

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF IOWA  
WESTERN DIVISION

FARM-TO-CONSUMER LEGAL	)	
DEFENSE FUND, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. 5:10-cv-4018-MWB
	)	
KATHLEEN SEBELIUS, Secretary,	)	
United States Department of Health	)	
and Human Services, et al.,	)	
	)	
Defendants.	)	

**PLAINTIFFS' DECEMBER 2010 STATUS REPORT**

Pursuant to the Court's Order of September 17, 2010 (doc. #29) and the text entry of October 19, 2010, the Plaintiffs hereby submit their status report.

Plaintiffs are submitting for the Court's review and for FDA's inclusion in the administrative record the following patient information announcements from the following pharmaceutical companies for the following drugs:

1. Advair, from GlaxoSmithKline;
2. Ambien, from Sanofi-Aventis
3. Ambien CR, from Sanofi-Aventis;
4. Avandia, from GlaxoSmithKline;
5. Celebrex, from Pfizer;
6. Lantus, from Sanofi-Aventis;
7. Lipitor, from Pfizer;
8. Lovaza, from GlaxoSmithKline;
9. Lyrica, from Pfizer;

10. Symbicort, from AstraZeneca;

11. Uroxatral, from Sanofi-Aventis.

The attached patient information announcements describe the harmful side effects and the potential dangers associated with taking each of the above prescription drugs. For example, patients who have asthma and who take **Advair** “may increase the chance of death from asthma problems.” Taking **Ambien** and **Ambien CR** “may cause a special type of memory loss or ‘amnesia’” and may cause “dependence” and “withdrawal” in addition to “hallucinations, worsening of depression, suicidal thoughts.” **Avandia**, a drug used to treat type 2 diabetes, has side effects that can “lead to heart failure,” “liver problems” such as nausea or vomiting, dark urine, yellowing of the skin or whitening of the eyes. **Celebrex** is used to treat heart conditions and these are some of the serious side effects it can cause: “heart attack, stroke, high blood pressure, heart failure from body swelling, kidney problems including kidney failure, bleeding and ulcers in the stomach and intestine ....” **Lantus** is another drug used to treat type 2 diabetes, and it can cause hypoglycemia which “may be life threatening” and it can cause allergic reactions, which may be “severe, life-threatening” including “anaphylaxis.”

**Lipitor** can cause “muscle problems” and “liver problems” and has common side effects such as “diarrhea, upset stomach, muscle and joint pain, changes in some blood tests.” **Lovaza** is used to lower fats in blood yet it can cause “infection, flu symptoms, upset stomach and change in sense of taste,” not to mention it may change the results of blood tests that measure liver function and cholesterol levels. **Lyrica** is used to treat muscular pain yet it “may cause serious, even life threatening,

allergic reactions,” it may also cause “suicidal thoughts or actions,” and its common side effects include “dizziness, trouble concentrating, blurry vision, swelling of hands and feet.” **Symbicort** is taken by individuals who suffer from bronchitis and emphysema, yet it “may increase the chance of death from asthma problems” while other health considerations include “increased risk of pneumonia,” “glaucoma and cataracts,” “increased bone loss,” “slowed growth in children,” “a higher chance for infections,” and “increased blood pressure, fast or irregular heartbeat, tremor, or nervousness.” Finally, **Uroxatral** is taken by men with an enlarged prostate and it can cause “a sudden drop in blood pressure” which can lead to “fainting, dizziness, or lightheadedness.”

These are all drugs that are approved by the FDA. It is irrational for the FDA to ban the interstate shipment or distribution of raw milk that does not have any of these symptoms or side effects yet allow these drugs to be sold in interstate commerce given the dangers they present.

Dated: January 18, 2011

Respectfully submitted,

/s/ DAVID G. COX  
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**CERTIFICATE OF SERVICE**

I hereby certify that on January 18, 2011, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system that will send notification of such filings(s) to the following:

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