

MEDICATION

A MONTHLY PUBLICATION FROM VA MEDSAFE:  
VA'S COMPREHENSIVE PHARMACOVIGILANCE CENTER**SAFETY IN SECONDS**

## Helping to achieve safe medication use

### **POTENTIAL INACCURACY OF ELECTRONICALLY TRANSMITTED MEDICATION CLAIMS DATA USED FOR MEDICATION RECONCILIATION**

A recent notice from the National Alert Network (NAN) warns about the inaccuracy of data within Surescripts, a major provider of automated medication history services to which health care facilities subscribe for medication reconciliation support.<sup>1</sup> Surescripts utilizes “aggregated patient medication history data from community pharmacies and patient medication claims history from payers and pharmacy benefit managers” as a surrogate for medication history.<sup>2</sup> The data error relates to incorrect strengths of a drug due to missing characters such as a decimal point, forward slash, or percentage sign as reported in some of Surescripts’ *Medication History Acute* and *Medication History Ambulatory* records, which could jeopardize patient safety. For example, the strength of a prescribed drug within their data source may be reported as “ramipril 25mg capsules” instead of “ramipril 2.5mg capsules”. Surescripts has detached from the flawed data source, com-

municated the potential risk of inaccurate data to all electronic health record (EHR) vendors affiliated with their network, and is in collaboration with the Institute for Safe Medication Practices (ISMP) to notify healthcare providers of this issue.<sup>1</sup>

Electronic systems facilitate easier access to and retrieval of medication claims data, but actual medication use must still be confirmed by talking to the patient and/or caregiver and reviewing their clinical profile. The above incident serves as an example of how importing information from a data source without actually performing the medication reconciliation can introduce errors, which may ultimately result in patient safety issues. Incidentally, inadequate reconciliation during admission, transfer, and discharge of patients has led to over 40 percent of medication errors.<sup>3</sup> Of these errors, about 20 percent are believed to result in harm.<sup>3, 4</sup> As part of its commitment to safety, the

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### VA PHARMACY BENEFITS MANAGEMENT SERVICES (PBM)

PBM maintains VA's national drug formulary, as well as promotes, optimizes, and assists VA practitioners with the safe and appropriate use of all medications.

### VA CENTER FOR MEDICATION SAFETY (VA MedSAFE)

VA MedSAFE performs pharmacovigilance activities; tracks adverse drug events (ADEs) using spontaneous and integrated databases; enhances education and communication of ADEs to the field; and promotes medication safety on a national level.

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NEWSWORTHY...

## from the pbm

- Alli (orlistat) Recall Due to Product Tampering – 04/04/14 - [National PBM Communication](#)

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# from the fda

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## CARDIOLOGY

### [FDA clarifies Warning about Pediatric Use of Revatio \(sildenafil\) for Pulmonary Arterial Hypertension](#) 3/31/2014

Sildenafil (Revatio®) received FDA approval for improving exercise ability and delaying clinical progression of pulmonary arterial hypertension (PAH) in adults under the WHO Group I classification. In August 2012, FDA recommended against the use of sildenafil (Revatio®) in children, and issued new product labeling that reflected this warning based on clinical trial results showing higher risk of death in children associated with high doses compared to low doses; and no improvement in exercise ability in children with lower doses. VA PBM/MedSAFE previously addressed this topic in the [Issue 8; Volume 2; September 2012](#) publication of this newsletter. Recently, FDA released an updated communication seeking to clarify their previous guidance since some health care professionals have interpreted this information as a contraindication. Even though sildenafil (Revatio®) holds an indication for the treatment of PAH in adults only, FDA asks health care professionals to consider whether the benefits of therapy with the drug outweigh any potential risks for each patient, including children faced with limited treatment options.

## Getting the most from our safety surveillance

### **MEDICATION INDICATED FOR MENOPAUSAL SYMPTOMS INCORRECTLY PRESCRIBED AS ORAL CONTRACEPTIVE**

The Institute for Safe Medication Practices (ISMP) reported two errors that occurred in Canada where Angeliq, a medication containing the hormone combination of drospirenone and estradiol indicated for the relief of menopausal symptoms, was improperly prescribed as an oral contraceptive. Angeliq is not a contraceptive and does NOT prevent pregnancy. Angeliq contains a much lower dose of drospirenone (0.25 mg or 0.5 mg vs. 3.0 mg) and a different estrogen than contraceptive products that contain drospirenone.

