FTC Follow-on Biologics Workshop
February 4, 2014
Segment 2
Transcript

SUSAN DESANTI: Our first speaker now will be Jessica Mazer.

JESSICA MAZER: Thank you, Susan. As Susan said, I'm Jessica Mazer. I'm the Assistant Vice Presidents of State Affairs at PCMA, the Pharmaceutical Care Management Association. And PCMA represents the nation's pharmacy benefit managers that administer prescription drug benefits for more than 200 million Americans across the country who have health coverage provided through Fortune 500 employers, labor unions, health plans, and Medicare Part D.

So in my position at PCMA, I have the privilege of seeing legislative trends as they go across the country each year as I cover all 50 states, DC, and Puerto Rico. And so one of the interesting legislative trends, at least last year, was the introduction of biosimilar legislation across the country. And so that's why I've been asked today to kind of run through with you what we saw last year, what was enacted, and what we're seeing this year briefly.

So first, typical requirements of biosimilar legislation that we have seen include a requirement that the pharmacist notify the prescriber within a specified amount of time after substituting an interchangeable biosimilar. There's also patient notification requirements by the pharmacist, as well as record keeping requirements, mostly for the pharmacy and in some states for the prescriber as well. And also a requirement that the board of pharmacy maintain a list, either on the website or some kind of accessible list, the FDA approved interchangeable biosimilars.

So what did we see in 2013? So in 2013 we saw 20 bills introduced in 18 states, which is pretty significant and kept people very, very busy last session working on the legislation. It was rejected in 10 states. As you can see, I've listed them there. And I'll talk a little bit about California in a few slides and the story about what happened there. Enacted in five states.

And I'll cover each of the states, so you can kind of see the differences and comparisons between them. And also carried over in three states. So those bills are still working this year along with a whole bunch of new ones that have been introduced this month or in January.

So I just wanted to first cover with you before we hit the states some of our concerns at PCMA about the legislative activity that we've seen. You've heard multiple times that the FDA is in the process of putting a path pathway together to prove biosimilars as well as determining interchangeability. So we're really concerned that the legislation we're seeing is premature, specifically with the notification requirements. We're worried that it'll cause confusion in state laws with substitution and that the legislation essentially attempts to undermine public confidence in biosimilar medications.

So who worked on this last year in opposition with PCMA? A lot of folks. We had national groups working together. We had state specific coalitions working together. It varied and state by state oftentimes. Our national partners were GPHA, AMCP, and ACDS. And then on the state

specific partners, AARP. They had their terrific state chapters who were really critical in helping us oppose legislation in a number of states, as well as with their state health plan association comrades.

Health insurers across the country, Kaiser. Blue Cross Blue Shield worked on it with us. Retail an independent pharmacies, Rite Aid, Walgreens are some examples. The generic manufacturers, [INAUDIBLE] worked to oppose the legislation with us. Unions.

A number of unions specifically in California worked on the legislation and opposition. And those included the AFL-CIO the Teamsters, the United Food and Commercial Workers Union. There was a large number there. And also a number of state pharmacy associations across the country worked in opposing the legislation.

So starting with the states North Dakota. North Dakota Senate Bill 2190, which was enacted, we consider this the most onerous legislation that was enacted in the country last year. It has some really stringent requirements, including a 24 hour notification after the substitution by the pharmacist to the prescriber.

There's also individual patient notification as well as the pharmacy and the subscriber have to keep records for no less than five years. It also has that board of pharmacy requirement that they maintain a list of the current FDA approved biosimilar products that were approved for interchangeability.

Moving on to these three. Oregon, Utah, and Virginia. I put these three together here because of what they have specifically in common is the fact that they have sunset provisions on the prescriber notification requirement. All three have patient notification requirements.

And then in Oregon, you have three business days. So the pharmacists within three business days have to notify the prescriber of the substitution of interchangeable biosimilar. The same requirements, three business days in Utah, and in Virginia it's five business days. So as you can see by the next column, all three states, that specific requirement actually sunsets in two years from the effective date of the enactment of the law.

Additionally, the pharmacy record keeping requirements, three years in Oregon. It's unspecified in Utah. Virginia, it's two years. And interestingly in prescribe a record keeping, there is none in Oregon, none in Utah, two years in Virginia. And specifically in Oregon, the actual prescriber record keeping requirements were in the bill as it moved through the legislature, and ultimately it was stricken in order to remove some of the opposition to the legislation from some of the medical groups.

One thing I curious about that is that the pharmacy is required to notify the prescriber after the substitution of the interchangeable biosimilar. How come the prescriber isn't required to keep some kind of record of that? It kind of doesn't make a whole lot of sense. But an interesting thing to note. In Oregon, they do have the board of pharmacy website list requirement, and that is not required in Utah or Virginia.

Now, in Florida, I think it was mentioned earlier, is unique in the fact that the notification requirement was striked from the bill right before passed, literally seconds before it passed the legislature. And therefore, the legislation essentially attempts to mirror the generic substitution long in Florida.

So no notification requirements and patient notification requirement, which is similar to what you have to do for a standard generic substitution in the state, a written records requirement for the pharmacy of two years, and the board of pharmacy also has to keep the listed in Florida of those interchangeable biosimilars available.

