Accessing and Assessing FDA data for new drugs

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Declarations: No conflicts of interest with any content

Fact:

Drug manufacturers know the most about their drugs, the FDA knows a little less and prescribers and clinicians know less than that

But, the labeling can now be a surprisingly fruitful area to look for information in 2025

The NEW ENGLAND JOURNAL of MEDICINE

October 29th, 2009

Perspective

OCTOBER 29, 2009

Lost in Transmission — FDA Drug Information That Never Reaches Clinicians

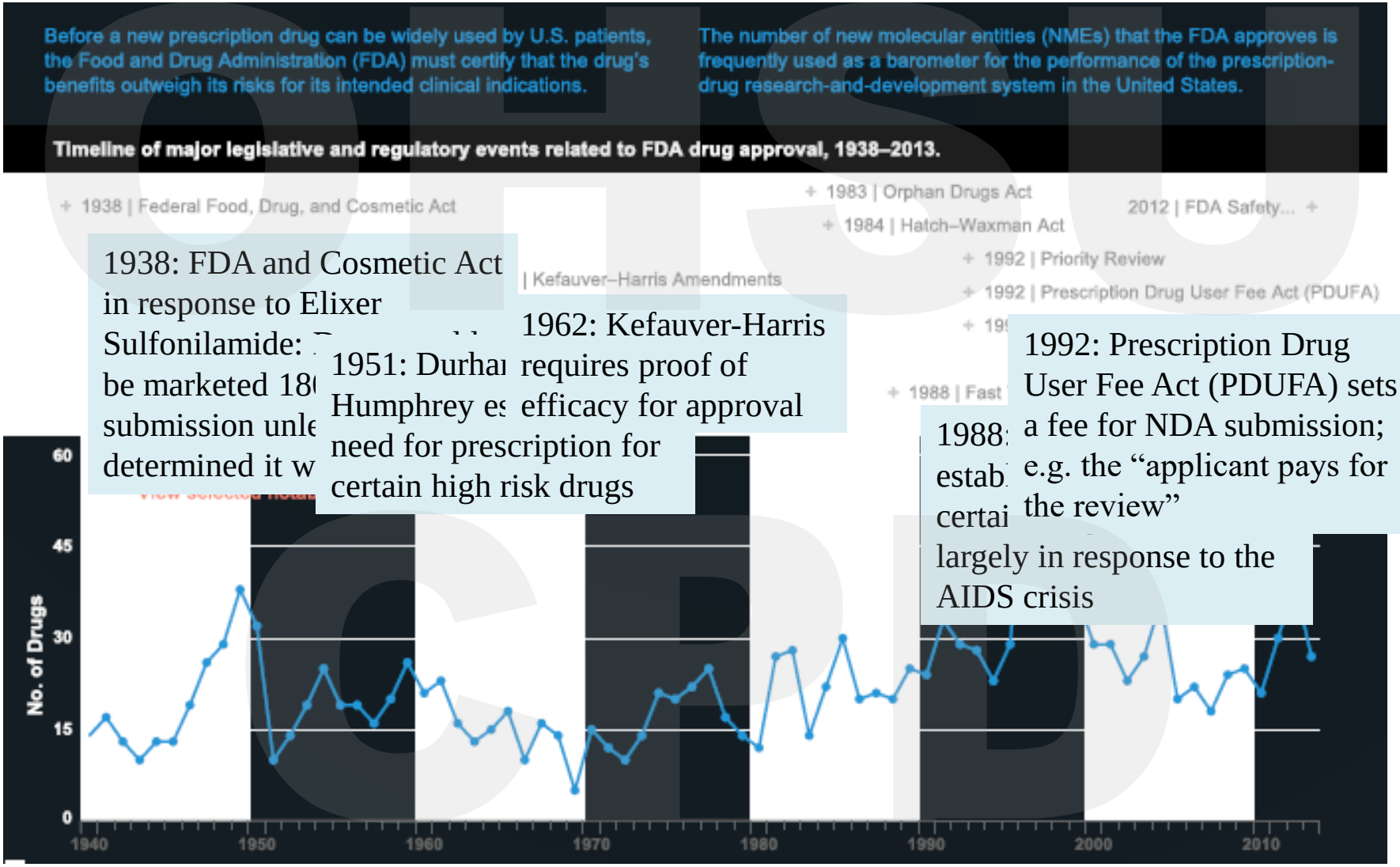
Lisa M. Schwartz, M.D., and Steven Woloshin, M.D.

