NYS-Insider

Wegmans School of Pharmacy

St. John Fisher University

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Points of Interest:

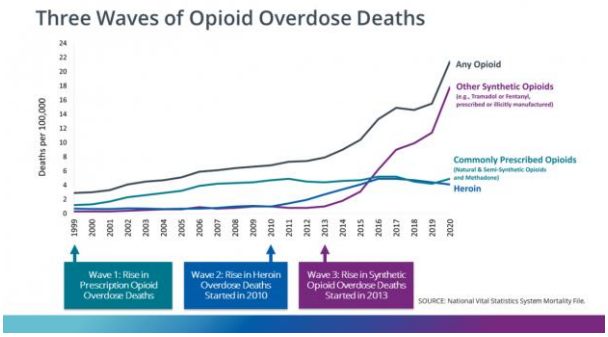
Wegmans School of Pharmacy ACCP Student Chapter Highlights

The ACCP student chapter at Wegmans School of pharmacy (WSoP), founded in 2014 by faculty advisor, Dr. Kathryn Connor, has now become an established collective of students ranging from P1 to P4 PharmD candidates. We currently have a total of 35 members from both our on campus program and our online pathway. Three years after the COVID-19 pandemic started we are now focused on expanding and resuming opportunities for our members to engage with the community and learn more about the various fields of pharmacy. The WSoP chapter of ACCP has previously offered the opportunity to participate in a mentorship program with the University of Rochester Medical Center. Through this program students have been partnered with a clinical specialist. Our students have been able to virtually connect with mentors in various specialties, such as, emergency medicine, oncology, bone marrow transplant, toxicology, and many others. As COVID-19 numbers continue to decline, we look forward to again offering students the opportunity to shadow their specialists at their practice sites. At WSoP we welcomed our inaugural class of the WSoP online pathway in the fall of 2020. This addition allowed our chapter to expand and network with new contacts in hospital systems from across the United States. This expansion of our mentorship program will allow for all of our members to be engaged with not only different specialties, but healthy systems as well. The WSoP ACCP chapter is looking forward to participating in the ACCP clinical research and clinical pharmacy challenge in the 2023 year.

-Nicolaus Anschutz, PharmD Candidate; WSoP Class of 2025, ACCP President

Walmart reaches $3.1 billion Opioid Settlement

On December 22nd of 2020, The Department of Justice filed civil Lawsuit against Walmart INC, alleging that; 1) " As a Pharmacy, walmart Violated the rules for dispensing controlled substances" 2) "As a distributor, Walmart violated its duty to detect and report suspicious orders of controlled substances" 3) "Walmart systematically violated the CSA even as it recognized the prescription drug abuse epidemic gripping the nation".[1] This filling was a result of a years-long investigation by the Department of justice's Prescription Interdiction & Litigation Task Force. The civil suit filed by the DOJ requested penalties that if Walmart were to be found liable the responsibility of up to $67,627 for each unlawful prescription filled, in addition to $15,691 for each suspicious order Walmart failed to report. [1]



The CDC defines the Opioid epidemic in three waves[2]. The first wave of three being defined as a rise in prescription opioid overdose related deaths from the 1990s to 2010. With more than 564,000 deaths between 1999-2020.

November 15th, 2022, Attorney General Ellen Rosenblum announced a settlement framework agreement had been reached between Walmart INC and the DOJ in the valuation of $3.1 Billion dollars. In this agreement, the $3.1 billion would be divided by the states that agreed to sign on with the stipulations that the settlement be used to provide treatment and recovery services to those with opioid use disorder. Additionally, Walmart will have to comply with court ordered measures in addition to preventing fraudulent prescriptions and flagging suspicious prescriptions moving forward.

In order for the plan to move forward, it first had to be approved by a majority of greater than 43 states by December 15th of 2022. As of December 20th, 2022 the agreement was reached with all 50 states, allowing the plan to proceed forward. Walmart is expected to dispense a majority of the settlement within the first year, with the remaining amount to be dispensed through 2028.

Walmart continues to "strongly dispute the allegations in these matters, and these settlements do not include any admission of liability"[4] In a statement made on their webpage walmart reinforces their commitment to helping fight the opioid crisis by; "educating and empowering pharmacists, reducing the amount of opioids dispensed, protecting against diversion and theft,Increasing access to overdose reversal medications, educating our patient and our communities about opioid abuse, and advocating for state and national policies aimed at curbing opioid abuse and misuse."[3]

Sources:

1) Department of Justice Files Nationwide lawsuit against Walmart Inc. for Controlled Substances Act Violations [Internet]. The United States Department of Justice. 2020 [cited 2023Jan8]. Available from: https://www.justice.gov/opa/pr/department-justice-files-nationwide-lawsuit-against-walmart-inc-controlled-substances-act
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4) Walmart announces nationwide Opioid Settlement Framework [Internet]. Corporate. 2022 [cited 2023Jan8]. Available from: https://corporate.walmart.com/newsroom/2022/11/15/walmart-announces-nationwide-opioid-settlement-framework

- Nicolaus Anschutz, PharmD Candidate, WSoP Class of 2025, ACCP President

UPDATED 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain

The CDC has issued an update to its 2016 Guideline for Prescribing Opioids for Chronic Pain. Upon the release of the previous 2016 edition, the CDC funded The Agency for Healthcare research and quality (AHRQ) to collect and evaluate data in relation to the effectiveness of long term opioid therapy in relation to pain, function, and quality of life. The agency for Healthcare research and quality looked at five areas of assessment; noninvasive nonpharmacologic treatments for chronic pain, nonopioid pharmacologic treatments for chronic pain, opioid treatment for chronic pain, treatment for acute pain, and acute treatment for episodic migraines. Scientific evaluation of these key areas indicated new scientific data was available and indicated an update was warranted. The 2022 CDC Clinical Practice Guideline for prescribing opioids for pain expands on and replaces the previous edition. The aim of the update is to ensure patients have access to safe and effective medications in the management of pain while improving function and quality of life.

The 2022 update brings confirmation of the appropriateness of the 2016 opioid prescribing guideline for using opioids for chronic pain, as well as a new topline recommendation to patients already receiving opioid therapy. The update continues to further define appropriateness of therapy between acute (<1 month), subacute (1-3 months), and chronic pain (>3 months). The 2022 CDC clinical practice Guideline for Prescribing Opioids for Pain addresses patients aged>18 years; excluding patient populations of: pain management related to sickle cell disease, cancer-related pain treatment, palliative care, and end of life care.[1]

2022 Clinical Practice Guideline for Prescribing Opioids for Pain

1) Determining Whether or Not to Initiate Opioids for Pain
2) Selecting Opioids and Determining Opioid Dosages
3) Deciding Duration of Initial Opioid Prescription and Conducting Follow-up
4) Assessing Risk and Addressing Potential Harms of Opioid Use

When determining whether or not to initiate opioids for pain management the pain indication of acute, subacute, or chronic should be reviewed. In patient populations for acute pain, nonopioid therapies have been shown to be as effective as opioids for many common forms of acute pain. Clinicians are encouraged to maximize nonpharmacologic and nonopioid therapies prior to initiating opioids. Opioid initiation should only be considered after discussing the potential benefits and risks associated with the patient.[1] if the potential benefit outweighs the anticipated risk to the patient opioid therapy falls under recommendation category: B; evidence type: 3. When the patient is experiencing subacute or chronic pain nonopioid therapies are preferred.

When selecting opioids and determining opioid dosages in patient populations already receiving opioid therapies, clinicians are encouraged to review the benefits and risks associated, while exercising care when changing dosages. Clinicians should work with patients whose benefits outweigh the risks associated with continued opioid use to ensure nonopioid therapies are being maximized with continued opioid treatment. If benefits are not outweighed by the possible risks of continued opioid therapy, clinicians should work closely with the patients to decide if and when to taper or discontinue dosing. Opioid therapy should not be readily stopped, nor should dose reductions be rapid from higher dosages. This addition to the 2022 update further promotes the HHS tapering guideline and HHS overdose prevention strategy; primary pillar, for the support and development of evidence based therapy in the treatment of pain management.

The 2022 update is meant to be used voluntarily and applied to each unique patient. This update is not intended to be used as a strict model, applied to all patients and populations, nor meant to be used as a protocol. The CDC is continuing to review gaps in data and continues to look at the most recent and effective scientific data as it is identified for future updates as deemed necessary.

Sources: Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1

-Nicolaus Anschutz, PharmD Candidate, WSoP Class of 2025, ACCP President

Effect of Teplizumab-mzwv in T1Dm onset

Teplizumab– is it the next leading preventative therapy for type 1 diabetes? As a segway into this topic, type 1 diabetes is caused by destruction of the body's own beta-cells in the islet of Langerhans of the pancreas. It is generally asymptomatic at first– that is, until the beta-cells can no longer continue to compensate for the drastic loss of others in the surrounding tissue. Usually, by the time someone is diagnosed with this disease, they are already symptomatic and have lost function in most, or all, of their beta-cells. This highlights the importance of early detection and prevention, especially in high risk populations. Teplizumab was developed to reduce the loss of pancreatic beta cells in the presence of type 1 diabetes mellitus and has been thought to delay destruction of these cells for as long as seven years. Current studies, however, have shown that patients at high risk for development of the disease also benefit from this drug therapy. Teplizumab is the first drug on the market used to delay onset of type 1 diabetes.

