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**From:** Condodina, Cynthia </O=CEPHALON/OU=US01 ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=CCONDODI>  
**To:** Richardson, Michael  
**Sent:** 11/28/2006 9:11:29 PM  
**Subject:** RE: Decision Tree  
**Attachments:** ACTIQ Promotional Guidelines Updated.ppt

Michael,  
Is this attachment the same thing that Terry gave you? The PCS would have implemented this algorithm throughout ACTIQ life cycle.

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**From:** Richardson, Michael  
**Sent:** Tuesday, November 21, 2006 1:59 PM  
**To:** Condodina, Cynthia  
**Cc:** Thibodeau, Laurie  
**Subject:** Decision Tree

Cynthia,

I am attaching today's WSJ article.

Do we still have a "decision tree" as described?  
If not, when did we stop using it?  
Do you have a copy of the materials they are describing and our current ones?

Terry gave me a copy of what appears to be the one used for the last Actiq training course (it is labeled as Actiq)

Thanks!

Cephalon Used Improper Tactics  
To Sell Drug, Probe Finds

By JOHN CARREYROU  
November 21, 2006; Page B1

PLAINTIFFS TRIAL  
EXHIBIT  
**P-18921\_00001**

From setting unrealistically high sales quotas to pushing larger prescriptions at higher doses, drug maker Cephalon Inc. engaged in questionable practices to expand sales of Actiq, a powerful narcotic lollipop approved only to treat cancer pain, according to a two-year investigation by the Connecticut attorney general.

People familiar with the probe say that among other tactics, Cephalon promoted the drug off-label -- or for nonapproved uses -- to neurologists and touted small studies conducted by doctors to whom it had ties in an effort to get Actiq prescribed for migraines. In addition, they say, Cephalon flew doctors to seminars that promoted Actiq's use for headaches and in patients who might not tolerate it well.

Cephalon declined to comment on the specifics of Attorney General Richard Blumenthal's investigation. Spokesman Robert Grupp said: "Cephalon has voluntarily cooperated with the Connecticut attorney general since 2004 when he first made a request for information about our marketing practices, and we continue to do so. Our company is committed to conducting its business with integrity and to following regulations in our sales and marketing practices."

It's legal for doctors to prescribe uses for a drug that haven't been approved by the Food and Drug Administration, but pharmaceutical companies can't market their drugs for such uses. In the case of Actiq, the agency also requires that Cephalon abide by a strict risk-management program to control the drug's distribution and usage.

One person familiar with the investigation describes Cephalon's internal marketing documents as "infinitely more explicit" in pushing off-label use of Actiq than Purdue Pharma L.P. was in promoting Oxycontin, another powerful narcotic that became widely

abused. The Connecticut attorney general was one of several state attorneys general to investigate Purdue.

Mr. Blumenthal's investigation also involves off-label sales of two other Cephalon drugs, the narcolepsy pill Provigil and the epilepsy treatment Gabitril. Cephalon is also being investigated by the U.S. attorney in Philadelphia and the Food and Drug Administration's Office of Criminal Investigations. Like Mr. Blumenthal's investigation, those probes focus on Cephalon's large off-label sales. The U.S. attorney and the FDA declined to comment.

Mr. Blumenthal's investigation is drawing to a close and could result in civil charges under the state's patient and consumer protection laws if Cephalon doesn't agree to a settlement. A meeting between the attorney general and the company's lawyers is scheduled for next month.

If Cephalon opts to settle the case out of court, Mr. Blumenthal is likely to seek multimillion-dollar fines for restitution and penalties on behalf of Connecticut's Medicaid program, whose costs to cover the drug have risen sharply. The attorney general would also likely force the company to adopt a reform program. "We want them to change the way they do business," Mr. Blumenthal says.

Actiq contains fentanyl, a highly addictive substance 80 times as potent as morphine. Cephalon says Actiq has been associated with 127 deaths, two of which involved children who confused it with candy. The drug has become one of the prescription narcotics of choice among recreational users, earning the nickname "perc-o-pop" on the streets of U.S. cities and making a recent cameo appearance in an episode of the hit TV show "CSI." In the first nine months of this year, Actiq sales reached \$471 million.

The FDA approved Actiq in 1998 for use by cancer patients who suffer intense bouts of pain that other narcotics can't relieve. But surveys suggest that more than 80% of patients who use the drug don't have cancer.

The trigger for Mr. Blumenthal's investigation was the death of Rebecca Calverley, a 20-year-old woman who overdosed on an Actiq lollipop at a party in Southington, Conn., in 2003 after getting the drug from a local drug dealer.

Mr. Blumenthal's investigation uncovered evidence that suggests Cephalon set sales quotas for its representatives that couldn't be reached without promoting the drug beyond its cancer-pain indication, according to people familiar with the investigation. Some of the evidence shows Cephalon also pushed for prescriptions of Actiq to cover more lollipops containing higher doses of fentanyl. Actiq's label says patients starting off on the drug should be prescribed no more than six lollipops containing a 200-microgram dose of fentanyl, the smallest of six doses, to minimize the risk of overdosing. Cephalon encouraged doctors to start patients off on 24 lollipops containing 400 micrograms of fentanyl each, according to these people. The higher dose costs more and brings in more revenue.

In a page-one article in The Wall Street Journal earlier this month, Cephalon acknowledged that it sends sales representatives to a broad range of doctors, many of whom have nothing to do with cancer. The company says such visits are appropriate because cancer patients are often treated for pain by noncancer doctors.

**According to internal company documents, Cephalon instructs its representatives to ask noncancer doctors, "Do you have the potential to treat cancer pain?" Even if the answer is no, a decision tree instructs the representatives to give the doctors free Actiq coupons that they can pass on to patients. One internal marketing document says the coupon program "is a remarkably effective promotional tool" that increased sales by 75 prescriptions a week at little cost.**

Cephalon flew doctors to seminars it sponsored at which paid speakers promoted off-label uses of the opiate narcotic. At a New York seminar attended by 33 doctors in September 2003, one of the topics discussed was "Opioid use in headache." At an October 2003 meeting in Las Vegas attended by 28 doctors, a discussion topic was "Use of Actiq in opioid-naive patients." Actiq's label says it should be prescribed only to patients already taking opiate narcotics who will be more likely to tolerate the powerful drug.

Mr. Grupp declined to comment on the seminars. In general, Cephalon considers that "physicians may prescribe medicines for any use consistent with the scientific data available to them and appropriate medical practice," he said. "The decision to prescribe

'off label' is theirs and theirs alone."

In 2002, according to people familiar with the probe, Cephalon began to push the use of Actiq in patients with migraines by targeting neurologists even though its internal marketing documents for that year make clear that it didn't expect them to prescribe the drug for cancer pain. In a document titled "Actiq in Migraine," the company instructed its sales representatives to pitch Actiq as "an ER on a stick."

Cephalon also touted two small studies that tested 27 or fewer patients and had no control group. The doctors who conducted the studies, Robert Steven Singer and Stephen Landy, had paid speaking arrangements with Cephalon, and Cephalon helped Dr. Landy with the study he conducted, according to the people close to Mr. Blumenthal's probe.

Dr. Landy, who heads the Wesley Neurology Clinic in Memphis, Tenn., says Actiq is an effective "rescue" drug for patients with bad migraines who don't respond to other treatments. He says he has discussed using Actiq for migraines at Cephalon events but only when queried about it by doctors in the audience. Dr. Landy won't say how much Cephalon paid him for speaking. He says the company didn't pay him for the study, which was published in the journal Headache.

Dr. Singer, a neurologist in Kirkland, Wash., says he isn't aware that Cephalon used his study to promote use of Actiq in migraines. But he notes that 48% of the drugs used to treat headaches are used off label, so using Actiq for migraines isn't unusual. He declines to say how much Cephalon paid him to speak.

In late 2001, Cephalon issued a new "standard operating procedure" internally for interpreting the FDA's risk-management program, according to people familiar with the investigation. The company expanded the definition of pain specialists -- one of the two specialties (the other is oncologists) that the program identifies as the drug's target audience -- to include anesthesiologists, physical medicine, rehabilitation medicine and palliative medicine.

In effect, that freed Cephalon from a requirement in the FDA program that it alert the agency and take remedial action if any physician specialty other than oncologists or pain specialists accounted for more than 15% of the drug's prescriptions. Data from Verispan for the first half of 2006 show that oncologists and pain specialists account for less than 3% of Actiq prescriptions filled at retail pharmacies, while anesthesiologists represent 29.5% of prescriptions.