"Drug labels are written by drug companies, then negotiated and approved by the FDA."

and therefore……

"Much critical information that the FDA has at the time of approval may fail to make its way into the drug label and relevant journal articles."

The number of drugs approved in U.S. every year is fairly stable



N Engl J Med; June 2014

HEALTH INC.

FDA Approves Drugs Faster Than Ever But Relies On Weaker Evidence, Researchers Find

January 14, 2020 · 11:03 AM ET
Heard on All Things Considered

SYDNEY LUPKIN

2-Minute Listen + PLAYLIST

FDA must be in the loop regarding studies intended to be used for U.S. labeling

Step 1: Animals investigated in "pre-clinical" phase of drug development

Step 2: Investigational New Drug (IND) application filed. The company often seeks advice from FDA and "must show the FDA what they plan for human testing."

n <100

Step 3: Phase 1 testing in healthy, volunteers to look for obvious toxicities (transaminitis, QTc prolongation, subjective symptoms, etc) and determine pharmacokinetics (peak concentrations, average half-life, etc) for purposes of establishing dose

n=100
-500

Step 4: Phase 2 testing to look for efficacy. Patients with condition are studied. Surrogate endpoints common (A1C, systolic BP, LDLc)

N=1000
-3000

Step 5: Phase 3 testing typically after consultation with FDA to look for clinical endpoints. Different dosages and often combinations of drugs are studied.

Once Phase I, II and III research completed, the "molecular entity" becomes a "drug" with hopes for $$billions in sales:

NDA: New Drug Application submitted with all pre-clinical and clinical data. The FDA has 60 days to decide whether to review. Goal is to complete 90% of reviews within 10 months of acceptance of submission.

Phase 4, post-marketing surveillance is "required" but is an area of much criticism for drug manufacturers. The FDA is more often requiring specific Phase 4 research to be conducted

What is still less than ideal about this process?

1. Labeling being initially drafted by the manufacturer is not ideal
2. Drugs which don't get approved don't have to release any of their clinical trial data into the public realm. It remains proprietary with the manufacturer and not even subject to FOIA requests.
3. Drugs that do get approved don't have to publish the data they don't like
4. The FDA is little concerned with magnitude of effect – the drug just needs to be superior to placebo or, no worse than a standard of care
5. Historically, CMS has been obligated to cover any drug approved by the FDA, although much of that is mediated through insurers

Jan. 17, 2008

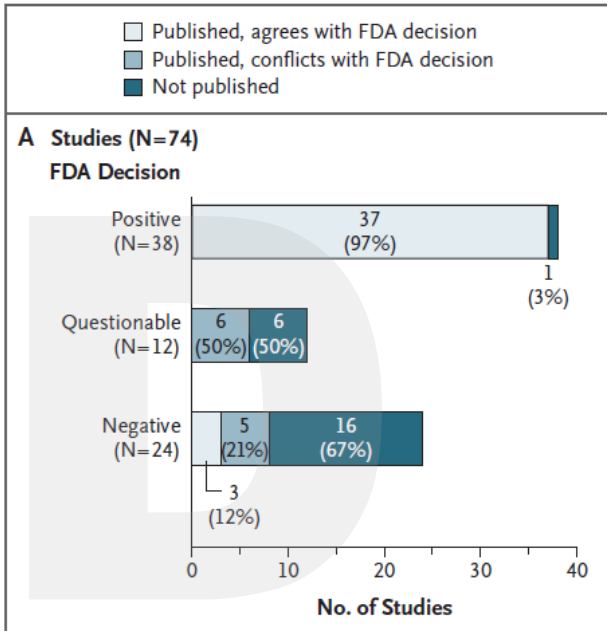
SPECIAL ARTICLE

Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy

Erick H. Turner, M.D., Annette M. Matthews, M.D., Eftihia Linardatos, B.S., Robert A. Tell, L.C.S.W., and Robert Rosenthal, Ph.D.

