

2013 HINTS Users Conference

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# Do Prescription Drug Ads Tell Consumers Enough about Benefits and Side Effects?

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# Conclusion

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- A plurality of Americans believes that DTC ads do not include enough information about both benefits and risks
- Especially those who are more educated, have higher income, purchase Rx drugs, and think Rx drug info is hard to understand

# Federal Food, Drug and Cosmetic Act

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Among other things,  
prescription drug promotion must:

- Not be false or misleading
- Have fair balance

# Example Print DTC Ad

High cholesterol can be serious—  
it's a risk factor for heart disease.



Some people have increased risk factors for heart disease: high LDL (bad cholesterol), low HDL (good cholesterol), family history of heart disease, smoking, age, and obesity. Votrea is an enzyme blocker, also known as a "statin," which reduces the amount of bad cholesterol (LDL) your body makes normally each day. If used along with a proper diet and exercise program, Votrea may help lower your bad cholesterol.

Votrea reduces bad cholesterol for people with several common risk factors for heart disease (starting from an average bad cholesterol of 160 mg/dL).

**VOTREA**  
trovastatin calcium tablets  
60 mg

#### Important risk information

Votrea is not for everyone, including people with liver problems and women who are nursing, pregnant, or may become pregnant. You need simple blood tests to check for liver problems. If you develop fever, unexplained weakness, or confusion, tell your doctor right away as these may be signs of a rare but potentially life threatening condition called TTP, which has been reported sometimes in less than 2 weeks after starting therapy. Also tell your doctor if you are taking other medications, or if you have any muscle pain or weakness, as this may be a sign of another rare but serious side effect. Common side effects include diarrhea, joint pain, and tiredness.



You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

## Important Information

**VOTREA**  
trovastatin calcium tablets  
60 mg (VOH-tree-uh)

#### What is VOTREA?

VOTREA is a prescription medicine that is used along with a healthy diet. It reduces the amount of bad cholesterol (LDL) that your body makes normally each day and increases the amount of good cholesterol (HDL). VOTREA can lower the risk of having a heart attack or stroke in patients who have heart disease and patients who have several common risk factors for heart disease such as age, smoking, high blood pressure, low HDL, or family history of early heart disease.

#### Who is VOTREA for?

VOTREA is available only by prescription for:

- People who cannot lower their cholesterol enough through diet and exercise alone.
- Adults and children over 12.

#### Talk to your doctor

Before you start taking VOTREA, tell your doctor:

- About all of your prescription and over-the-counter medications as well as vitamins and herbal supplements.
- If you have more than 2 alcoholic drinks a day.
- If you have diabetes.
- If you have kidney or thyroid problems.

#### Possible side effects of VOTREA

- **TTP**, a very serious blood condition, has been reported rarely, sometimes less than 2 weeks after beginning therapy with VOTREA. TTP (Thrombotic Thrombocytopenic Purpura) is a rare disease in which small blood clots form suddenly throughout the body. TTP is a life threatening condition that requires prompt treatment upon diagnosis. Warning signs may include fever, unexplained weakness, or confusion.

- **Muscle problems** that can lead to kidney problems, including kidney failure.
- **Liver problems.** Your doctor should give you blood tests to check your liver function before and during treatment and may adjust your dosage.

#### Call your doctor right away if you have:

- Muscle aches or weakness.
- Unexplained weakness or confusion, a fever, or feel very tired.
- An allergic skin reaction or swelling in your face, lips, tongue, or throat. Reactions that cause difficulty breathing or swallowing may require treatment right away.
- Nausea, vomiting, or stomach pain.
- Brown or dark colored urine.
- A yellow color on your skin or the whites or your eyes.

#### Common side effects of VOTREA are:

- Diarrhea
- Joint pain
- Tiredness

#### Who should NOT take VOTREA?

- Women who are pregnant or may become pregnant. VOTREA may harm a developing fetus. If you become pregnant, stop taking VOTREA and call your doctor right away.
- Women who are nursing. VOTREA can be absorbed into breast milk and may harm your baby.
- People with liver problems.
- People who are allergic to any active or inactive ingredient in VOTREA.

#### How should I take VOTREA?

- Take VOTREA exactly as prescribed by your doctor.
- Take VOTREA around the same time every day, with or without food.
- If you miss a dose, take it as soon as you remember unless it has been more than 12 hours since your missed dose. Then take the next dose at your regular time.
- Do NOT change your doses or stop taking VOTREA without talking to your doctor.
- Do not break the tablet.

#### Need more information?

- Talk to your doctor or health care provider.
- Talk to your pharmacist.
- Call 1-888-6-VOTREA.



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# 2002 FDA Survey



- 944 adults who visited healthcare professional in  $\leq 3$  months
- 44%: not enough info about benefits
- 61%: not enough info about risks

# Study Aims



- Get current perceptions of DTC ads using nationally representative data

# Method: Measures



Two items on HINTS 4 Cycle 1:

Ads for prescription drugs tell me enough about:

- the benefits of using the drugs
- their negative side effects

Agree/ Disagree/ No Opinion

# Results





**Ads for prescription drugs tell me enough about the benefits of using the drugs**

**Ads for prescription drugs tell me enough about their negative side effects**

**Agree**

**Disagree**

**No Opinion**

**Total**

Agree

Disagree

No  
Opinion

Total

23%

4%

2%

29%

9%

41%

2%

52%

<1%

<1%

18%

19%

33%

46%

21%

100%

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18%





19%

33%

46%

21%

100%

	DTC ads tell enough about risks <i>and benefits...</i>		
	Disagree	Agree	<i>p</i> -value
<b>Education</b>			.01
<b>Income</b>			.04
<b>Purchase Rx drugs</b>			<.001
<b>Agree that Rx drug info is easy to understand</b>			<.001

# Discussion



What additional information are they looking for?

- Onset?
- Duration?
- Likelihood?
- Magnitude?
- Clinical trial info?

# Thank you!



- Helen.Sullivan@fda.hhs.gov
- OPDP website:  
[http://www.fda.gov/AboutFDA/CentersOffices/  
OfficeofMedicalProductsandTobacco/CDER/  
ucm090142.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm)