

Opening Remarks for Drug Safety and Risk Management Advisory Committee Meeting

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Recap of Day 1

- Day 1 discussion focused on:
 - The FDA’s framework for selecting strategies to manage the teratogenic risk of drug products
 - The “at-risk” populations for teratogenicity
 - The benefits and drawbacks of targeting a REMS to only the “at-risk” populations
 - The risk management approach for a teratogenic drug when it is used to treat different medical conditions

Objective of Today's Meeting

- FDA will solicit the Committee's views on the risk management tools for contraception use and pregnancy testing that should be considered when dealing with teratogenic drug products.

Background

- CDER's recommendations for contraception use and pregnancy testing has varied.
 - Recommendations have been very specific for some drugs, and more general for others
 - Not clear how much information, if any, should be provided

Today's Agenda

- Begin with an update on the Agency efforts to standardize REMS
 - May apply to certain risk management tools
- Focus on two common risk management tools used to help manage the risk of teratogens
 - Contraception use
 - Pregnancy testing
- Discuss strategies for communicating information to
 - Patients
 - Health care providers
- Invited speaker will provide an overview of current practice re: pregnancy planning and prevention counseling and assessment of most helpful tools

Committee Discussion

- Discuss whether FDA should be making contraception use recommendations for patients taking a teratogenic drug.
- Discuss what contraception use information in drug labeling and/or REMS materials FDA should provide for patients and providers.
- Discuss whether FDA should be making pregnancy testing recommendations for patients taking a teratogenic drug.
- Discuss the period of time within which pregnancy testing should be performed and the type of test that should be used.

- This meeting involves issues of a general matter and will not include an in-depth discussion of:
 - Any drug-specific information
 - Specific examples will be provided, but the discussion should not focus on any one drug
 - The proposed pregnancy labeling rule
- We look forward to the discussion

Overview of REMS Standardization Efforts at FDA

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Objectives

1. Describe FDA's current thinking on REMS standardization.
2. Illustrate how this thinking can be applied to questions of teratogenic risk management.
3. Briefly describe our approach to REMS standardization going forward.

PDUFA V Standardization Commitments

Under its PDUFA V commitments, FDA has agreed to seek to integrate REMS into the existing and evolving healthcare system.

- By October 2013:
 - Hold public meeting(s) on REMS standardization with the goal of reducing REMS burden.
- By the end of 2013:
 - Issue a report of our findings.
 - Identify priority projects in several areas.

Why do REMS vary?

CDER seeks to preserve necessary variation in REMS while minimizing unnecessary variation.

REMS may vary for a number of reasons:

1. Risks vary.

- REMS are designed to address specific serious risks, and the steps needed to mitigate these risks will vary.

2. REMS goals vary

- Some REMS seek only to inform, others to change behavior in a specific way.

Why do REMS vary?

3. The context of care varies.
 - Different REMS drugs are used by different providers in different healthcare settings and different patient populations.
4. Knowledge about establishment of REMS goals and requirements has evolved.
 - Our approach to establishing REMS goals and objectives has evolved over time.

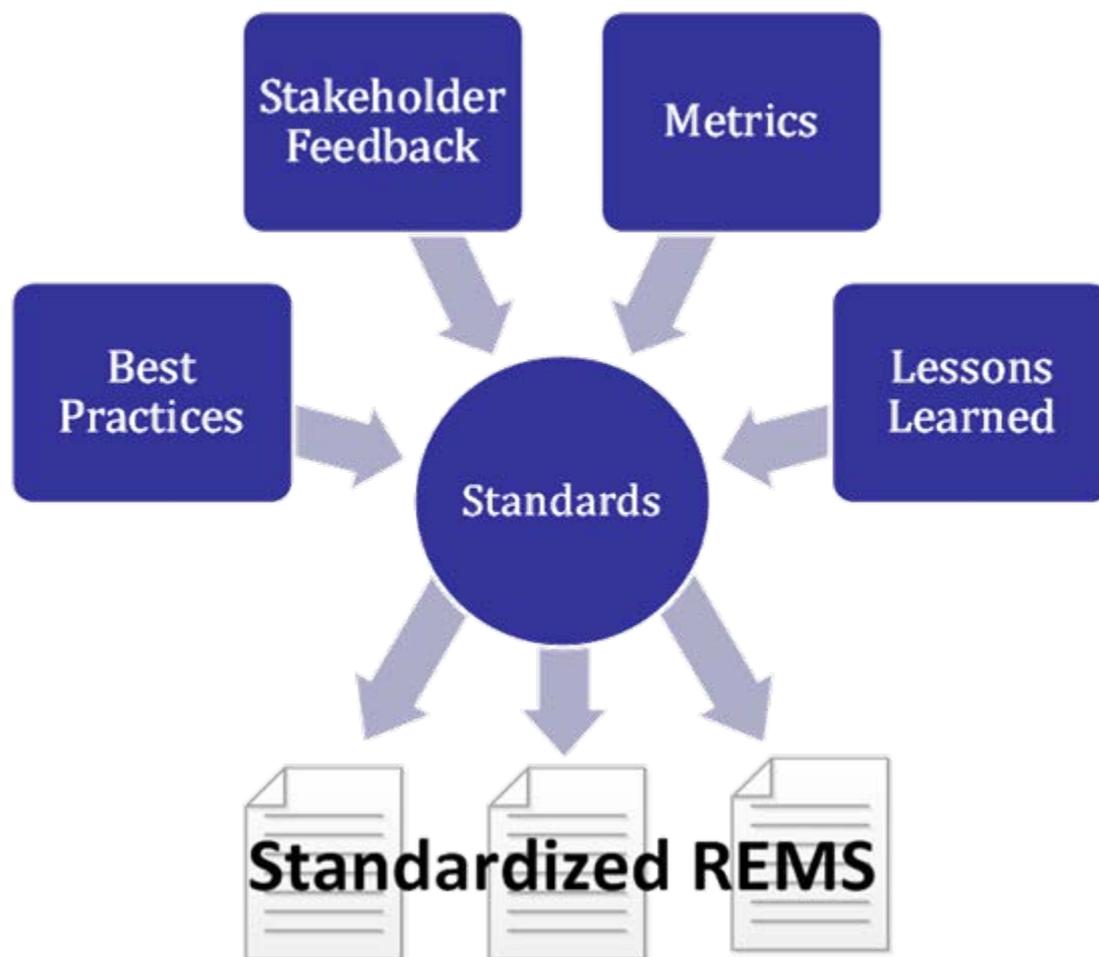
Why do REMS vary?

5. The science of pharmaceutical risk mitigation is comparatively new and continues to evolve, and REMS “best practices” are still being developed.
 - Even when REMS goals are consistent, there may still not be agreement on the best way to meet that goal.
6. REMS are developed through negotiations between FDA review teams and sponsors.
 - FDA specifies the general elements a REMS needs to contain, and the sponsor develops the REMS.
 - Specifics of the REMS are negotiated between FDA and the sponsor and approved if deemed adequate.

REMS Standardization achieves two goals

1. REMS standardization can help eliminate unnecessary variation between REMS programs
2. Standardization allows us to identify and implement “best practices” that make REMS...
 - Less burdensome.
 - Better integrated into the healthcare system.
 - More effective.
 - Easier to assess.
 - More helpful to stakeholders.

How standardization improves REMS quality



Standardization leads to REMS that:

- Follow best practices
- Incorporate stakeholder feedback
- Use common metrics
- Take lessons learned from previous REMS

Principles Guiding REMS Standardization

In summary, the following principles can serve as a guide for FDA's REMS Standardization efforts:

- Be informed by best practices.
 - Base standards on the best evidence of what works in the real world.
- Work iteratively.
 - Allow standards to evolve over time as the science of pharmaceutical risk management evolves and we learn more about best practices.

Principles Guiding REMS Standardization

- Be flexible.
 - Tailor standards to specific risks and contexts of use.
 - Encourage new and innovative risk management approaches.
- Listen to stakeholders.
 - Work collaboratively with patients, practitioners, industry, and outside experts to identify best practices.

Our work going forward

I. Standardize our approach to selecting REMS interventions.

- Use standardized methods to assess and characterize risks to help select appropriate REMS tools or interventions.

II. Standardize how REMS interventions are designed.

- Identify best practices in designing and implementing REMS interventions and minimizing unnecessary variation.

Our work going forward

III. Integrate REMS into existing systems.

- Identify new ways to integrate REMS into existing systems.
- Work with external stakeholders and standards-development organizations (SDOs) where needed.

To achieve this, we will continue to seek out stakeholder and expert input.

Contraception and Pregnancy Testing

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FDA

Agenda: Contraception and Pregnancy Testing

- Overview of available contraception methods
- Emergency Contraception and Abstinence
- Factors that affect contraception recommendations
 - Effectiveness Rates
 - Safety Data
 - Other Factors
- Pregnancy Testing
 - Urine
 - Serum

Overview of available contraception methods

- Hormonal Methods
 - Oral Contraceptives
 - Combined Oral Contraceptives
 - Progesterone only
 - Transdermal patch
 - Vaginal ring
 - Injection
- Intrauterine devices and Implant /Long acting reversible contraception
 - Copper IUD, progesterone IUD (i.e., levonorgesterel IUD)
 - Subdermal implant (progesterone)

Overview of available contraception methods

- Barrier Methods
 - Male condom
 - Female condom
 - Diaphragm
 - Cervical cap
 - Sponge

Emergency Contraception and Abstinence

- Emergency Contraception
 - Not considered a first line method of contraception
 - Available in case of primary contraception method failure or unprotected intercourse
- Abstinence
 - Complete abstinence results in no pregnancy
 - Periodic abstinence associated with 25% failure rate



How to choose a method ?



Factors that affect Contraception Recommendations

- Typical Use Effectiveness Rate
 - lower than “perfect use” rate
 - user dependent factors: correct and consistent use
- Medical conditions and/or co-morbidities*
 - smoking
 - chronic/acute medical conditions
 - age
- Adverse reactions
- Drug-drug (contraceptive) interactions
 - resulting in possible decrease in contraceptive efficacy

**U.S Medical Eligibility Criteria for Contraceptive Use 2010 CDC MMWR;59:1-86*

Factors that affect Contraception Choice

- Noncontraceptive benefits
- Patient compliance
- Personal preference
- Patient access/convenience

Typical Use Failure Rates for Contraceptive Methods

- Hormonal Methods: (6%-9% failure rate in 1st year)
 - oral contraceptive pills
 - transdermal patch
 - vaginal ring
 - injection
- Barrier method: (12%-25% failure rate in 1st year)
 - male condom
 - female condom
 - diaphragm
 - cervical cap
 - sponge

Failure Rates for Sterilization and Long-Acting Reversible Contraception

- Permanent: (<1% failure rate in 1st year)
 - Female sterilization
 - Male sterilization
- Reversible: (<1% failure rate in 1st year)
Long-acting reversible contraception (LARC)
 - IUDs: copper, levonorgesterel IUD (LNg)
 - Implant

Summary of typical use effectiveness of contraceptive methods

More effective



<1 pregnancy per 100 women in first year:

Vasectomy, female sterilization, implant and IUDs

6-9 pregnancies per 100 women in first year:

Hormonal methods

12-25 pregnancies per 100 women in first year:

Barrier methods and Fertility awareness

Less effective

Adapted from WHO 2007 Family Planning Handbook and
Hatcher R, Trussel J. et al. Contraceptive Technology 2011

Serious Safety Risks of Contraception Methods

- Combination estrogen/progesterone methods
 - Pill, patch, vaginal ring
 - Venous thromboembolism (approx. 3-9 per 10,000 women years)
 - Myocardial infarction, stroke in smokers, >35, hypertensive
- Progesterone only methods
 - Progesterone only pill
 - No serious safety risks*
 - Injection
 - Decrease in bone mineral density with prolonged use
 - Implant
 - No serious safety risks*