So California. California was and a long, drawn out, and interesting battle last year. And the introduced version of the legislation required notification of the substitution within five business days to the prescriber and it was specific to just interchangeable biosimilars. Now, early on in the legislative process, the prior to January 1, 2017 you see there tacked, on that sunset provision, was amended into the bill. And additionally, the language was changed to include a notification of either a biological product or interchangeable biosimilar, which was unique to California.

Now, there were huge coalitions on each side of the issue in California and on the opponent side worked with more than 30 organizations. We had health plans, insurers, pharmacists, retailers, unions that I mentioned earlier. Of course the PBM is the generic, some of the brands. It was a big group of folks on our side.

And ultimately the bill went through the legislature, went to the governor, and lot of folks weighed in with the governor, including CalPERS who weighed in with a veto request. And ultimately, the governor vetoed the legislation. I think it's interesting. I put Governor Brown's veto message out there where he ultimately found that the legislation struck him as premature. And I think that's important to note.

OK. An example for you I'm kind of what's going on here. This leads from last year to this year. Massachusetts [INAUDIBLE] carry overrule. So Massachusetts was unique in itself last year because it tied the notification requirements to the interoperability of how electronic health records systems. So in Massachusetts, the pending legislation doesn't require notification until this full interoperability of electronic health record systems is actually reached and an entry of the substitution in the patient's electronic health record shall constitute notification.

Now, the reason why this is unique to Massachusetts is because in 2012, Massachusetts enacted a law that required all providers by 2017 to implement fully interoperable electronic health record systems that connect to their statewide health information exchange. This is unique to Massachusetts, the requirement for providers. And there's no additional notification requirements, at least to the prescriber, that are included in this version of the legislation.

But as I move on, this kind of leads into this year and the trend we're seeing this year. Now, this was at the last Thursday. I just got an email that Vermont introduced a bill. And I think we've got one coming very soon in a couple other states. But here's what we've got pending so far.

And the unique thing about 2014 that we're seeing is this tie to this interoperable electronic health information exchange showing up in a lot of bills. However, most states don't have a requirement for providers to connect to those kinds of systems.

And what's also unique to the 2014 legislation is that if the state doesn't have this electronic exchange available, then notification is still required to the prescriber within 10 days is the average of what we've been seeing. So really doesn't solve the issue. It looks like a great idea, but doesn't actually solve the problem, because most states don't have the requirement like Massachusetts does. So it's interesting to note.

Another unique amendment that we're seeing being added to some of the legislation across the country relates to including in the notification requirements and the restrictions on substitution insulin products. We're seeing that attached in a couple of states. Where that goes remains to be seen, but I thought was important to note as well.

So in summary, as you've heard a million times, the FDA is the only regulatory body with that scientific expertise to determine interchangeability. And as I stated, we're really concerned about the onerous requirements on substitution of interchangeable biosimilar, as we think it's premature and we believe that it may conflict with the national standards the FDA is currently developing.

And I thought I'd leave you with one quote from the FDA. Now, the FDA doesn't engage in state legislative battles, however, this quote was said publicly by the FDA commissioner and I think it's important. "The high standards for approval biosimilar and interchangeable products means that patients and health care professionals can be assured that when those products go to market, they will meet the standards of safety, efficacy, and high quality everyone expects and count on. Efforts to undermine trust in these products are worrisome and represent a disservice to patients who could benefit from these lower cost treatments." Thank you.

[APPLAUSE]

GEOFFREY EICH: Perfect. Thank you. Good morning. I'm Geoff Eich, Amgen's Executive Director for Research and Development Policy and a member of our Biosimilars Policy Group. As Susan mentioned, we're going to represent an industry view. But I wanted to caveat that the industry is not necessarily one of the reference product sponsors. And what I'll represent is also our biosimilar perspectives. We and many others that are engaged in a lot of these issues.

I think Ron sort of put together a really nice slide, an overview of what this industry looks like. The biologics industry is increasingly a mixture of small companies partnered with large biologics companies partnered with generic companies. And so what you see in terms of the industry that's evolving is a very different mix than what we've seen historically. So I'll try and represent that view.

My colleague [INAUDIBLE] and I who's also here today to speak on naming, we represent Amgen's very significant investment in research and development of biosimilar products for the US and for other regions of the world. And so our commitment to the success of the US biosimilar program really cannot be dismissed.

There are three things that FTC must consider as it evaluates biosimilars and policies surrounding it. First, and its fundamental, biologics are not generic products. We've heard this before and there's many good examples of this. The issues of state legislation, naming of the products, and also the way the FDA labels the products, are going to be collectively important to biosimilars and I'm going to talk more about how that evolves.

And also that empirical data demonstrate the need for a complete and accurate patient medical record. We're going to talk about what exactly is behind the concept of communication between the health care team. And the objective is a complete and accurate patient medical record.

We have the benefit of being both a pioneer in biotechnology and a leading developer of biosimilar products. We know and understand the complexity of biologics and can state categorically that there are important differences between these products and generic drugs. Every biologic medicine, every single biologic medicine, is in fact unique. And this fact is absolutely fundamental from a scientific, regulatory, and health care policy perspective.

We can tell the difference between a process change for a product that we've known for years and a biosimilar product to a reference product that we've just met. Along with regulators in the scientific community, we can empirically tell the difference between three biosimilar products of the same reference product.

