

FDA

**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DRUG EVALUATION & RESEARCH
OFFICE OF CLINICAL PHARMACOLOGY

Bridging Drug Efficacy and Safety to the Obese: Considerations and Scientific Approaches

FDA-MCERSI Workshop

November 9th, 2022

This presentation represents the personal opinions of the speaker and does not necessarily represent the views of the FDA.



INTRODUCTION

- Prevalence of obesity has reached epidemic proportions globally. It is estimated that more than 1 billion adults are overweight, of whom at least 300 million are clinically obese;
- During the past 20 years, there has been a dramatic increase in obesity in the United States affecting both children and adults.

INTRODUCTION

- Obesity is associated with comorbidities such as diabetes, hypertension, cardiovascular disease, respiratory failure, cancer etc.
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- Major health and socioeconomic implications
- Individuals with obesity (BMI >30 kg/m²) have been reported to have higher mortality rates as compared to non-obese
- Obese patients exhibit different physiology including changes in regional blood flow, and increases in cardiac output, fat mass, and lean mass all of which can significantly affect drug disposition
- **These pathophysiological changes can lead to alterations in the pharmacokinetics (PK) and pharmacodynamics (PD) of drug products that, in turn, call for potential dosage regimen adjustments in both the adult and pediatric obese populations**

INTRODUCTION



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Drug Dosages Often Incorrect For Obese Patients

Date: November 16, 2007
Source: Oregon State University

Summary: As if severely overweight people didn't already have enough health concerns, experts are raising another red flag -- the possibility that some of their prescription medications, especially antibiotics, may not be prescribed at the appropriate dosage and could be ineffective.

Obesity is in the news!

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Health care costs steadily increase with body mass

Date: December 16, 2013
Source: Duke Medicine

Summary: Researchers are giving people another reason to lose weight in the new year: obesity-related illnesses are expensive. According to a study published, health care costs increase in parallel with body mass measurements, even beginning at a recommended healthy weight.

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Prescription drug labels provide scant dosing guidance for obese kids

Progress seen in pediatric drug labeling, but more dosing guidance needed for obese children

INTRODUCTION



- Obese patients are not routinely included in drug development programs
- There are no regulatory requirements at present to study obese population as a special population

WORKSHOP GOALS

The goals of this workshop are:

- (1) To review the implications of obesity on drug disposition in adult and pediatric patients

- (2) Discuss:
 - a. If adult and pediatric patients should be identified and studied as a specific patient population in new drug development programs

 - b. When it may be appropriate to include obese patients in drug development studies to develop specific dosing guidelines for this population

WORKSHOP AGENDA

- **8:25 am - 8:40 am** *Opening remarks*
- **Robert M. Califf, M.D.**,
Commissioner of Food and Drugs
Office of the Commissioner, FDA
- Morning session:
 - Obesity as a public health problem;
 - Approaches to specific patient populations in drug development;
 - Use of modeling for drugs in obese patient populations;
 - Case examples
- Afternoon session:
 - Obesity in pediatric patient populations and drug development considerations
 - Panel discussion
- Wrap up
 - **Dr. Issam Zineh**, Director, Office of Clinical Pharmacology



WORKSHOP PLANNING COMMITTEE

- FDA
 - Althea Cuff, MS, Senior Regulatory Health Project Manager, CDER, OCP
 - Varsha Mehta, Pharm.D., MS., Senior Staff Fellow, CDER, OCP
 - Gilbert Burckart, Pharm.D, CDER, OCP
 - Jaya Vaidyanathan, Ph.D., CDER, OCP
 - Hao Zhu, Ph.D., CDER, OCP
 - Amal Ayyoub, Ph.D., CDER. OCP
 - Lauren Milligan, Staff Fellow, CDER, OCP

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 - J Gobburu, Ph.D., University of MD
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