*limited data

Serious Safety Risks of Contraception Methods

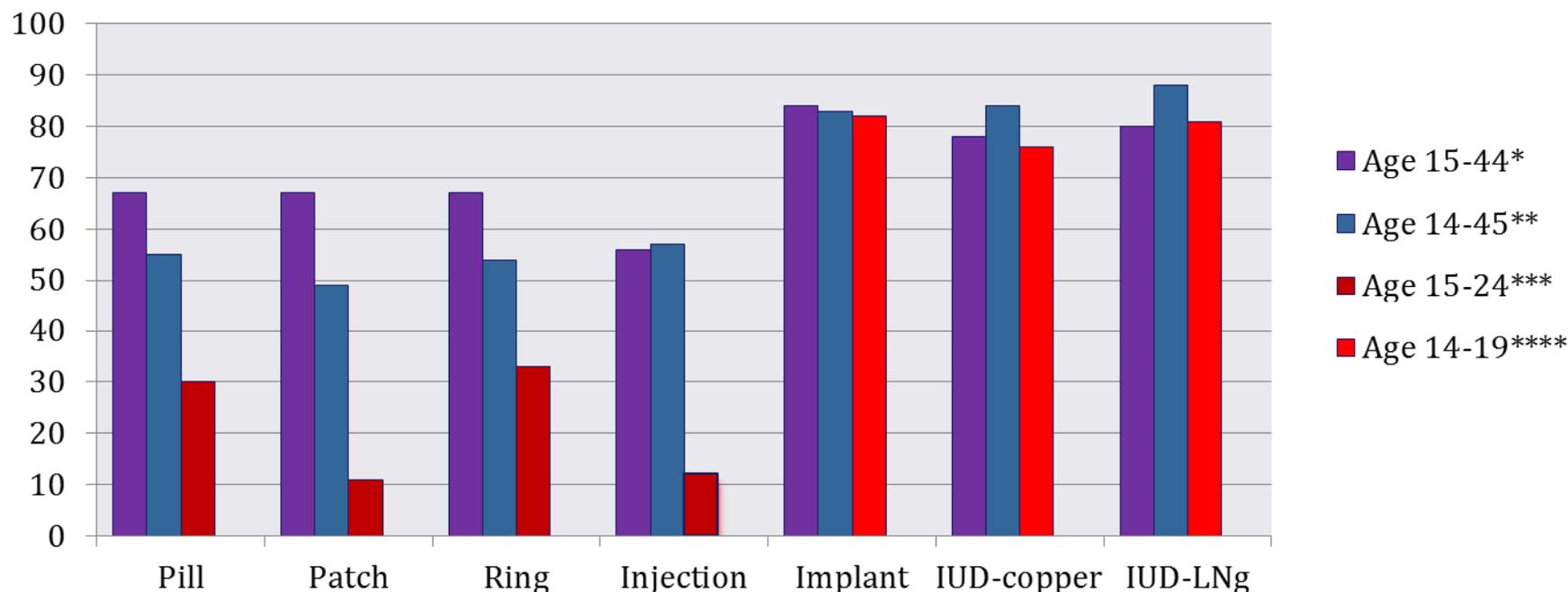
- IUDs
 - Perforation of uterus (1/1,000)
 - Pelvic inflammatory disease (1/1,000)
- Barrier methods
 - Latex condom, diaphragm: anaphylaxis
 - Diaphragm, sponge and cap:
 - toxic shock syndrome if prolonged placement

Adverse Reactions

- Combination estrogen/progesterone methods
 - Pill, patch, vaginal ring: Headache, nausea, menstrual irregularities
- Progesterone only methods
 - Progesterone only pill: Menstrual irregularities
 - Injection: Menstrual irregularities, weight gain
 - Implant: Menstrual irregularities, weight gain, insertion and removal problems
- IUDs
 - LNg IUD: Menstrual irregularities
 - Copper IUD: Cramping, bleeding problems
- Barrier methods
 - Local irritation, allergy

Other Factors that affect Contraception Recommendations

Continuation Rates at one year



*Hatcher R, Trussel J. et al. Contraceptive Technology 2011

**Peipert J, Zhao Q. et al. Continuation and Satisfaction of Reversible Contraception. Obstet Gynecol 2011;117:1105-13.

***Raine T, Foster-Rosales A. et al. One-Year Contraceptive Continuation and Pregnancy in Adolescent Girls and Women Initiating Hormonal Contraceptives. Obstet Gynecol 2011;117:363-71.