Amgen and other leading manufacturers have long experienced managing manufacturing risks and designing rigorous quality systems, both to prevent errors and to quickly identify errors that cannot be prevented. We have seen both predictable and surprising changes in product quality with our biologics and with others. We know that hubris is for the uninitiated.

We have pioneered systems to perform post market surveillance and statistical signal detection for each lot of our biologic medicines. We've also experienced misattribution of adverse events to the wrong manufacturer and we have experienced also that these can change the benefit risk profile of an entire class of medicines.

Biologics are materially different than chemical drugs, oral chemical drugs. They're utilized differently in patient care and these differences are central to discussions on product selection and nomenclature. Biologics are injected and infused, as you've heard today. They're frequently and doses that are specific to the patient and her disease. They have unique degradation profiles, limited shelf life, and are rarely stocked in quantity in pharmacy inventories.

Approximately 70% of all biologics in scope of the biosimilar law are dispensed in physician offices, clinics, hospitals, and other institutions with their own procedures. 25% are dispensed via mail order and only 5% are distributed in traditional brick and mortar retail pharmacies. This is a distinctly different scenario than in 1979 when the Federal Trade Commission considered product selection laws the first time.

Looks like I'm missing a slide here. This is the new kind of product in a new era. And all appropriate policy options should be considered and our history with generic drugs should not guide us to overly narrow or false choices. That's the second one.

Must we choose between increased access or the ability to monitor specific medicines reliably? Must we choose between low cost medicines or for patients to have an incomplete or a complete medical record? Must we choose between vigorous competition or enabling manufacturers to voluntarily stand accountable to the patients we serve?

Why not transparently label biosimilars to engender patient and physician confidence? Why not enable patient medical records they clearly identify specific products? And why not select distinguishable non-proprietary names for distinguishable products?

Increased access to biologic medicines can and should include policies that are appropriate to these classes of medicines. We believe in and, not or. Let's be clear. An inability to identify a specific product reliably jeopardizes all biologic programs equally. That's fundamentally important to understand.

And people understand ask me why Amgen is so passionate about this. And the answer is, it's simply the right thing to do. This will stand the of time and of rhetoric. We do not have to make false choices.

Framing the debate based on our history with generic chemical drugs or the state of affairs years before the recombinant DNA medicine were first introduced is misguided and will not lead to a lasting or robust biosimilar marketplace. However, this 1979 FTC report is a valuable reminder for some regarding the characteristics of a model product selection law and how it can be distinguished from a mid century anti-substitution measure.

The US health care community today is well educated, globally aware, and increasingly knowledgeable in the science that underpins biologics. Patients and their families share highly informed perspectives and we're pleased by the interest of policy makers. We are paying close attention to the perspectives of the pharmacists who will dispense these products, the clinicians who prescribe and often administer them, and the organizations that will pay for them.

It is clear to us successful competition in the biosimilars marketplace will be grounded in patient and physician confidence. Indeed, in its 1979 report on this subject, FTC noted, and I quote, "Increased communication as well as lower prices may explain why most pharmacist report that product selection laws have had a product positive effect on their relations with patients." Surprising? We think not.

Efforts to describe biosimilars as generics and all but name do a fundamental disservice to health care professionals, patients, and their families. They intentionally obscure from pharmacists, patients, and providers the scientific reality that each biologic is unique and hence these are anti-consumer. They are often a conscious effort on behalf of special interest. They are offensive to protein scientists and increasingly disparaged by academia regulators and competitors as misleading.

Some even journal articles argue emotionally that biosimilars have to be foisted on patients, switched furtively at a pharmacy before administration. Others want the physician removed entirely from the conversation about which biologic medicine has been administered.

These views demonstrate an inferiority complex and it's a belief that biosimilars are not as good as their reference product. We fully reject these views. We have no inferiority complex about our biosimilars and we have no shyness about the important potential enabled by FDA's regulatory construct. It allows a significant design, development, and product flexibility.

We appreciate and will use the freedom allowed by the biosimilars pathway here and around the world. We want our biosimilars to have distinguishable names because they are distinguishable substances. We want patients to have complete and accurate medical records so we may be accountable when they're administered to patients.

The product selection approach we advocate for, along with patients, physicians, scientists, and the leading biologic and biosimilar manufacturers, is to update existing state product election laws to include interchangeable biologic medicines when determined by FDA to be appropriate for alternating or switching between products. The legislation also seeks to address an unintended but important consequence of product selection. Absent some level of interoperable health records or after the fact communication between pharmacy and clinicians office, the patient's medical record will be rendered either ambiguous or inaccurate.

This is fundamentally important. The patient's medical record will be rendered ambiguous or inaccurate and that is an important record. The records help accountability and this is the only area where the proposed biosimilar legislation differs from the model product selection acts that the FTC has helped to advocate for. Communication between the health care team for purposes of record keeping after product selection and administration hardly constitutes an intervention. And those who would suggest as much are confused.

So why does this matter? Here is a chart of European patients experiencing an increased rate of adverse events. The actual medicine doesn't matter and nor does the setting.

But the important thing is that each line you see here represents a patient's medical history as reconstructed by a researcher in Paris. By the way, these are all brand medicines before the EU approval of biosimilars. The different colors on each line represent different biologic medicines or routes of administration administered to each patient.

If you look closely, and I realize they're small, the red dots note the onset of clinical symptoms and the green dots represent diagnosis of a rare but serious adverse event. At the time, records were not as accurate as they needed to be and determination of the manufacturer having a problem took too long.

But what's also important is where the green or red dots occur on a product other than a yellow line, we now know that the agent the patient was receiving at diagnosis was not the root cause of the problem and the products administered previously were the likely cause. This is the point on records. This is not a hypothetical scenario. It is our reality in the biotechnology space. In the US today, a lengthy process to identify or resolve a quality problem in the context of multiple manufacturers, because medical records were rendered ambiguous or inaccurate, will neither engender confidence nor enable our collective objectives for a biosimilars.

Patient medical records also play an important role in data collection and communication of adverse events. This is information that serves often as the first warning of a quality problem with the medicine. The information on past drug history and suspect medicine or medicines in a report are of important value. When it comes to post market surveillance and accurate record keeping with biologics, it's neither wise nor reasonable to invalidate experience based procedures and processes for drug safety.

So here in a single figure, depicting the concentration of a biologic medicine in a patient's body, we can actually examine the problem posed by product selection absent any level of communication or an interoperable health record. We modeled the biologic monoclonal antibody that's frequently used in self administration.

For purposes of argument, we've assumed here that it's an identical set of product characteristics, including absorption, clearance, immunogenicity. In practice we expect subtle differences between all products, some that could result in important but latent events, or quality changes that occur throughout the product's life cycle. The red, yellow, and blue sections depict the concentration of each medicine in the patient's body.

And the graph shows exposure of what it would look like with the patient receiving a recommended dose every two weeks. Given current practices, the patient could well received a product from a different manufacture every 30 or 90 days. Here, conservatively, we've assumed every 90 days.

What you can see in the tail of these curves, in the red, the yellow, and the blue, is that biologics persist within the body for a much longer period of time than most small molecule drugs. Overlap to exposure to circulating biologics from different sources is likely. To make this more clear, the patient may have two or three of the biologic medicines in their body at a point at which they report to their physician and are having a loss of efficacy.

There's also a black hash line that shows the rate at which anti-drug antibodies are detected in patients when treated with just one source of the biologic. Many patients develop an immune response against some biologics and, as stated before, this can manifest in a loss of efficacy or allergic type reaction. The immune reaction starts on the first injection, but it can take many months to be detected. This occurs with the original medicine and is equally expected to occur with the biosimilar.

So let's take a look at the blue vertical line. The blue vertical line highlights the question of what happened seven to eight months into a patient's course of therapy if they're losing response to the medicine. Which product is responsible? Which one is not? How can this be ascertained in a timely fashion so that patient care is optimized?

As you all know, our immune systems have long memory and vaccines frequently provide 10 years of immune surveillance. For a biologic medicine that elicits a strong immune response, this can to last for over a year. The immune system is ready to react vigorously should the foreign substance appear again. So this is the reason we need to ensure a complete and accurate medical

records with all biologics. When a problem is identified, the initiating biochemical event may have occurred long before.

Our scientists are motivated by the work we've done on biosimilars and many of our biosimilar candidates are now in their pivotal trials. Our manufacturing scientists and experts have risen to meet a number of vexing challenges. We have not yet talked about virtual interchangeability, but that's certainly something we can address with the agency.

Biologics are not generic drugs. State legislation naming and labeling are collectively important for biosimilars and empirical data clearly demonstrate the need for a complete and accurate patient medical record. Rules that would impede transparency or frustrate post market drug surveillance will not be successful in this age of technology.

We believe if we're transparent, specific, science based, and most importantly, accountable, we'll earn the trust and confidence of physicians, of patients and their families, and we will see a meaningfully more successful biosimilar program in the United States. We believe in and, not or.

[APPLAUSE]

STEVEN MILLER: I want to thank the FTC for inviting us today. My name's Steve Miller, I'm the Chief Medical Officer with Express Scripts. Germane to my comments today about the consumer and their views on biosimilars, I need to give you a little bit of my background.

My career started as a transplant kidney doctor. I was a basic scientist throughout most of my career doing primary drug discovery and actually hold patents with several of the companies that are represented here today. After that, I actually open a dialysis network for the university and we became the largest provider of dialysis services in the state of Missouri during the 1990s.

That was followed by a stint as the Vice President Chief Medical Officer for Washington University and Barnes Jewish Hospital, at which time I actually had the opportunity to oversee 13 hospitals' pharmacy practices. And most recently for the last nine years, I've been the Chief Medical Officer for Express Scripts.

This unique background gives me an opportunity to talk about almost every aspects of the channels in which biologics are used. And my comments reflect that of the 65,000 pharmacies in the United States, including the specialty pharmacies that dispense specialty drugs. But it also represents the thousands of clients that we serve and 100 million patients that we represent.

Biologics are a really challenging part of the future of health care, as demonstrated by this pie chart. If you look at drug spend today. So if you think about this pie as being about a $300 billion pie, about 30% of drugs right now are specialty drugs. The vast majority of those being biologics.