Table 1. Overall Publication Status of FDA-Registered Antidepressant Studies.

Publication Status	No. of Studies (%)	No. of Patients in Studies (%)
Published results agree with FDA decision	40 (54)	7,272 (58)
Published results conflict with FDA decision (published as positive)	11 (15)	1,843 (15)
Results not published	23 (31)	3,449 (27)
Total	74 (100)	12,564 (100)



So…..our comprehensive literature search would lead us to believe that antidepressants are very effective: Of 51 published trials, 37 would have been positive and 3 negative

So, given some persistent glitches in U.S. drug approval process, the FDA has responded to pressure to improve labeling…..let's look ….www.fda.gov

Highly Pathogenic Avian Influenza (HPAI)

FDA's Response to Ensure Continued Effectiveness of Federal-State Milk Safety System

Know When and How to Use Antibiotics, and When to Skip Them

Antibiotics are powerful medications that save countless lives every day. But they're not the answer for every illness.

FDA Modernization Efforts for Establishing a Unified Human Foods Program

The unified Human Foods Program, a new model and name for field operations and other modernization efforts are now in effect.

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Drugs

The Center for Drug Evaluation and Research (CDER) ensures that safe and effective drugs are available to improve the health of the people in the United States

Regulating and Approving Drugs Video Series

FDA uses science and data to ensure that approved drugs are of a high quality, safe, and effective. Learn more about the FDA's role in reviewing, approving, and monitoring drugs in the latest videos that are now available in Spanish.

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Find information about most FDA-approved prescription, generic, and over-the-counter drug products.

Drug Shortages
Find information about drug shortages caused by manufacturing and quality problems, delays, and discontinuations.

National Drug Code Directory Search
Find information about finished drug products, unfinished drugs, and compounded drug products.

Orange Book
The Orange Book identifies drug products approved by FDA on the basis of safety and effectiveness.

Can also generally Google “FDA PI and drug _____”

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Search by Drug Name, Active Ingredient, or Application Number*