****Rosenstock JR, Peipert J, et al. Continuation of Reversible Contraception in Teenagers and Young Women. Obstet Gynecol 2012;120:1298-305.

Summary: Goal of Contraception Recommendations

- For the purpose of prevention of unintended exposure to a teratogen:

< 1% failure rate

Not user dependent

Good safety profile

Well tolerated

Ideally, can be accomplished with one method

If one method is not possible, what is the most appropriate strategy?

Pregnancy Testing Overview

- Pregnancy tests detect human chorionic gonadotropin (hCG)
 - qualitative tests: urine or serum
 - quantitative test: serum

Pregnancy Testing-Urine

- Highly sensitive and specific qualitative test : positive at the time of the missed period
- Detecting all pregnancies may require 5-7 days after missed period due to variable range of hCG in early pregnancy
- Urine tests commonly used for screening prior to medical procedures or prescribing medications
- Point of care and home tests have similar sensitivity
- Home tests subject to user error

Pregnancy Testing-Serum

- Serum qualitative test
- Serum quantitative test: specific hCG value
 - Can detect pregnancy 7-10 days earlier than urine test
 - Also used to follow trend of hCG levels in diagnosing:
 - Early pregnancy problems: ectopic pregnancy, spontaneous abortion
 - A viable pregnancy following assisted reproduction

Summary

- Currently available pregnancy tests are all highly sensitive
- Qualitative testing offers a yes/no answer
 - The urine test has advantages: easy to do, can be done in the office, and results immediately available
- Quantitative serum testing allows for earlier detection of the pregnancy
- However, all tests are limited by inability to detect all early pregnancies

Contraception Use and Pregnancy Testing In Management of Teratogens

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Outline

- Background: Contraception use and pregnancy testing in management of teratogens
- Findings from the retrospective review for contraception use and pregnancy testing
- Examples of contraception use and pregnancy testing recommendations from drug/biologic products

Background

- The goal of managing a teratogen is to prevent or minimize fetal exposure
 - Use of contraception to prevent pregnancy, avoiding fetal exposure
 - Use of pregnancy testing to identify fetus at risk for drug exposure

Background

- There are variations in product recommendations regarding contraception use and pregnancy testing
 - Many factors considered in deciding what contraception and pregnancy testing recommendations are necessary, that may contribute to the variations
- No established FDA policy/guidance regarding contraception use and pregnancy testing recommendations in managing teratogens
- Contraception use and pregnancy testing are potentially important risk management tools, but need to gain better understanding of how to best apply them

Retrospective Review

- Review of 17 currently approved products with teratogenic potential to examine teratogenic risk management approaches and considerations determining the approach
- Evaluated based on risk management approach
 - Labeling only (n=8)
 - Labeling plus a risk evaluation and mitigation strategy program (REMS) (n=9)

Retrospective Review: Contraception, Pregnancy Testing and Counseling Information

- Review included whether information was present for
 - Contraception use and/or
 - Pregnancy testing and/or
 - Counseling information
- Review included whether contraception use and/or pregnancy testing and/or counseling was recommended or required
- Indicated if drug access was dependent on documentation of contraception use and/or pregnancy testing outcomes

Labeling Only Outcomes

- Four of 8 products had no specific language for either Contraception use or Pregnancy testing
- The remaining four
 - 2 had only contraception use information
 - 2 had contraception use and pregnancy testing information
- Recommendations did not restrict access to drug
- Pregnancy testing not always recommended when contraception recommended

Labeling + REMS Outcomes

- Pregnancy testing and/or contraception use and/or counseling was:
 - Required for 5 products, patient access to drug **is** dependent on documentation of contraception use and results of pregnancy testing
 - Recommended for 4 products, patient access **not** dependent on documentation of contraception use and results of pregnancy testing