As you've already heard, by the year 2018, 50% of pharmacy spend will be for biologic drugs, or specialty drugs. If you dissect this and look at who's using this, this is 1% to 4% of any given

population. So you're talking about 4% of the patients in the United States will be consuming 50% of the pharmaceutical spend, most of it for biologics.

Now, you can't read the drugs in these stat charts, but all you need to do is look at the colors to understand what I'm talking about. In 2010, as you can see, seven of the top 10 drugs in blue are traditional oral solid drugs. Or six of the top 10.

So as you can see, the vast majority of the drugs that are big spend drugs right now our traditional oral solids. If you just fast forward to 2016, what you see is seven of the top 10 will be biologic drugs. And so we have a complete flip of what spend is going to be for pharmaceuticals going forward.

And the great news is, is that the innovative community of the pharmaceutical and biotech industry has really hit a stride where they're having great success. They continue to bring to the market truly remarkable new products. And our view is you want to save every dollar possible to spend on these new products.

And so when you can have substitution to a cheaper, equally effectively biosimilar, that's a great opportunity not just for consumers. It's a great opportunity for the pharmaceutical industry, because those dollars can be repurposed for patients who need these great new drugs. And these drugs truly work. They are incredibly remarkable.

When I was a med student and I'd go to the nursing home to see family members, you'd see family members or old people with these incredibly slow and painful hands. They could not even grip the utensils at the table and needed these special little bumpers to actually hold their forks and knives.

If you go to a nursing home today, because of the advent of phenomenal new drugs, you don't see this. Your kids or you won't have this same experience as your grandparents did. So these products truly are not just life saving, they're life altering, and they're really important to have in the marketplace.

Now, we did a study to look at what would happen if biosimilars actually made it to the United States. And we've been talking about this for a long time. And so we've actually had the opportunity to do this study on several occasions. But we looked at 11 products that would be losing their patent protection over the next decade. And we've made some assumptions. And the assumptions are relatively conservative.

Whereas in Europe you're seeing discounts of 30% to 50%, we said the largest discount you'll see in the United States ever is 30%. We start at 30%. It never goes up despite more competition coming into the marketplace. We thought that inflation would slow.

So if you had a file somewhere enter the marketplace, the brand inflation would drop and so we put in a drop for brand inflation. We thought that there would be modest switching, but oftentimes we would only be able to get the new patients. Many patients would be grandfathered,

so we assume that there would be very modest switching to the products, and we assume no interchangeability until the year 2020.

On top of that, we put almost no growth in the market. We put 0.1% increase in utilization annually over time. So we made every assumption as conservative as possible.

And for these 11 products, what you see is that this is the trajectory of their spend over the next decade. If you have biosimilars for these products, with slow uptake what you see is a delta that occurs that over the next decade you could have a quarter of a trillion dollars of savings in the United States for just these 11 products.

Now will we be wrong in these projections? And the answer is probably right. We will be wrong. Sometimes we'll have guessed too low. Sometimes a discount to be way greater than 30%. Sometimes the uptake's going to be way greater than 0.01%. But we know directionally this is correct and we know that the opportunities are enormous if we can get biosimilars into the marketplace.

But as you've heard over and over today, there are several concerns. And these concerns are around two things that we'll address today, and that is the nomenclature. What's the naming of these products and what are the state substitution laws? As you've heard from several speakers already today, the United States actually has a robust and vigorous system that has protected patients over the course of the last many decades, even with the advent of generics.

We now have a generic substitution occurring 84% of the time, and patients are being well served by this. And so now we have new arguments coming about the purity of the medical record. I can tell you as a practicing physician, the medical record is ambiguous. And I will also predict the medical record will continue to be ambiguous into the future. But we can't let the perfect be the enemy of the good.

On top of my other credentials, one of the things I didn't mention is I'm also the Chairman of the Board of Surescripts, the number one router of electronic prescriptions in the United States. The idea of bidirectional interoperablility is not only unlikely in the near future, it's actually often not even desired by doctors. When we have transactions that the doctors actually thought they want to get, oftentimes in reality they don't.

I'll give you an example. When we were first creating the system, we asked the doctors, "Would you like to be notified if a patient picks up their prescription at the pharmacy?" You would think that a doctor would want to know that. But we found out when we started piloting it is that the doctor's, in fact, did not want to get those notifications.

Not only do they not want to keep the records, but they wanted to limit their liability and they did not want to be liable for that period of time when the patient doesn't pick up their drugs. And so this assumption that doctors want all this data is actually often misplaced.

There are four major channels in which biologics are distributed, and you've heard about those already today. They are delivered through the pharmacies, and that includes both the retail pharmacies but also the specialty pharmacies.

They're delivered through the hospitals. They're delivered through the hospitals clinics. The pharmacy, hospital, hospital clinics. The third place is mainly through dialysis units. And the fourth is physicians doing buy and bill and dispensing in their office space.

It turns out that the records in the pharmacies are extraordinary. And we'll show you the data for that coming up. It turns out that the records in the hospitals are extraordinary. And it's mainly because the hospitals want to be reimbursed from their clinics or inpatient facilities and they need to have that data. It turns out the dialysis units, which I worked for many years, are phenomenally capable of keeping great records and know which products they're dispensing.

The only hole in the system is actually when it's the physicians who are buying and billing. So physician notification to physicians who are already failing to keep the records in their own buy and bill is unlikely to add safety to the system. And so this idea that bi-directional physician notification is the key to this whole problem is actually misplaced.

So what we all want to do is we want to improve access and we want to create the savings that are out there. It turns out the reason pharmacy is so effective is because the amount of data that's available to every single pharmacy, every single hospital, every dialysis center, is actually an extraordinary amount of data because of the way we bill. Every product already has three unique identifier on it besides the INN. It has a trade name, it has an NDC, and it has a manufacturer.

If you require the use of one of these unique modifiers for billing purposes, for reimbursement, doctors, hospitals, dialysis units, are phenomenally effective the collecting that data and submitting it. And so the idea that we can have great pharmacovigilance is actually true because we already have very accurate records in most settings. The idea that the biggest hole was where physicians do buy and bill that notification will close at hole just leads to inefficiencies in the system. It's fear mongering. It adds confusion. But it does nothing to make the system safer.

So let me show you some data. We looked at the prescribing habits of doctors and we looked at several things. We looked at not only could we track every product that went out the door, we looked at how the doctor prescribed it. Atorvastatin is the generic for Lipitor. And as you've heard already today, the vast majority of times even when products are generic, the doctor is using the brand name to prescribe the medication. So making the INN unique for the product will not add safety.

So even when it comes to Atorvastatin and the vast majority of those scripts come to my pharmacy written as Lipitor. But if you take a drug even well older than that, Azithromycin, we still get the majority of our scripts Z-Pak. And so the reality is, physicians prescribe by the branded name.

Now in Atorvastatin, in a one week period we dispensed about 160,000 prescriptions from Atorvastatin. We adjudicated these. They went out from almost 52,000 pharmacies from 15

different manufacturers. We could tell you the exact product in the hands of every patient because of the use of the NDC codes that are required for pharmacy reimbursement.

If you look at the biologic drugs, 419 scripts for growth hormone, 11 different trade names, one INN, 145 different pharmacies, seven different manufacturers. Again, we could track down to the individual patient exactly not just what product they got, but what vial size they obtained the drug in. And finally, for EPO, 333 claims, 285 pharmacies, two manufacturers.

The reality is the system that the FDA has created in the United States is safe and effective. It's safe and effective for the biologic companies to use today. And it will be safe and effective for the biologic companies and the biosimilar companies to use in the future.

If we're going to have effective biosimilar regulations, we need players and plan sponsors to work together. Because they're phenomenally concerned about the rising costs of this. This is an unsustainable pace we're on, and we need to do something so that we have more money to spend on the great new products people want to bring into the marketplace.

The high price of specialty drugs clearly represents a barrier for patients to be able to use these drugs. And patient assistance programs are inadequate in and of themselves. If we're going to have success, it has to be all the stakeholders in the room today working together to create a system that works better to keep safety the way it is and to drive down costs so we have a more efficient system.

Adding inefficiencies like doctor notification is nothing more than adding confusion to the marketplace, putting in inefficiencies that will cost time, cost money, and prevent patients from getting the products they need. And the PVMs and the pharmacies are going to play a crucial role in this going forward. Thank you all very much.

[APPLAUSE]

BRUCE LEICHER: I feel like I don't need to say good morning anymore. I'm Bruce Leicher. I'm here for Momenta Pharmaceuticals and I guess like my prior colleague, Geoff, I'm also here to represent the industry viewpoint, I guess. Which isn't necessarily unified.

What we're focused on at Momenta is actually the innovation that you heard a little about from Ronnie earlier and from Dr. Schacter about how the pathways driving innovation. The notion that we needed to invest in developing the characterization and analytical tools to demonstrate biosimilarity and interchangeability is based on the fact that there'd be a return on an investment. I'm sorry. I should get closer to the mic. And we think we're seeing the fruits of that now.

Momenta is much like many other biotech companies. Let me just say that we were spin out from MIT and were largely focused on it. And the company was principally involved in the original characterization and development of Enoxaparin, which you heard about earlier.

So in short, let me just say our view on this is much-- I'm going to try and synthesize some of what we heard this morning, because much of what I was going to say I think was covered by

many speakers. But we think that the biosimilar and interchangeable biologics policy that's adopted should be designed to promote innovation and attract investment like the investment Momenta and many other companies are making in making innovative interchangeable biologics. And that it should be designed, as Steve Miller was just saying, to address the patient needs as well as patient safety. And that it should avoid using anti-competitive restraints to do so.

And I think what I'm going to focus on through much what I'm saying this morning is that I think when you tie together the big proponents of the state law bill,s what you're going to see is one common denominator. And that is really, in our view, part of a commercial marketing campaign to make interchangeable biologics look like biosimilars. In other words, they're really not interchangeable. They're different. And to discourage substitution at the state level and to have a forum where you can make disparaging type comments without the risk of enforcement.

I think it's stuck.

This one. There we go. We really need to put this in context. There's been a long established campaign against biosimilars from well over 10 years. The first message was generic biologics are impossible. And then it translated into, well, they have to be biosimilars and we shouldn't have an interchangeable part of the pathway. And the whole point, in either case, was to prevent substitution.

And then the same messages reappeared in the comments from opponents at the FDA in the biosimilar guidance documents. They were used in support of citizens' petitions to delay biosimilars and to put in place the naming restrictions that you've heard about. And you saw this earlier in a presentation, but there's an effort underway to seek to use restricted access to limit access to comparative product as well.

It's interesting to me listening to the talk from Geoff this morning that there's a key part, and maybe I should have to add another one to the list here, a key opposition strategy that seems to have fallen out of the talk. And it was the argument that brand products drift and are made in different manufacturing facilities and therefore it's not really-- and since we have differences, just think of the differences we'll have with interchangeable biologics or biosimilars. And that one seems to have gone away.

But the point I want to make on that subject is the whole benefit of having interchangeable pathway was what Emily Schacter described earlier, which is it created a fertile field for companies like Momenta-- we're not the only ones-- to learn how to develop the science to make products that can be substituted and can be switched and reviewed by the FDA to demonstrate that that's possible.

And while yes they may not exist today, the reason we fought for the interchangeability pathway in the law was to create that opportunity to attract the investment. And if we allow the states to put the barriers in place that make substitution a challenge, then I think we're going to remove the opportunity for that investment and the kind of innovation we've seen in the last couple years is going to be diminished.

So now we're faced with the next tactic. And I think we heard the next tactic described perfectly. And it's, essentially, the states are being asked to join in a campaign to say there's a problem with pharmacovigilance now, just like there was a problem with brand draft.

And if you think about it, each of these arguments that's been made historically is true in the sense that there are problems with systems. But there's nothing necessarily unique about those problems to either biosimilars or to interchangeable biologics. And what should be fixed is the problem. It shouldn't be used as an anti-competitive tool.

So for example, by thoroughly characterizing, as Emily described, and understanding what's in a vial, one has the ability to substantially reduce the risk of brand drift and product changes at new manufacturing facilities. And it's the technology that's being developed by companies developing interchangeable biologics that's going to make that possible.

So we heard a little about this this morning. But why is substitution so important? Well essentially, and I think this is really the guts of it, eliminates the need for sales and marketing to physicians and payers. And you'll note that there are some companies that now support a so-called compromise that you've heard about, where it's going to say, well, we're going to have interoperability at the state level, but when we don't have interoperability, we're going to still require a special notice.

And what that does is it enlists the state in an effort to say, "You know what? Interchangeable biologics are different." And It's interesting. If you read the California statute, it described their interchangeable biologics in the statute as biosimilar. It didn't describe them as interchangeable biologics.

And I think there's a conscious effort to, if you look at a lot of the presentations, to try and confuse that there really is a higher level of proof associated with interchangeability and it's something FDA would determine is substitutable and switchable.

And I think the other thing to look at as you examine the companies that are supporting this compromise legislation is, are they really developing interchangeable biologics through innovation, which they may or may not be? And are they planning to market those through substitution or market those through a sales force?

And I'll at least posit the hypothetical that the companies that have lined up behind the compromise are companies are looking at using sales and marketing as the principal mechanism. And they're trying to basically enact into law competitive restrictions so that those who can obtain substitutability won't be able to achieve the benefit of it. And that would be a shame.

And just to make this point, the notice provisions are really just designed to make the point that interchangeable biologics really aren't interchangeable. They're different. And that they're suspect. And this point was made actually point quite forcefully by bio recently in the food area where there were a number state laws being proposed to require labeling of GMO foods. And the legitimate response to that is that that's just a disparaging comment.

So in the end, what I think you heard from a number of the folks here on the pharmacy and on the payer and consumer side is it matters to patients, it matters to physicians, it matters to payers. And we think it matters because we're a novel development company as well.

We think it matters for novel products as well. Because in the absence of it the presence of interchangeable biologic competition biosimilar competition, there won't be headroom in the budgets to pay for novel products as they launch.

Now, last year I think there was quite a bit of press around the issue was the laws came out. And people were catching on to the fact that this really was a commercial campaign. And that's probably why we saw some of the toning down of the message.

And I'm not going to dwell on this because Steve did such an excellent job, but it really does matter, based on just looking at the Express Scripts data, to have this competition available. This is one set of data that shows if you look at specialty products, we could be looking at over 65% cumulative price increases just in the next three years.

So what is Momenta doing? Well, I actually want to thank Emily Schacter, She described a lot of what we're doing. No, it's OK. And this a standard biosimilar. And this is what people had in mind perhaps 10 years ago when they thought about what was being developed in and raised concerns, before people started thinking the way the FDA is and perhaps the way we were and we were developing generic Enoxaparin. And that there we're going to be things you might know that are the same about it, there are things you might know that are different, and there are things you might not know at all about it.

And what we've focused on, and I think what other companies are starting to focus on, is you actually can get to a much higher level, high similarity, which is really the middle segment, by focusing on the thorough characterization. It's not the clinical trials that are going to provide the differentiation. They'll provide explanations to whether anything that remains is an issue or not.

And ultimately, we believe we can get to where it's blue and blue. And we're not saying we can get there today, but if we have state laws that take away the economic advantage of investing in that innovation, I think the opportunity for that to occur is really put in jeopardy. And from our perspective, we think this isn't fantasy.

Everyone made the same arguments on the opposition when we were working on the development of generic Enoxaparin. And you'll see from Dr. Sherman's quote, in her view she felt this was about as complicated as any biosimilar application would be in terms of demonstrating similarity.

Now let me switch to what's wrong with special notice. Essentially the reason I said before, the reason they argue for it is really to give it competitive advantage in the marketplace companies have sales forces and that can deliver the message. If the state determines that you're not substitutable or it's hard to substitute, it's going to be a lot easier for sales reps to go out there and point that out. It's going to indicate they're different. If they have different names, it's going to indicate they're different.

And so as you heard from Steve Miller, and I learned some more about it today, there already is an existing Surescripts network that largely covers or has the opportunity to cover most pharmacies. It's interesting here his comments about doctors' interest in actually getting the information.

But the advantage of this system if you look at it is it allows the physician not only to know what was dispensed, but to know what was dispensed before, so that when a prescription is written, you can take into account conflicts. It avoids what the real basic purpose was, to prevent prescription error.

And what I'd also add is the adoption. This is just an example because I'm from Massachusetts. The adoption of Massachusetts, which is not mandatory for another couple years of interoperable health records, which is a bigger system, but the adoption of e-prescribing is in the high 90% and it's grown at very substantial rates in the rest of the country. This is an innovative way to make available information to doctors if they want to know.

And what's also important for people to know is that the national e-prescribing patient safety initiative we set up recently, and it makes available access to this system for free to any doctor in the United States who wants. There's no barrier to entry. A doctor can write a prescription on a script pad, but they can join this system if they want to know what the patient was dispensed, and they an look it up.

So as you heard earlier, Massachusetts adopted a law which doesn't effectively put in place a notice requirement. And if there's no intervention required, no prior notice, no special record keeping. And it uses the interoperable health records as the mechanism so that it doesn't disparage or distinctively label that an interchangeable biologic is different.

And one of the interesting things that I've noticed, that Mass Biohad a legislative breakfast in Massachusetts about a year ago. And they invited a panel of speakers. Some of them are here today perhaps. And to speak to the legislature about what's biosimilars bill ought to be, and I think they expected it to be the messaging that biosimilars are different.

And they invited Professor Hancock, who's one of the leading researchers in the United States on analytics to speak. He got up and basically said what Emily said. I want people to know that the state of the science for analytics in the last 10 years has dramatically improved. And he said others may disagree with me, but I can show that two proteins are the same.

And I think that kind of affected the power of the commercial message that was being displayed on the legislature, which caused them to be a little more innovative in their approach. And as you heard, the California bill similarly was vetoed as people focused on it.

So just took to briefly summarize, we see that the state laws conflict with the BBPCIA, which provides that a biologic may be substituted at the pharmacy without the intervention of a physician. We believe that the special notice requirements are designed to get physicians to intervene and are designed to create negative disinformation about biosimilars. And we see that it's a real burden on the statutory provisions.

What is important to note is Hatch-Waxman never provided the generic drugs are substitutable at the pharmacy. But this law expressly provides that they are. So it seems to me, and this is really what we think the FTC ought to recommend and we think what FDA and CMS ought to do, is put into their guidance documents that these provisions that restrict substitution are in violation of the provisions in the BBPCIA and that we should just solve the problem simply.

So I'm going to take the last couple minutes just to make a statement or two about naming, which really I think follows the same path. I think you've heard people believe that biosimilars when they're approved by the FDA are going to be therapeutically equivalent. And the interchangeable biologics to get approved by the FDA have to be substitutable and capable of being switched.

So the standard for approval is going to be quite high. And it would seem to me there's no defensible basis for creating a distinction that would interfere with their appropriate use. And the notion that you would have a different name for an interchangeable biologic, which is intended to be substituted and switched, just seems beyond what's intended by the law.

Here's some examples of the messaging around this issue that we collected. You may hear a little less today because we've been criticizing it for some time. But I think over the course of the past year and the past 10 years, it's always been a campaign of biosimilars are different, interchangeables are biosimilars and therefore they're different. And this is all about patient safety.

And one of the things that I reacted to when I was watching the presentation on pharmacovigilance earlier is when you're making a biologic and you have multiple manufacturing facilities, or you may have multiple manufacturing changes, there are often, not all the time but there can be often multiple manufacturing company versions of a product on the market at the same time.

And none of the companies are suggesting that they have a different name or that they have a notification at a state level of which particular flavor of the brand is being dispensed. That's for some reason not a safety issue. But it's a safety issue when you dispense an interchangeable biologic, which has actually been proven to the FDA, with tests that were not necessarily conducted in doing comparability testing to be switchable and substitutable.

And it's also interesting to get feedback from the EMEA, where they're increasingly paying attention to the issue of characterization and recognizing that the variability in the brand products should more than encompass the variability that could be made in an interchangeable.

I'm just going to close on this one note. The other thing I just want to bring up, I saw it in a few other presentations, is there are a number of companies, and I don't know that it's become prevalent yet, that are looking to use restricted access programs to affect competition. And I would encourage the agency to pay attention to that as well.

So let me just conclude with the following points. We think that the policy should be driven and measured by how it promotes innovation through the development of interchangeable biologics and that we have an ability to attract investment by having a pathway available. We think it's

important to address patient needs and patient safety and we think that a policy should be picked that avoids using the least innovative and the most anti-competitive solutions. And we'd encourage the FTC to encourage the FDA and CMS to interpret the statutes to properly restrict these laws. Thank you.

[APPLAUSE]