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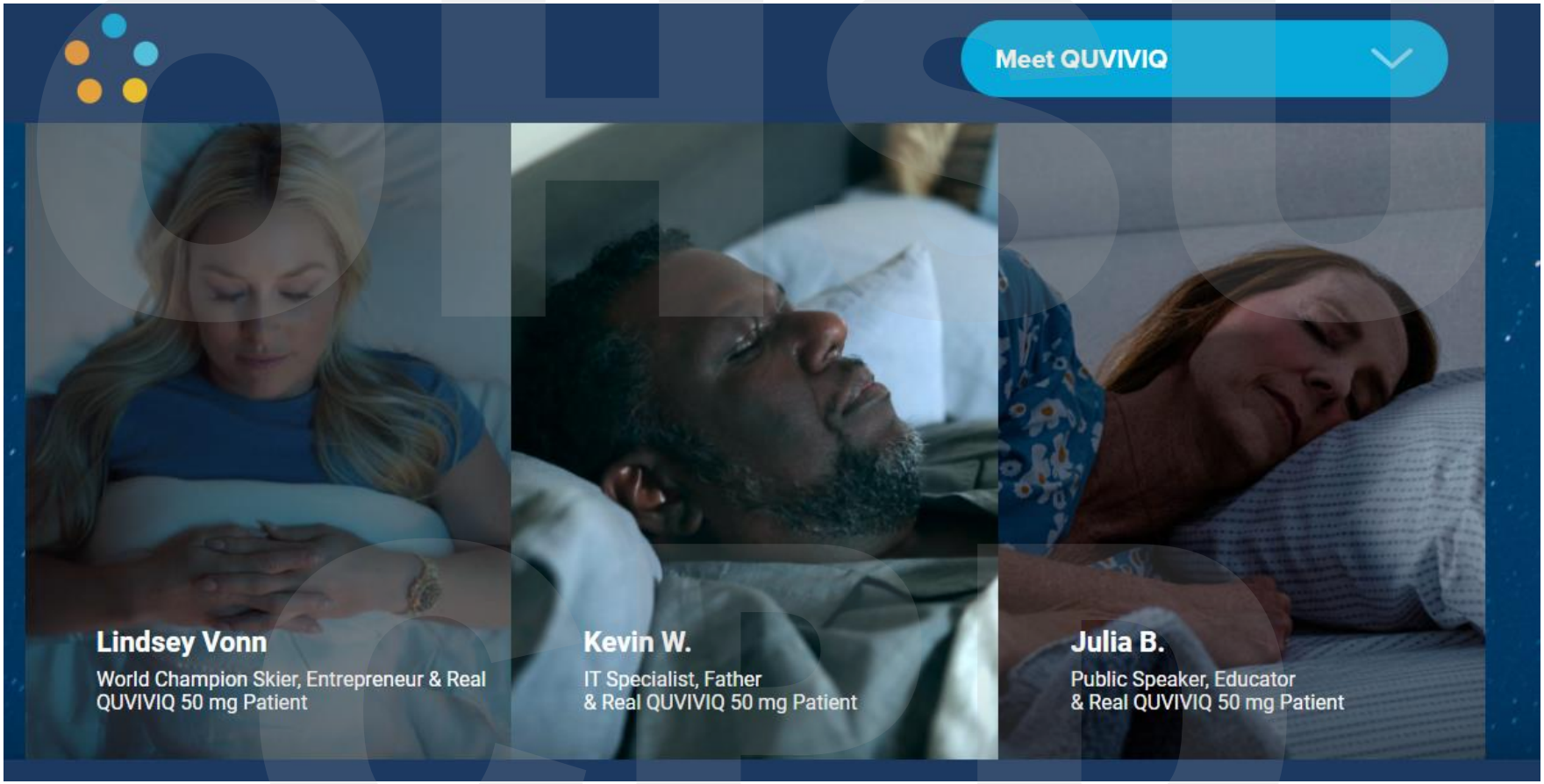
Lindsay Vaughn Sleep Med ad….



New Drug Application (NDA): 214985
Company: IDORSIA

EMAIL

- Medication Guide

Products on NDA 214985

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
QUVIVIQ	DARIDOREXANT HYDROCHLORIDE	EQ 25MG BASE	TABLET;ORAL	Prescription	None	Yes	No
QUVIVIQ	DARIDOREXANT HYDROCHLORIDE	EQ 50MG BASE	TABLET;ORAL	Prescription	None	Yes	Yes

Approval Date(s) and History, Letters, Labels, Reviews for NDA 214985

Labels for NDA 214985

Labels for NDA 214985

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/30/2024	SUPPL-12	Labeling-Package Insert	Label (PDF)	
09/30/2024	SUPPL-11	Efficacy-Labeling Change With Clinical Data	Label (PDF)	
09/30/2024	SUPPL-10	Efficacy-Labeling Change With Clinical Data	Label (PDF)	
10/30/2023	SUPPL-8	Labeling-Package Insert	Label (PDF)	
10/30/2023	SUPPL-7	Labeling-Package Insert	Label (PDF)	
03/24/2023	SUPPL-4	Labeling-Package Insert	Label (PDF)	
03/24/2023	SUPPL-4	Labeling-Medication Guide	Label (PDF)	
11/08/2022	SUPPL-2	Labeling-Medication Guide	Label (PDF)	
11/08/2022	SUPPL-2	Labeling-Package Insert	Label (PDF)	
01/07/2022	ORIG-1	Approval	Label (PDF)	

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use QUVIVIQ safely and effectively. See full prescribing information for QUVIVIQ.

QUVIVIQ (daridorexant) tablets, for oral use, CIV
Initial U.S. Approval: 2022

----------RECENT MAJOR CHANGES----------

Contraindications (4)	10/2023
Warnings and Precautions (5.5)	9/2024

----------INDICATIONS AND USAGE----------

QUVIVIQ is an orexin receptor antagonist indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. (1)

----------DOSAGE AND ADMINISTRATION----------

- The recommended dosage is 25 mg to 50 mg once per night, taken orally within 30 minutes before going to bed, with at least 7 hours remaining prior to planned awakening. (2.1)
- Time to sleep onset may be delayed if taken with or soon after a meal. (2.1)
- Hepatic Impairment: (2.3)
  - Moderate hepatic impairment: Maximum recommended dosage is 25 mg no more than once per night.
  - Severe hepatic impairment: Not recommended.

----------DOSAGE FORMS AND STRENGTHS----------

Tablets: 25 mg, 50 mg. (3)

----------CONTRAINDICATIONS----------

- Narcolepsy. (4)
- Known hypersensitivity to daridorexant or other components of QUVIVIQ. (4)

----------WARNINGS AND PRECAUTIONS----------

- CNS-Depressant Effects and Daytime Impairment: Impairs alertness and motor coordination including morning impairment. Risk increases when used with other central nervous system (CNS) depressants. For patients taking QUVIVIQ, caution against next-day driving and other activities requiring complete mental alertness. (5.1)
- Worsening of Depression/Suicidal Ideation: Worsening of depression or suicidal thinking may occur. (5.2)
- Sleep Paralysis, Hypnagogic/Hypnopompic Hallucinations, and Cataplexy-like Symptoms: May occur with use of QUVIVIQ. (5.3)
- Complex Sleep Behaviors: Behaviors including sleepwalking, sleep driving, and engaging in other activities while not fully awake may occur. Discontinue immediately if complex sleep behavior occurs. (5.4)
- Compromised Respiratory Function: Effect on respiratory function should be considered. (5.5, 8.7)
- Need to Evaluate for Co-morbid Diagnoses: Reevaluate if insomnia persists after 7 to 10 days. (5.6)

----------ADVERSE REACTIONS----------

The most common adverse reactions (reported in ≥ 5% of patients treated with QUVIVIQ and at an incidence ≥ than placebo) were headache and somnolence or fatigue. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Idorsia Pharmaceuticals Ltd at toll-free phone 1-833-400-9611 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

- Strong CYP3A4 inhibitors: Avoid concomitant use. (2.2, 7.1)
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See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 9/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

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14 CLINICAL STUDIES

14.1 Controlled Clinical Studies

The efficacy of QUVIVIQ was evaluated in two multicenter, randomized, double-blind, placebo-controlled, parallel-group studies, Study 1 (NCT03545191) and Study 2 (NCT03575104).

A total of 1854 patients with Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5®) insomnia were randomized to receive QUVIVIQ or placebo once daily, in the evening, for 3 months. Study 1 randomized 930 subjects to QUVIVIQ 50 mg (N = 310), 25 mg (N = 310) or placebo (N = 310). Study 2 randomized 924 subjects to QUVIVIQ 25 mg (N = 309), 10 mg (N = 307), or placebo (N = 308). The 10 mg dose is not an approved dose.

In Study 1, patients had a mean age of 55.4 years (range 18 to 88 years), with 39.1% of subjects ≥ 65 years of age, including 5.8% ≥ 75 years of age. Patients were identified as female or male and by US census-based racial and ethnic categories. The percentages of patients in the respective categories were: female sex (67.1%), White (90%), Black or African American (8%), Asian (1.0%), or Other race (< 1%).

In Study 2, patients had a mean age of 56.7 years (range 19 to 85 years), with 39.3% of subjects ≥ 65 years of age, including 6.1% ≥ 75 years of age. Patients were identified as female or male and by US census-based racial and ethnic categories. The percentages of patients in the respective categories were: female sex (69.0%), White (88%), Black or African American (8%), Asian (4%), or Other race (< 1%).