Summary Retrospective Review

- Retrospective review illustrates variations in:
 - Teratogenic risk management approach
 - Contraception use and pregnancy testing requirements and/or recommendations
 - Product specific contraception use/pregnancy testing/counseling information

Contraception Use and Pregnancy Testing Recommendations: Examples

- Three examples with different specific recommendations regarding contraception use/pregnancy testing/counseling
 - Thalomid (thalidomide)
 - Letairis (ambrisentan)
 - Erivedge (vismodegib)

Example 1- Thalomid (thalidomide)

- Indicated for treatment of newly diagnosed multiple myeloma; acute cutaneous manifestations of erythema nodosum leprosum, approved in 1998
- Known human teratogen with very public history
- Risk management information in product labeling and has a REMS program with restricted distribution
- Prescribed by specialists
- Small percentage of females of reproductive potential population for labeled indication

Thalomid (thalidomide): Pregnancy Testing

- Women of child bearing potential* should have a pregnancy test within 24 hours prior to starting drug (sensitivity of at least 50 mIU/mL)
- Pregnancy test done by doctor every week during the first 4 weeks of treatment
- Pregnancy test every 4 weeks there after, if monthly menstrual cycles regular
 - Or, pregnancy test every 2 weeks if monthly menstrual cycles irregular
 - Pregnancy test if missed period or have unusual menstrual bleeding

* Females of Reproductive Potential

Thalomid (thalidomide): Contraception Use

- Women of child bearing potential* must abstain continuously from heterosexual sexual contact or
- Use two methods of reliable contraception, including
 - at least one highly effective method (e.g., IUD, hormonal contraception [birth control pills, injections, hormonal patches, vaginal rings or implants], tubal ligation, or partner's vasectomy) and,
 - One additional effective method (e.g., male latex or synthetic condom, diaphragm, or cervical cap)

* Females of Reproductive Potential

Thalomid (thalidomide): Contraception Use

- Patients must use contraceptive method beginning
 - at least 4 weeks prior to initiating treatment, during therapy, and
 - continuing for at least 4 weeks following discontinuation of therapy
- If hormonal or IUD contraception is medically contraindicated, two other contraceptive methods may be used simultaneously

Thalomid (thalidomide): Contraception Use

- Male patients taking drug (including those with vasectomy) who have female partners of reproductive potential must either:
 - Completely abstain from sexual contact or,
 - Must always use a latex or synthetic condom during any sexual contact
- Provide contraception counseling with each new prescription prior to and during treatment

Example 2- Letairis (ambrisentan)

- Indicated for treatment of pulmonary arterial hypertension (PAH), approved in 2007
- An endothelin receptor antagonist (ERA) inhibitor with potential to affect fetal development
 - Positive animal data, consistent with known teratogenic effects of drug class
- Risk management information in product labeling and has a REMS program with restricted distribution
- High risk of increased morbidity and mortality for female patients with PAH during pregnancy
- Prescribed by specialists who treat PAH

Letairis (ambrisentan): Pregnancy Testing

- Pregnancy test should be obtained monthly in women of child bearing potential*
- Treat women of child bearing potential only after negative pregnancy test
- Pregnancy test must be ordered and reviewed by prescriber prior to initiation of drug and monthly during treatment
- If pregnancy is suspected for any reason, a pregnancy test must be performed

* Females of Reproductive Potential

Letairis (ambrisentan): Contraception Use

- Women of child bearing potential* must use highly reliable contraception during drug treatment and for one month after stopping treatment
 - If the patient has a tubal sterilization or chooses to use a Copper T 380A IUD or LNG 20 IUD for pregnancy prevention, no additional contraception is needed
 - Women who do not choose one of these methods should always use two acceptable forms of contraception
 - One hormone method and one barrier method, or two barrier methods where one method is the male condom
 - Partner's vasectomy must be used along with a hormone or barrier method
- * Females of Reproductive Potential

Letairis (ambrisentan): Contraception Use

- All women of child bearing potential* patients should undergo contraceptive counseling, with either the prescriber or another designated healthcare practitioner trained in contraceptive counseling
- Educate and counsel women of child bearing potential on the use of emergency contraception in the event of unprotected sex or known or suspected contraceptive failure

* Females of Reproductive Potential

Example 3-Erivedge (vismodegib)

- Indicated for treatment of metastatic basal cell carcinoma, approved in 2012
- A hedge hog pathway inhibitor, with potential to affect pathways essential in embryonic development
 - Positive signals in non-clinical animal studies
- Risk management information for contraception and pregnancy testing found in product labeling
- Small percentage of females of reproductive potential in the patient population for the labeled indication
- Prescribed by a specialists (oncologist)

Erivedge (vismodegib): Pregnancy Testing and Contraception Use

- Determine pregnancy status within 7 days prior to initiation of treatment in females of reproductive potential
- For females with a negative pregnancy test, initiate a highly effective form of contraception (failure rate of less than 1%) prior to the first dose
- Continue highly effective contraception during therapy and for 7 months after the last dose of drug

Erivedge (vismodegib): Pregnancy Testing and Contraception Use

- Male patients should use condoms with spermicide, even after a vasectomy, during sexual intercourse with female partners while being treated with drug and for 2 months after the last dose to avoid exposing an embryo or fetus to drug
- Counsel female and male patients regarding pregnancy prevention and planning

Summary of Key Points

	Thalomid	Letairis	Erivedge
Risk Management Approach	Labeling + REMS	Labeling + REMS	Labeling only
Contraception Use	Required -Choice: abstain or 2 forms -Very specific description -Information for male patients	Required -Highly reliable form -Choice of 1 form or 2 -Specific description	Recommended -Highly effective form -Information for male patients
Pregnancy Testing	Required -Test 24 hrs prior & at defined intervals	Required -Test prior to start & monthly	Recommended -Determine pregnancy status within 7 days prior to start

Conclusions

- No established FDA policy/guidance regarding contraception use and pregnancy testing recommendations in managing teratogens
- There are variations in the recommendations within and between the risk management approach
- Need to improve consistency across drug products while addressing individual drug specific issues

Communicating with Providers and Patients about Teratogenic Medicines

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Objectives

- To provide an overview of considerations for communicating teratogenic risks and contraception information to
 - Providers
 - Patients
- To obtain feedback from the panel on how to improve communications about teratogenic risks

Overview

- Background
 - Considerations for developing health communications for providers and patients
- FDA's communication strategies about teratogenic drugs
 - Sources of information for patients and providers
 - Examples of product labeling and REMS materials used to inform providers and patients about teratogenic risk, contraception, pregnancy planning
- Next steps-- panel feedback and discussion of recommendations moving forward

Background

- Important to develop an effective and efficient health communication effort, based on the needs of patients and providers
- Challenges with communication about teratogenic risk
 - Sensitive topic that patients and providers may have difficulty discussing
 - Time constraints for patients and providers may interfere with obtaining knowledge
 - Training of patients and providers can add burden to the process of delivering care
- Behavior change does not always follow knowledge

Considerations for developing health communications

- Goals
- Target population
- Communication strategies
- Developing messages and pretesting
- Implementation
- Evaluation

Goals of health communications

- Program/material development should be based on goals
 - Knowledge of risk
 - Change behavior to minimize exposure
 - Patients: contraception adherence
 - Provider: pregnancy testing, contraception counseling
- Goals may be difficult to reach
 - Different target groups have different considerations

Target population

- Providers
 - Generalist or specialist
- Females of reproductive potential
 - Age of patient and other demographics
 - Underlying disease
 - Expected number of potential patients
- Male patients

Selected communication strategies

- Labeling
- REMS program

FDA's communication about teratogenic drugs: Providers

Sources of information for providers

- Product labeling
 - Boxed Warning
 - Contraindications
 - Warning and Precautions
 - Use in Specific Populations
 - Pregnancy
 - Females and Males of Reproductive Potential
 - Patient Counseling Information
- REMS program communications
 - Print materials
 - E-mails
 - Websites