**Michael H. Richardson**  
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**File Provided Natively**

# Promotional Guidelines

QUESTION	RESPONSE
Dr. Smith asks a question concerning a subject covered in a WLF article. What can you present from the article?	<p>The Territory Sales Specialist <b>can</b> discuss with the physician:</p> <ol style="list-style-type: none"> <li>1. The patient types and number of patients involved in the WLF article</li> <li>2. The methodology or design of the study (i.e. double blind, dosage range, placebo-controlled...)</li> </ol> <p>The Territory Sales Specialist <b>cannot</b> discuss with the physician:</p> <ol style="list-style-type: none"> <li>1. The results of the study (i.e. discussion, summary)</li> <li>2. Make claims about Cephalon's products</li> <li>3. Suggest the product is effective and safe in an unapproved disease state</li> <li>4. Ask the physician to use Cephalon's product in an unapproved indication</li> </ol>
Dr. Smith asks about the results or the conclusion of the WLF study.	Remind the physician this article presents information on a use for a Cephalon product that is outside of our current indication. You as a Territory Sales Specialist cannot discuss the results or the conclusion of the study. However, you can have someone from Professional Services contact the physician directly to discuss the conclusions of the article and any other pertinent data.
Dr. Smith questions specific information that is contained in a MIRF letter.	The Territory Sales Specialist <b>cannot</b> summarize the information provided in a MIRF letter before or after the physician receives the letter. You can offer to have Cephalon's Professional Services Department contact the physician to answer any questions.

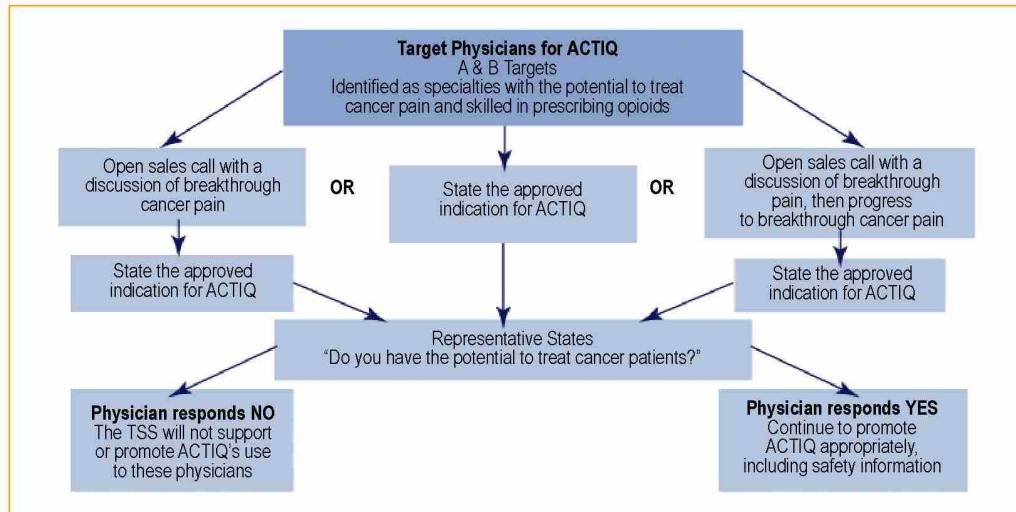
**For internal educational purposes only - Not to be used for promotion.**

QUESTION	RESPONSE
<p>How can a sales representative respond to the following physician question:</p> <p>"How does ACTIQ compare to MSIR in the treatment of BTCP?"</p>	<p>The Sales Representative <b>can reply</b> to this question only if they have an approved reprint or WLF article to disseminate related to that disease state.</p> <ol style="list-style-type: none"> <li>1. Introduce the WLF article and provide patient types, number of patients, the methodology or design of the study (i.e. double blind, dosage, the purpose, and methodology).</li> <li>2. Remind physician of the approved indication</li> </ol>
<p>What is the proper response to the following example of an off-label question?</p> <ol style="list-style-type: none"> <li>1. "How should I dose ACTIQ for migraine headaches?"</li> </ol> <p style="text-align: center;"><b>or</b></p> <ol style="list-style-type: none"> <li>2. "How would I prescribe ACTIQ for my patients suffering form back pain (or any other off-label pain condition)?"</li> </ol>	<p>The following are proper responses to a HCP off-label questions:</p> <ol style="list-style-type: none"> <li>1. Remind physician of the approved indication.</li> <li>2. Refer physician to another physician using the product (only if the physician agreed to be a reference). A Sales Representative may offer to set up a discussion with another physician using the product in an off-label use but may not plan a dinner or MEP program around the discussion.</li> <li>3. Always offer to MIRF additional information for all unsolicited questions.</li> <li>4. Utilize additional resources if appropriate. For example provide physician information on a CME program or invite them to a MEP program where the physician can ask the question.</li> </ol>

