Excerpt from *Elidel* Speech
Marketing Overview/Treatment Options
General Session – Focus: The Market
20 minutes

*After the musical number, Trash, a Voice Over introduces the Speaker*

Thank you.

*(referring to dance number)*

Wasn’t that great?

*(slight pause)*

Too bad we can’t detail the physicians with that musical number.

*(slight pause for laughter)*

This afternoon’s General Session Focus is on The Market. Elidel’s place in the expanding eczema market. And I think the ending to that number sums it up:

“THIS IS MY COURT NOW.”

This is our court now. Elidel is about to enter the game, so move on over Protopic.
And not just Protopic—it’s time to bench some of the corticosteroid players, too, because it’s an entirely new game now.

*(slight pause)*

So just how do we get into this game? How do we help Elidel gain entry onto this jam-packed court?

To enter this market you need a solid grasp of all the factors that can potentially effect our product’s success: a look at market conditions, an understanding of the customer base, review of the competition and a complete profile of the eczema patient.

So let me give you the lay of the court, a market overview.

The first thing that surprises people is this disease’s prevalence.

**SLIDE**

Twelve percent of the US population—that’s over 35 million people—have eczema. More than 5 million children and almost 30 million adults suffer.

What I want you to notice here is not the number of eczema sufferers who are receiving prescriptive treatment, but the number who aren’t.

More than half the pediatric and almost three quarters of adult eczema sufferers are not being treated with prescriptive medications.

This is a huge untapped market.
Just how huge? What kind of potential sales are we talking about?

SLIDE

Last year the eczema market peaked at XXX* million dollars and prescription volume rose to XXX* million.(1)

Those figures represent sales to and volume for just one quarter of all US eczema sufferers. When you consider the remaining 25 million who remain untreated, you get some idea of Elidel’s potential.

But I’m getting a little ahead of myself. Let’s go back to the year 2000 and take a look at some of the conditions that shaped this market.

SLIDE

In 2000 overall sales had inched up to XXX* million dollars. There were a large number of branded and generic players competing for limited share, growth rates were low and conditions static.

Prescription volume had leveled out at XXX* million.

Then in 2001 we saw a major change.

SLIDE

The market jumped by 11%, and sales soared to XXX* dollars. Prescription volume rose 5.4% to XXX* million. What happened?

Two things. Corticiosteroid makers raised prices.

And our friends at Fujisawa introduced Protopic, touted as the first steroid-free topical ointment for the treatment of eczema.
The words “steroid-free” carry tremendous power.

Of course, Fujisawa chose not to emphasize Protopic’s origins as the powerful oral immunosuppressant, tacrolimus, used in organ transplants.

In Protopic’s first year on the market it nabbed 2% of all prescription volume. Remember this was the year that total volume rose by 5.4%--Protopic was responsible for almost half of that growth.

Fujisawa managed to penetrate this jam-packed playing court with only 50 sales reps.

And a very modest sampling strategy.

The Protopic story tells us something very positive.

There is entry in this market.

There is room for major growth because there is a crying need for something new and Elidel, the first topical immunomodulator created specifically for inflammatory skin disease, is it.

(Pause)

We know Elidel’s potential for success. The ball is in our court: how are we going to play the game?

The winning strategy begins and ends with physician support. To effectively target your doctors, you need to get inside their heads, learn about their patients, understand current treatment options and
be completely familiar with physicians’ treatment preferences.

Each specialty has a different take—and slightly different treatment—for this disease.

We are targeting the specialists who see the most eczema patients: dermatologists, pediatricians, primary care physicians, and allergists.

SLIDE

Notice something very important here: the vast majority of eczema patients, 93%, present mild to moderate symptoms—this is our label.

How do physicians presently treat these patients?

SLIDE

All of our specialists use combination therapies. While no specific combination is favored over another, the common denominator is low to medium corticosteroids.

Let’s take a closer look at each specialist.

Dermatologists are the cutting edge customers. While the number of calls we make to derms is relatively small, the dermatological market is crucial.

These physicians see huge numbers of eczema patients, both from their own base and through PCP referrals.

Like all the other specialists, derms use corticosteroids-- but with a difference. Compared to the other specialists, dermatologists are likely to opt for a higher potency corticosteroid and more aggressive therapies in general.
Derms also seem a little more open to trying a safe new product: they prescribed Protopic for one quarter of their patients 24 months of age or older.

Pediatricians tend to be more conservative with treatment options and are likely to recommend OTC hydrocortisone for all age groups, especially patients from 3 months to 24 months.

They will prescribe low to medium potency corticosteroids when patients are over 24 months.

Even when a patient has severe symptoms, peds tend to prescribe low to medium corticosteroids—although the doctor might add in an antihistamine.

Primary care Physicians are also conservative and tend to treat with low to medium potency corticosteroids.

Allergists are another group to focus on because of the association between allergic rhinitus, asthma with eczema.

While each specialist has a different comfort level prescribing these medications one thing is obvious: corticosteroids are the overwhelming treatment of choice.

But does this mean that most physicians are happy using them?

I DON’T THINK SO.

I think up til now it’s been a case of no better options. Corticosteroids have been around for 40-50 years. They are very familiar and they are a known risk.
Let’s try to put a face on the corticosteroid competition.

Corticosteroids are sort of the Michael Jordan of the game.

*(slight pause)*

—they’re a powerful presence on the court, but they’re getting old—and they refuse to retire.

*(pause for laughter)*

And like some star athletes we won’t mention, corticosteroids have a dark side.

**SLIDE**

- Skin side effects.
- Tachyphylaxis.
- HPA-axis suppression.
- Cushing syndrome and potential growth retardation.
- Risk of cataract and glaucoma.(2)

Of the huge number of branded and generic players on the court, one claims to be different. Let’s put the spotlight on Elocon and see if it lives up to its self-proclaimed reputation.