Then you can pause and ask yourself some questions – What outcomes would I hope to see measured (what matters to patients?)? What adverse effects would I want to know about to help inform a decision to prescribe? For a sleep aid specifically……

How would you do a sleep study objectively? Can you trust a home diary? Do I need to house patients for 1 week to study objectively? Two weeks? A month? What measurements do I collect?
If patients look like they're resting comfortably, are they asleep? Should peaceful rest count?

These sorts of questions are why the FDA wants to be informed and notified of potential studies for U.S. labeling BEFORE the studies are performed

Primary efficacy endpoints for both studies were the change from baseline to Month 1 and Month 3 in Latency to Persistent Sleep (LPS) and Wake After Sleep Onset (WASO), measured objectively by polysomnography in a sleep laboratory. LPS is a measure of sleep induction and WASO is a measure of sleep maintenance.

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From the NEJM "Perspective" on lack of FDA drug information in labeling:

NEJM, Oct. 29, 2009

Data on Efficacy That Do Not Appear in the Label for Lunesta (Eszopiclone) for Chronic Insomnia in Adults.

2004 Drug label: clinical trials section (the only efficacy statement in label)*

"Adults with chronic insomnia (N=788) were evaluated using subjective measures in a double-blind, parallel group trial comparing the safety and efficacy of Lunesta 3 mg with placebo administered nightly for 6 months. Lunesta was superior to placebo on subjective measures of sleep latency, total sleep time and WASO [wake time after sleep onset]."

* The label also reports that Lunesta is better than placebo in two sleep laboratory studies but provides no data.

FDA Review Document: Phase 3 Study Results†	Placebo	Lunesta 3 mg
Fall asleep 15 min faster (median sleep latency)	45 min	30 min
Sleep 37 min longer (median total sleep time)	5 hr 45 min	6 hr 22 min
Spend 9 min less time awake after initially falling asleep (median WASO)	30 min	21 min

† The effects were measured by means of a sleep diary.

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Revised: 9/2024

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Table 4 Primary and Secondary Efficacy Results for Change from Baseline in Sleep Onset, Sleep Maintenance, and Subjective Total Sleep Time at Month 1 and Month 3 in Patients with Insomnia (Study 1)

Treatment group/ dose (N)	Baseline	Month 1			Month 3		
	mean (SD)	mean (SD)	Change from baseline LSM (95%CL)	Difference to placebo LSM (95%CL)	mean (SD)	Change from baseline LSM (95%CL)	Difference to placebo LSM (95%CL)
WASO (wake after sleep onset, min): sleep maintenance, assessed by PSG							
50 mg (310)	95 (38)	65 (35)	-29 [-33, -25]	-23* [-28, -18]	65 (39)	-29 [-33, -25]	-18* [-24, -13]
25 mg (310)	98 (39)	77 (42)	-18 [-22, -15]	-12* [-17, -7]	73 (40)	-23 [-27, -19]	-12* [-17, -6]
placebo (310)	103 (41)	92 (42)	-6 [-10, -2]		87 (43)	-11 [-15, -7]	
LPS (latency to persistent sleep, min): sleep onset, assessed by PSG							
50 mg (310)	64 (37)	34 (27)	-31 [-35, -28]	-11* [-16, -7]	30 (23)	-35 [-38, -31]	-12* [-16, -7]
25 mg (310)	67 (39)	38 (32)	-28 [-32, -25]	-8* [-13, -4]	36 (34)	-31 [-34, -27]	-8* [-12, -3]
placebo (310)	67 (40)	46 (36)	-20 [-23, -17]		43 (34)	-23 [-26, -20]	
sTST (subjective total sleep time, min): patient-reported							
50 mg (310)	313 (58)	358 (74)	44 [38, 49]	22* [14, 30]	372 (79)	58 [51, 64]	20* [11, 29]
25 mg (310)	310 (60)	345 (66)	34 [29, 40]	13* [5, 20]	358 (72)	48 [41, 54]	10* [1, 19]
placebo (310)	316 (53)	338 (65)	22 [16, 27]		354 (73)	38 [31, 44]	

* doses that were statistically significantly superior ($p < 0.05$) to placebo after controlling for multiple comparisons.