One double-blind clinical trial in particular has shown the effectiveness of Teplizumab as a preventative strategy for high risk populations. In this clinical trial, 76 participants were randomly assigned to be treated with either Teplizumab or a placebo for a set 14-day treatment period, and progression of the disease was monitored with oral glucose tests every 6 months. 43% of those who received Teplizumab were diagnosed with type 1 diabetes mellitus within the next year, in contrast to 72% of the placebo group. Median time to diagnosis in this clinical trial was 48.4 months in the group who received Teplizumab, as opposed to the placebo group (24.4 months).[1]

Teplizumab has made a huge stride in delaying the diagnosis of type 1 diabetes mellitus. Even the slightest delay in onset of this disease state can be beneficial to patients by allowing them to live free of the destructive nature of type 1 diabetes for much longer than would have been possible before. This can be an important tool for health professionals to combat this autoimmune disease. Having a drug like this on the market is a step toward a better future for high risk patients and it is truly an amazing breakthrough in the treatment and prevention of type 1 diabetes, which was, until only recently, unpreventable.

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2. Morris A. Teplizumab delays onset of type 1 diabetes mellitus. Nat Rev Endocrinol. 2019 Aug;15(8):437. doi: 10.1038/s41574-019-0233-3. PMID: 31243389.

- Brenna Nash, PharmD Candidate, SFJ Wegmans School of Pharmacy Class of 2025.

Advocating for Insulin Accessibility & Preventing Consequences of Further Rationing

It is no secret, in recent years, profit seeking pharmaceutical entities surging prices and convoluted insurance company policies on insulin products, have been a major topic of discussion. Many such exposés have been conducive to shedding light not only upon practices contributing to the skyrocketing premium for insulin, but also, the cost suffrage by which the insulin dependent diabetic population within the U.S. are regularly forced to bear. The overwhelmingly inflated fee for insulin is so great, that many already underserved populations living with diabetes are often further deprived in the manner of their most basic health needs. Financial constraints tend to be the most common reported form in which patients are robbed of their insulin. Unfortunately, the problem is only expected to worsen as economic forecasts predict further price hikes. With few alternatives available, insulin rationing can be the only option left to attempt to maintain subsistence for some.

This harsh reality is not a rare occurrence amongst those who need insulin. A recent study found a total of 10.8% of higher-income, 19.8% of middle-income and 14.6% of low-income persons all reported rationing.[2] Uninsured persons had the highest rate of rationing 29.2% followed by those with private

insurance 18.8%, other coverage 16.1%, Medicare 13.5%, and Medicaid 11.6%.[2] 20.4% of younger insulin dependent patients rationed their insulin versus 11.2% of those aged 65 years or older.[2] Additionally, a whopping 23.2% of Black persons experienced rationing alongside 16.0% of White and Hispanic persons.[2] When put into perspective, those who require insulin, no matter their ethnicity or financial circumstance are not immune to the prospect of insulin rationing.

But what is being done here and now to bring life-essential insulin within reach of those who need it most? So far, New York has been one of the few states pioneering laws that give insulin users relief. As of January 1st, 2021 an insulin price copay cap of $100 per 30 day prescription, regardless of deductible, was signed into law by governor Cuomo.[3] Although this is indeed a great start to curbing out-of-pocket insulin costs for those with policies and/or contracts issued or renewed in New York, it still leaves others with the same problem as before. Those who either have multiple insulin prescriptions or are not insured by the state remain confined to the crushing or unattainable insulin overhead. Then, even those who ration what little insulin they can get, risk the possibility of experiencing detrimental side effects of their condition up to and including death.

What's more is this serious issue stands to affect many beyond the insulin dependent and even their loved ones. Every state taxpayer likewise is sharing in the burden created by exorbitant insulin list prices. Hospital charges, that are similarly out of budget for those who can't afford their prescribed insulin, serve as the inevitable consequence of inhibiting insulin access and are then the public's obligation to fund. In 2017 alone, New York incurred an annual cost of $21.23 billion that was attributed to diabetes, the 4th highest ranking nationwide.[1] Needless to say, there is room for reallocating funds to prevention of diabetes complications, namely insulin availability.