One thing is indisputable: with 12% of total prescription volume in 2001, Elocon is the #1 branded corticosteroid in the eczema market today.

This corticosteroid’s claim to fame is that it needs only once-a-day application—and it has comparable
improvements relative to other mid potency corticosteroids.

But buyer beware. Patients are warned not to use the product continuously for more than two weeks.

While Elocon may have comparable improvements, it also has comparable side affects:

Referring to above slide:

Skin atrophy. Tachyphylaxis. HPA-axis suppression…and so on.

Lastly, there is Elocon’s limited label: moderate to severe.

Remember that 93% of the market is mild to moderate.

And what about the new kid on the block?

Protopic came into the game posturing—as we saw in the musical number—as the “slam dunk” of eczema treatments.

And it actually makes a claim that a lot of athletes wish they could make:

(slight pause)

“I don’t use steroids.”

(pause for laughter)

And it’s true: Protopic does not cause skin atrophy, striations, or vascular constriction.

But what about complaints of stinging and burning?
*Confidential figures

Well, that’s not surprising when you consider that patients are slathering their skin with a topical version of a very potent immune-suppressant, a powerful medication used in organ transplants.

Like Elocon, Protopic’s label is for moderate to severe symptoms.

Did I say that 93% of the market is mild to moderate?
Rumor has it that Protopic may add on another 100 reps. Even if they do, we will still outnumber them almost 7 to one.

In sampling and promotion spending alone, we are going to blow them off the court.

But your physician is not interested in market figures. He wants to know how Elidel can help his patients.

Of course, the very first thing you’ll tell him is that Elidel is steroid-free. You are going to be saying that over and over, so let’s practice here. Everybody say “Steroid-free.”

(wait for audience to respond, then:)

I can’t hear you. One more time: “STEROID FREE!”

(wait as they respond, then pause a beat:)

I think you can skip the sales training tomorrow. You’ve got half the detail down.

And there’s more good news.

SLIDE entitled VIS/AID page entitled Eczema Control is Here

- Elidel is safe for short and intermittent long-term use.
- It prevents flare ups.
- Elidel gives significant immediate relief from itching and inflammation.
- It is safe for use on the face and neck
- And it is well tolerated.(3)
And while your doctor will love hearing what Elidel does, he will be even more delighted to hear what it doesn’t do: skin side effects, tachyphylaxis, HPA-axis suppression— you probably know the list by heart.

Oh, and Elidel has one last advantage: its label is for symptoms that are mild to moderate.

(To audience)

Okay, this is a quiz. What percentage of the eczema market is mild to moderate?

(Pause for answer.)

(Then ad lib response:)

“You all got an ‘A’”

(Or)

“That’s right, 93%”

(Or)

“I heard someone whisper 93%.”

(Or)

“Now I know you were all thinking 93%.”

Ninety three percent of all patient’s suffer with mild to moderate symptoms. Let’s learn a little bit more about the typical eczema patient.

Well, first off, there is no typical patient. This disease runs from cradle to grave with sufferers found in every age category and presenting with
symptoms ranging from mildly annoying to completely debilitating.

SLIDE entitled Atopic Dermatitis

For the vast majority, symptoms begin early in life. Sixty five percent of all sufferers are struck with the disease within the first year of life and 90% are affected before age 5.

While many patients outgrow the disease, 50% of all sufferers will continue be affected throughout their lives.

SLIDE entitled Eczema Most Bothersome in Infancy and Childhood.

In children, the rash often appears on the backs of knees, inside elbows and on the face.

SLIDE entitled Local Corticosteroid Skin Side Effects

For a large number of adults, the disease is localized on their hands and it is especially prevalent and disabling for people who work with their hands.

Severity ranges from a few isolated dry patches to body-wide rash. As with the case of Ellie, the little girl in our musical presentation, itching can be unbearable and sometimes so persistent that the sufferer scratches til she bleeds.

While the physical aspects of this disease can be horrendous, don’t underestimate the emotional and psychological toll.

SLIDE entitled Parents Suffer as Well...

Parents’ emotions swing from …
- Embarrassment...
- To worry...
- To feelings of guilt and inadequacy.(4)

SLIDE entitled NEASE Survey Supports High Impact of Eczema

A recent survey conducted by the National Eczema Association for Science and Education showed that eczema had a strong impact on:

- Performance at School.
- Sports and outdoor activities.
- Sleep.(5)

And what do patients think of the available treatment options?

SLIDE entitled The NEASE Survey...

In the same NEASE survey, patients got to voice their opinions.

Over a third all patients using OTC therapies and almost a third of those using prescriptive therapies considered their treatments completely ineffective.

The survey also revealed the extent of patients’ fears over corticosteroid use.

SLIDE entitled Topical Corticosteroid Phobia

Almost two-thirds of patients with eczema worry about using corticosteroids.

And close to one quarter of all patients are so anxious that they admit to noncompliance.
What do they fear most? By now you should be familiar with the ugly side effects.

Skin thinning—or atrophy— is patients number one concern.

Second is what I call the “black hole”—the fear of just not knowing about long-term side effects.

And lastly, the anxieties over absorption in the blood and effects on growth.

I personally can relate to these fears because my two year old daughter has eczema on her face and back.

I have to say, my wife and I are apprehensive about using the corticosteroids her physician prescribes. As a father I look forward to Elidel being available.

I hope this review of patient profiles, the competitive situation, customers, and market conditions has helped you consider how you will plan strategy for your own particular game.

Of course, the moment of truth comes when you detail the physician. Information and enthusiasm aren’t worth a dime if you can’t convey the Elidel message to your physician.