Product Labeling- Section summary

Section: Boxed Warning

- Includes fetal risk information
- May include requirements for pregnancy testing and birth control for patients
- May include information about REMS program
 - required training/enrollment for provider
 - patient enrollment

Section: 4. Contraindications

- Use in pregnant women could be contraindicated if the risk clearly outweighs benefit to patient

Product Labeling- Section summary

Section: 5. Warnings and Precautions

- Fetal risk information
- May include detailed recommendations or requirements for
 - pregnancy testing
 - contraception
- May include REMS program information
 - provider enrollment, training
 - patient enrollment

Product Labeling- Section summary

Section: 8. Use in Specific Populations

- **Pregnancy**
 - fetal risk information
 - clinical data- animal, human
 - pregnancy registry or surveillance information
- **Females and Males of Reproductive Potential**
 - determine pregnancy status of female
 - advise females of contraception options
 - counsel female and male patients regarding pregnancy prevention and planning

Product Labeling- Section summary

Section: 17. Patient Counseling Information

- Includes specific information for provider when counseling patient
 - pregnancy test requirements
 - birth control options
 - contacting provider if patient becomes pregnant

Provider materials in REMS

- Print materials

Content: risk information, pregnancy testing, contraception counseling, REMS program

- Overviews, Counseling tools
- Training materials
- Enrollment forms

- Websites

Content: duplicates print materials

- Online training, enrollment
- Can provide information during enrollment

FDA's communication about teratogenic drugs: Patients

Sources of information for patients

- Medication Guide
- REMS program communications
 - Print materials
 - Website
 - DVDs
- Counseling information (may be part of provider materials)

Medication Guide (MG)

Section summaries

“What is the most important information I should know about (drug name)?”

- Information on the risk of pregnancy loss and risk of birth defects
- Pregnancy testing that may occur
- Instruction on specific birth control options to use and duration of use
- The need to discuss pregnancy or partner’s pregnancy with healthcare provider

Medication Guide

Section summaries - 2

“What should I tell my healthcare provider before taking (drug name)?”

- May include reference to being pregnant or planning to become pregnant

Birth control options table

- This information has also been included on some MGs for drugs with teratogenic risk. (See next slide)

Acceptable Contraception Methods

Option 1

Methods to Use Alone

- Intrauterine devices (IUDs)
- Implant
- Tubal sterilization
- Patient's partner had a vasectomy

Option 2

Choose One Hormone Method AND One Barrier Method

Hormone Methods

Choose 1

Estrogen and Progesterone

- Oral contraceptive pill
- Transdermal patch
- Vaginal ring

Progesterone- only

- Injection

AND

Barrier Methods

Choose 1

- Diaphragm with spermicide
- Cervical cap with spermicide
- Contraceptive sponge
- Male condom
- Female condom

Option 3

Choose One Barrier Method from each column *(must choose two methods)*

Barrier methods

Choose 1

- Diaphragm with spermicide
- Cervical cap with spermicide
- Contraceptive sponge

AND

Barrier Methods

Choose 1

- Male condom
- Female condom

Patient materials included in REMS programs

Print Materials

- Patient guides, booklets, overviews, brochures

Content: risk information, birth control options,
REMS program information

Format: text, bullets, tables, graphics

Length: 2 - 18 pages

Patient materials included in REMS programs -2

Print Materials

- Patient-Prescriber Agreement Forms

Content: risk information, acknowledgement of taking birth control

- Patient Enrollment Forms

Content: risk information, acknowledgement of taking birth control

Website

Content: duplicates print materials

Media

- DVDs

Counseling information

- May be part of provider materials
 - Patient Counseling in Labeling
 - Counseling tool as part of REMS materials
- Referral to specialist
 - Template letters as part of some REMS programs

Feedback from panel

Discussion of preferred content and information sources for both provider and patient materials

- Content

- Current: drug risk, pregnancy testing, contraception
- Other?

- Information sources

- Print
 - Current: overviews, brochures, patient-prescriber agreement forms, enrollment forms, counseling tools
 - Other?
- Website
- Counseling
 - Current: provider, referrals
 - Other?
- Other resources?