To work towards furthering the closure of health disparity gaps among those requiring insulin, pharmacists have been proven to support these efforts. Connecticut, for instance, allows pharmacists to dispense emergency insulin for those with a prescription and less than a week's supply available. The applied tactic has the potential to help alleviate patient hardship as well as reducing overall state costs of emergency room visits and deaths associated with insulin rationing. In fact, New York has already introduced the idea of following suit by putting a similar program in place. Assembly bill A194 is a proposed emergency insulin program currently before the New York assembly committee and, with enough traction, may serve as a soon coming reprieve for insulin users.[4]

Until insulin generics become available and force insulin prices down, the diabetic community will stay in crisis with expenditures 2.3 times higher than those without diabetes.[1] In the meantime, other means can be used to stifle the blow of insulin's lingering cost. With such a widespread need, pharmacists have the potential to help address these gaps in care as they present as one of the most accessible healthcare resources available to the public. Approving a route in which pharmacists can be mobilized to offer increased insulin attainability to those who are in desperate need is a viable answer to the compounding separation from wellness insulin users currently experience. To participate in the future advancement of bringing insulin to those who desperately need it, you can support assembly bill A194 here.

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- Raquel Bayle, PharmD Candidate, SFJ Wegmans School of Pharmacy Class of 2025.

Celebrating a New Chapter for One of Fisher's Own

WSoP Online Adjunct Professor, Director of Domestic Operations and RCP research at Global Volunteers

Many at St. John Fisher University are already familiar with the name Melinda (Mindy) E. Lull, whether as a colleague or an instructor for good reason. Dr. Lull began her Fisher career more than qualified, boasting an impressive educational background including a Post-Doctoral Fellowship at Virginia Commonwealth University, a PhD at Penn State College of Medicine and a BA from St. John Fisher College. Since obtaining a position, Dr. Lull has been active in supporting various projects including scholarship of teaching, learning by assessing and publishing on innovating teaching methods, devising systems for assessment of student learning, and development of co-curricular programs. Additionally, building upon her experience with drug abuse and toxicology, Dr. Lull has worked to improve understanding of the relationship between drug levels and behavioral effects, as well as promote public awareness of drug effects.

What's more is she has used her faculty platform to extend her influence beyond the St. John Fisher campus pursuing research on the impacts of health education, resources, and health care access on the health of individuals in developing countries. This has been in the form of conducting "research with Global Volunteers looking at the growth and development of children in communities that Global Volunteers serves which helped the organization to show that their Reaching Children's Potential program was effective," and she plans to "…continue doing this research… to expand the analysis to more communities."

Her efforts have been more than stellar in practice and have not gone unnoticed, having obtained multiple "Teacher of the Year" and "Advisor of the Year" awards as a direct impact of her exceptional work throughout her St. John Fisher career. In fact, it is her success and passions for both higher learning and love for connecting with the individuals in the communities she has served, that have paved the way for her next life chapter. Dr. Lull will be moving on as the Director of Domestic Operations and RCP Research at Global Volunteers where she looks to "bring… experience to push forward the evidence-based work that will take the service programs at Global Volunteers to the next level."

This new opportunity grants students the chance to be trained under Dr. Lull under a new entity but with all the same vigor and capacity she has applied while at St. John Fisher. Having been able to provide "life-saving care that would have otherwise been impossible," and other services spanning a number of places around the world, including Guinea, West Africa, El Salvador, Montana, Peru, and Tanzania, she encourages students to much the same. The "better understanding of people – what motivates them, how their life experiences influence both their health and approach to care, to listen more than… talk," are the uniquely invaluable benefit gained by those who choose to provide aid to the most underserved communities. Exposure to these societies serve the dual purpose of bettering not only student learning, but personal growth and societal commonwealth "it allows students to truly experience a culture and community outside their own... [immersing] you in the community you are serving, I have learned more about the world and people in my time on service programs than in any other setting."

"Dr. Lull takes time to connect on a personal level with a local girl during a Peru service program trip. (2022)"

"Dr. Lull at Sagrada Famlia joining in on some playground fun with the children in Peru. (2022)"

The departing advice she has for her colleagues and students is to:

"Never stop learning... Understand the why, the how. Then when you are faced with a new topic or new problem, you pull from the "whys" and "hows" of old knowledge to solve the new problem!… I consider myself a lifelong learner, and it helps me not only to keep current with my knowledge, but to keep myself excited about my profession. Stagnation leads to dissatisfaction, and if you are always learning and trying new things, you won't stagnate."

The legacy she hopes to leave behind is:

"…a legacy of focusing on the individual student... all students are different – different goals, priorities and life circumstances - and therefore require an individualized approach when helping them meet goals and be successful. I hope that in those I have mentored (both faculty and students) I have instilled the same belief, so that this student focus continues and expands beyond the School of Pharmacy."

"2019 Tanzania team with staff at the Ipalama General Clinic"

Dr. Melinda Lull has made her own unique mark at Fisher and her departure will certainly be felt. However, her lasting contributions will live on in the passionate love of learning she has imparted to her students, encouraged in her work counterparts, and applied to her own life's work.

Sources: Email Interview with Dr. Melinda Lull

-Raquel Bayle, PharmD Candidate, SFJ Wegmans School of Pharmacy Class of 2025.