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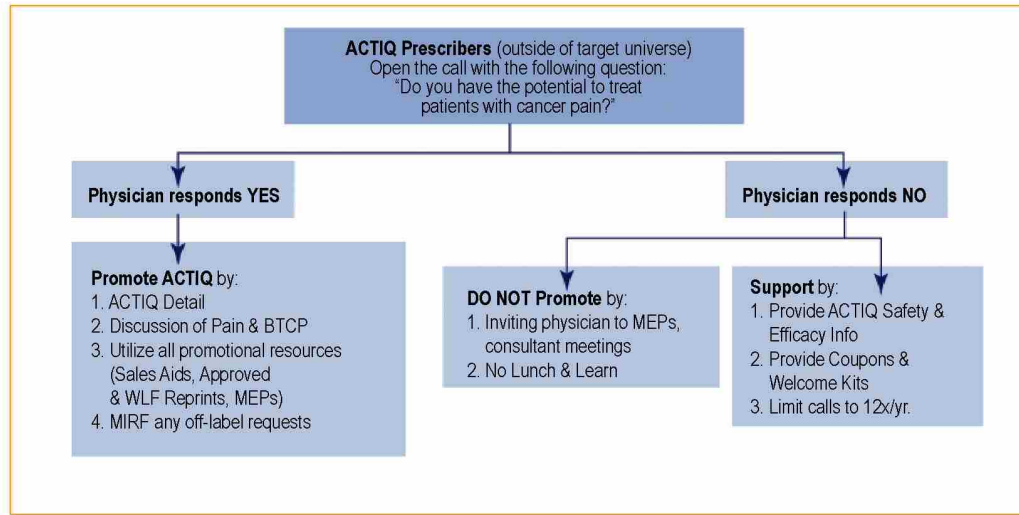
QUESTION	RESPONSE
How are other physicians prescribing ACTIQ?	<ol style="list-style-type: none"> <li>1. Provide the indication.</li> <li>2. Tell the doctor that physicians are using Cephalon's products for a variety of patients, and then ask the physician for more specific information to see if there is a specific area of interest.</li> <li>3. Offer to MIRF if appropriate.</li> </ol>
What are the guidelines surrounding CME invitations?	<ol style="list-style-type: none"> <li>1. The CME invitation is not to be used as a promotional tool.</li> <li>2. Do not mention Cephalon's product in relation to the CME program.</li> </ol>

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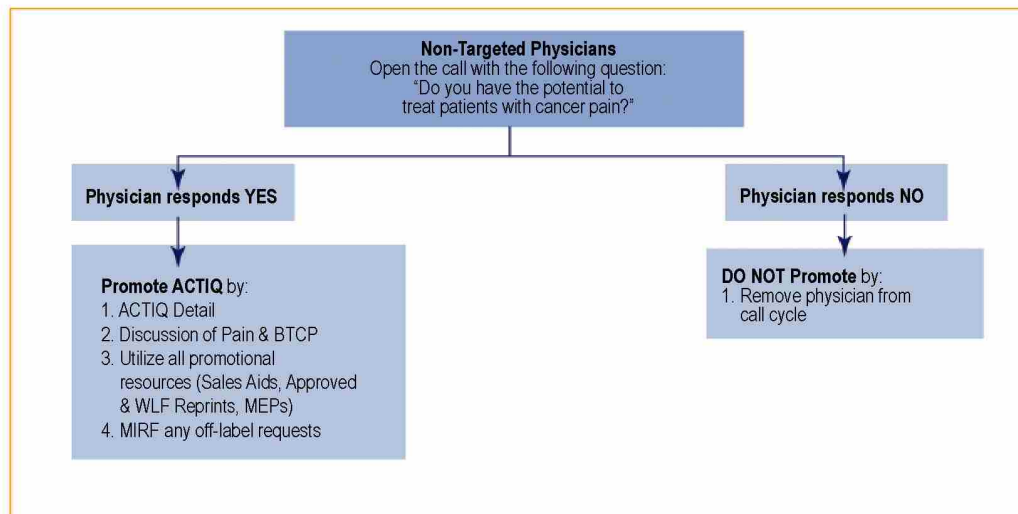


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