CL = confidence limit; LPS = latency to persistent sleep; LSM = least squares mean; PSG = polysomnography; SD = standard deviation; sTST = subjective total sleep time; WASO = wake after sleep onset.

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What would I expect for ADRs from a sleep aid? What would I want to see measured?

6 ADVERSE REACTIONS

Most Common Adverse Reactions

The most common reported adverse reaction (in at least 5% of patients and greater than placebo) during double-blind treatment in Study 1 was headache.

Table 1 shows adverse reactions that occurred in at least 2% of patients treated with QUVIVIQ and more frequently than in patients who received placebo in Study 1.

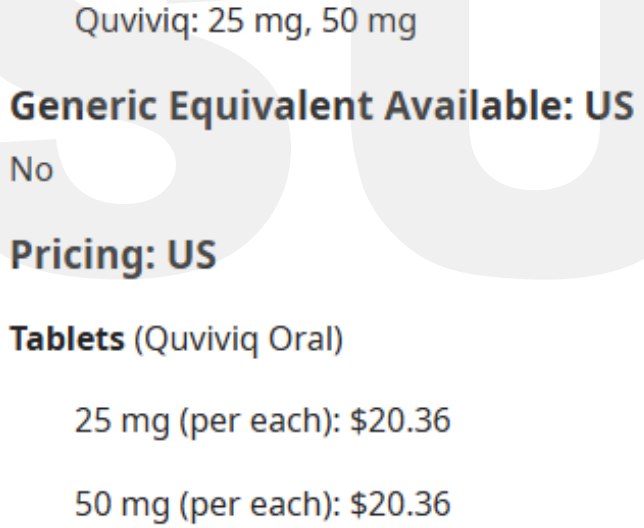
Table 1 Adverse Reactions Reported in ≥ 2% of QUVIVIQ-treated Patients and Greater than in Placebo-treated Patients in a 3-Month Placebo-Controlled Study (Study 1)

	QUVIVIQ 25 mg (N=310) %	QUVIVIQ 50 mg (N=308) %	Placebo (N=309) %
Nervous System Disorders			
Headache*	6	7	5
Somnolence or fatigue*	6	5	4
Dizziness*	2	3	2
Gastro-intestinal disorders			
Nausea*	0	3	2

*The following terms were combined:
Headache includes: headache, tension headache, migraine, migraine with aura, head discomfort
Somnolence or fatigue includes: somnolence, sedation, fatigue, hypersomnia, lethargy
Dizziness includes: dizziness, vertigo, labyrinthitis
Nausea includes: nausea, vomiting, procedural nausea

So what do we think of QUVIVIQ?

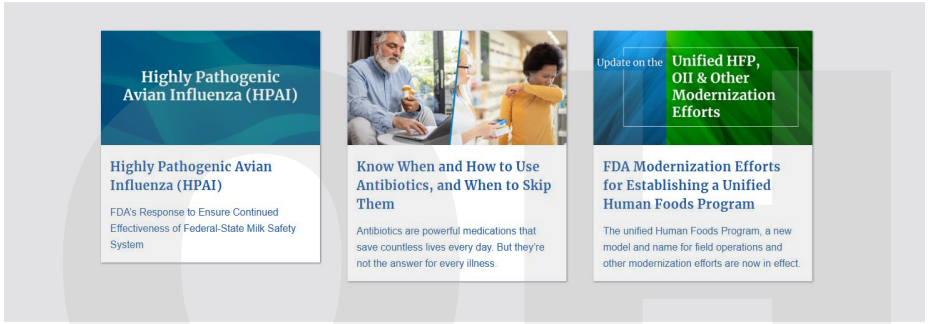
What would we pay for it if it was out-of-pocket?