Angeliq bears similarities to birth control pills that may have influenced the mix-up:

- Angeliq is packaged as a 28-day blister pack, analogous to the casing design of birth control pills.
- Like some birth control pills, Angeliq contains the progestin, drospirenone, and an estrogen.

The dose and potency of the hormonal components in Angeliq are different from those used for birth control, which is why Angeliq is not effective as a contraceptive. If a provider inappropriately prescribes Angeliq for contraceptive purposes, as in one instance documented in ISMP's consumer error reporting program, the patient will not have contraceptive benefit and will not reduce her risk of pregnancy.

ISMP recommends:

- Informing providers of the potential for mistaking Angeliq for an oral contraceptive when ordering this medication via a prescriber order-entry system, especially if selection of



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# Getting the most from our safety surveillance

## MEDICATION INDICATED FOR MENOPAUSAL SYMPTOMS INCORRECTLY PRESCRIBED AS ORAL CONTRACEPTIVE

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medications occurs via an alphabetic medication list or if listed by hormonal components.

- Ensuring that a method is in place to help differentiate Angeliq from oral contraceptive products when using electronic prescriber order-entry systems.

Other recommendations include:

- Carefully checking the name, dosage, and indication when Angeliq is ordered, especially if selection of medications occurs via an alphabetic medication list or if listed by hormonal components.
- Pharmacy review of their stock for Angeliq and oral contraceptives to ensure that a method is in place to distinguish between the agents with different indications for use in or-

der to avoid future look-alike confusion (i.e., warning stickers/ labels).

- When ordering Angeliq via the Computerized Patient Record System (CPRS), sites should consider using a DRUG TEXT (sometimes referred to as the BLUE LINE instructions) to identify this as FOR MENOPAUSE; NOT A CONTRACEPTIVE.
- Sites may consider adding this item to the TDrugs order check as another safeguard if ordered on a pre-menopausal woman.

### REFERENCE:

Institute for Safe Medication Practices. Angeliq-not a birth control pill! *ISMP Medication Safety Alert! Acute Care*. 2014; 19(7): 2-3.

**Table 1. Drospirenone-containing products FDA-approved in the United States.** Note: All drospirenone-containing hormone medications that are contraceptives for pregnancy prevention contain ethinyl estradiol (not estradiol) as the estrogenic active ingredient.

INDICATIONS		PRODUCTS
<b>Drospirenone + Estradiol</b>	Treatment of vasomotor symptoms and/or vulvar/vaginal atrophy associated with menopause	<ul style="list-style-type: none"> <li>• Angeliq (drospirenone 0.25mg + estradiol 0.5 mg)</li> <li>• Angeliq (drospirenone 0.5 mg + estradiol 1.0 mg) (currently no generic equivalents)</li> </ul>
<b>Drospirenone + Ethinyl Estradiol</b>	<ul style="list-style-type: none"> <li>• Pregnancy prevention</li> <li>• Treat symptoms of premenstrual dysphoric disorder</li> <li>• Treat moderate acne</li> <li>• Raise folate levels in women who choose to use an oral contraceptive (Beyaz , Safyral only)</li> </ul>	<ul style="list-style-type: none"> <li>• Yasmin (drospirenone 3mg + ethinyl estradiol 0.03mg)</li> <li>• Yaz (drospirenone 3mg + ethinyl estradiol 0.02mg)</li> <li>• Beyaz (drospirenone 3mg + ethinyl estradiol 0.02 mg)</li> <li>• Loryna (drospirenone 3 mg + ethinyl estradiol 0.02mg)</li> <li>• Safyral (drospirenone 3mg + ethinyl estradiol 0.03mg)</li> <li>• Syeda (drospirenone 3mg + ethinyl estradiol 0.03mg)</li> <li>• Equivalent generics</li> </ul>

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## POTENTIAL INACCURACY OF ELECTRONICALLY TRANSMITTED MEDICATION CLAIMS DATA USED FOR MEDICATION RECONCILIATION

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Joint Commission evaluates medication reconciliation across the care continuum since its addition as a National Patient Safety Goal in 2005.<sup>5,6</sup> Within the VA, medication reconciliation falls under the purview of the Medication Reconciliation Directive 2011-012.<sup>7</sup> Guidance on what to import into a medication list for review, management, and communication is outlined in the Essential Medication Information Standards Directive in concurrence.

### REFERENCES:

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