. (2014). *International Osteoporosis Foundation Global Report 2014*. Washington, DC: International Osteoporosis Foundation.
4. National Osteoporosis Foundation. (2014). *International Osteoporosis Foundation Global Report 2014*. Washington, DC: International Osteoporosis Foundation.
5. National Osteoporosis Foundation. (2014). *International Osteoporosis Foundation Global Report 2014*. Washington, DC: International Osteoporosis Foundation.
6. National Osteoporosis Foundation. (2014). *International Osteoporosis Foundation Global Report 2014*. Washington, DC: International Osteoporosis Foundation.
7. National Osteoporosis Foundation. (2014). *International Osteoporosis Foundation Global Report 2014*. Washington, DC: International Osteoporosis Foundation.
8. National Osteoporosis Foundation. (2014). *International Osteoporosis Foundation Global Report 2014*. Washington, DC: International Osteoporosis Foundation.
9. National Osteoporosis Foundation. (2014). *International Osteoporosis Foundation Global Report 2014*. Washington, DC: International Osteoporosis Foundation.
10. National Osteoporosis Foundation. (2014). *International Osteoporosis Foundation Global Report 2014*. Washington, DC: International Osteoporosis Foundation.

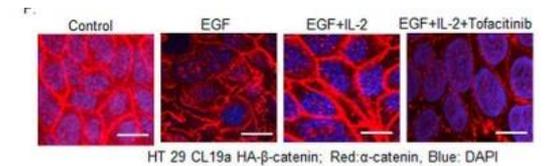
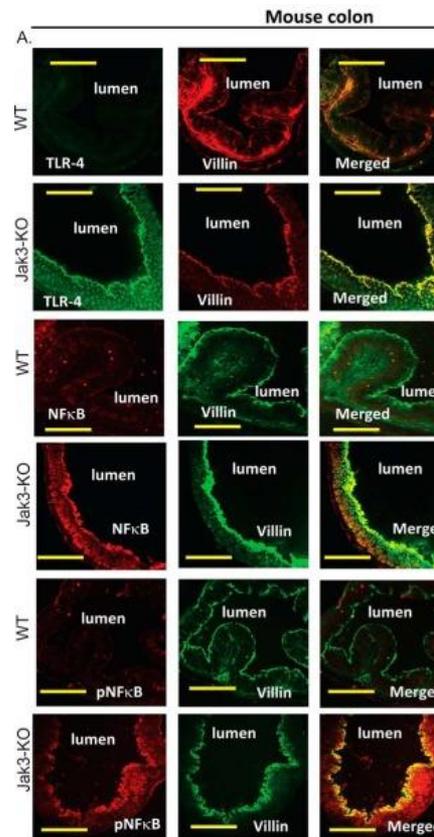


# DR. MISHRA'S LAB

Dr. Mishra's lab focus:

- Role of drug transporters during chronic inflammatory diseases.

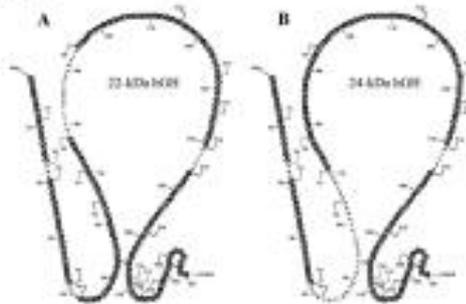
Confocal microscope



# Dr. Juan Bustamante

## Research Area

- Liver regeneration
- Maternal liver growth
- Growth hormone



Clinical pathology: plate reader

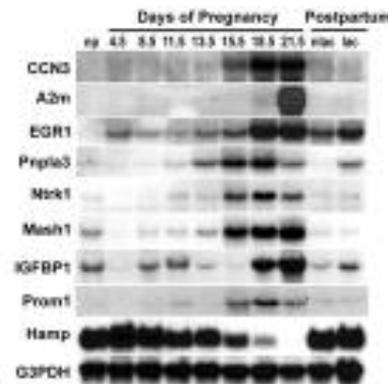


Chiral HPLC

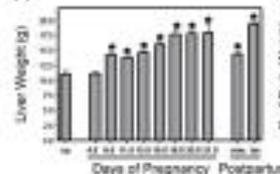
## Techniques

- proteomics
- molecular
- cellular biology
- *in vitro*
- mouse model

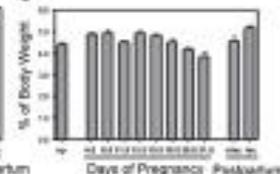
A



A



C



B



Clinical pathology: cryostat



Thanks & Gig 'em!