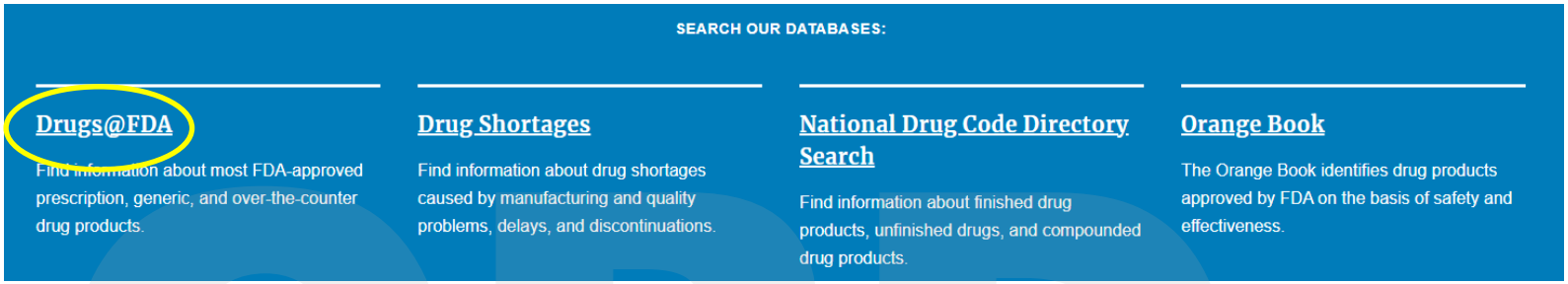


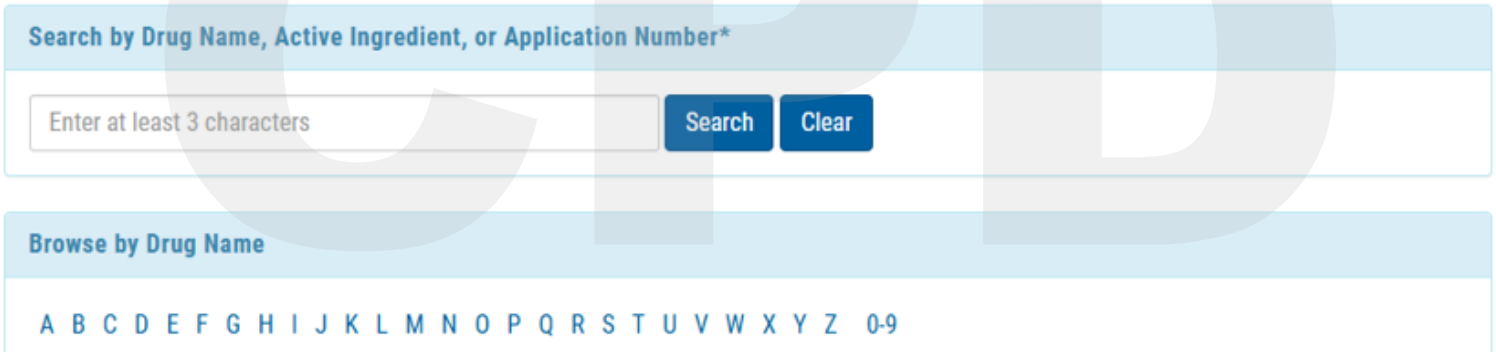
Should insurers make it highly available (tier 1 status? Low co-pay?) or put restrictions in place to limit use (high tiering, require other agents be tried first? High co-pay?)

So, FDA labeling has improved in the past 2 decades but quality of the drugs approved still varies

www.fda.gov







So, pick your favorite new drug and start exploring. And if you see a drug ad on TV that you decide is misleading….

The Bad Ad Program

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Reporting:

To report potentially false or misleading prescription drug promotion:

- Email: BadAd@fda.gov
- Call toll-free 855-RX-BADAD or 855-792-2323

Thank you. Questions anytime

Craig Williams, PharmD
williacr@ohsu.edu