

Preparing Promotional Review for the Shift to Omnichannel Marketing

Featuring Jason Cober, Lead Project Manager, OPDP, OMP, CDER, FDA and Zoë Dunn, President and CEO, Hale Advisors

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SPEAKER: Zoë Dunn

Okay, great. So let's get going. Thank you all for walking across the hall, getting your steps in, and coming to join us for this case study. Jason and I are excited to walk you all through this.

SPEAKER: Zoë Dunn

00:17 As a quick point of introduction, I'm Zoe Dunn, I'm president and CEO of Hale Advisors, you can go to our website and find out lots and lots more about us. But we've been working in the industry, I've been working in industry for 30 years. And our specialty is really in terms of governance. So we sit between promotional review teams, folks like yourselves mainly, and commercial marketers. And our goal is to streamline the promotional review process, especially when it comes to digital.

So we do a lot of governance work. And that's why we are talking today with Jason, who I think you all already know. Yeah? Jason.

So um, so I actually came to Jason about a month ago or so now, and asked if he would do this case study with us. We have spoken in the past, last year about some work that is near and dear to our heart, which is working across the industry on making sure that companies are ready for omnichannel, which is like

TODAY'S SPEAKERS



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President & CEO
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the biggest buzzword in the industry to date.

How many people here feel like they can clearly articulate what omnichannel marketing is? Anyone? No one? Fantastic.

SPEAKER: Zoë Dunn

01:31 Well, luckily, we do have a bit of a primer on that. You can go to Regulatory Focus, which is the RAPS website, and you can see an article that we just published at the end of January.

And it is really a primer on understanding what omnichannel marketing is, and really importantly, how it relates to your world. So it's not just a buzzword for marketing. It's how we're trying to get business done. And wherever your companies are in this journey, whether they've just told you that you will understand it, you will figure it out, and you will make it work—or they're actually investing really heavily in supporting you in that journey—we're going to we're going to talk about kind of a couple of the key things that you need to know today. And Jason and I are going to kind of have a fireside chat about getting you ready for all of it. So I hope this will be interesting and informative.

So the first thing I want to start out with—and by the way, Jason is a deep technology expert. He really got his start on the IT side of things, right, if you want to just talk about that for a moment. Jason, before we talk about this.

SPEAKER: Jason Cober

02:35 Yeah. So before I joined FDA, I was actually a software developer. I worked in behavioral health in Florida for about three years doing software development. So that was where I started before I came to FDA. I've been at FDA, so it'll be 16 years now. So you know, a lot more experience with FDA than programming, I couldn't find my way around code any longer. But you know, if you heard the last presentation, you know, the technology side really is fun. For me, this is what I like doing. Yeah.



Navigating the shift to omnichannel marketing

Zoë Dunn, BA

Pharmaceutical and biotechnology companies are shifting from multichannel to omnichannel marketing with a modular content approach to drive better customer experience. The industry is in the early to middle stages of formalizing roadmaps, establishing infrastructure, and performing pilots that will serve as the foundation for fully operationalizing and scaling the transformation. This article discusses omnichannel and modular content, their impacts on regulatory and promotional review, and considerations for preparing review organizations for the change.

Keywords – modular content, personalization, promotional review

Introduction

Many pharmaceutical and biotech companies are preparing to transition to an omnichannel marketing approach for their promotional materials and are being challenged by management to implement the systems, processes, and personnel changes needed to support this flexible and personalized approach to marketing. The issue is that the term *omnichannel* is often misunderstood and, as such, is causing confusion.

While the term may mean different things to different people, *omnichannel* is generally used as a catchall to describe a customer-centric approach that uses data to create and deliver personalized promotional and nonpromotional communications in a seamless experience across channels, thereby facilitating better and faster treatment decisions that contribute to better patient outcomes.

To make that vision a reality – and realize the benefits of an omnichannel strategy while also remaining fully compliant – not only will there be changes to

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SPEAKER: Zoë Dunn

3:03 Which is really great. I mean, Jason and I definitely have bonded over that, over kind of geeking out around digital and technology. But you know, today, I want to set the stage for you on really the difference and what is omnichannel marketing. So hopefully, by the time you walk out of the room, you will all be able to articulate for your companies, you won't be like, "No, I don't know what omnichannel marketing is," you'll all be able to articulate at least the way that we see it.

SPEAKER: Zoë Dunn

03:27 So. So there is something in place right now in terms of marketing that I would call multichannel marketing. And that is, that really grew with the rise of digital as a communication channel. And that is really using a variety of different channels to communicate your, your offering, your whether it's promotional or nonpromotional. There are a bunch of different streams of communication. And so those could be print, those could be television, and those could be digital, those could be webinars, those could be conferences or congresses that you attend. These are all the different channels. So when we talk about channels, that's really what we're talking about is multiple channels of communication.

It means being able to communicate in a personalized way across those channels. So leveraging insights from all of those different channels in order to serve up a much more targeted, personalized message to whoever it is you're speaking to, whether it's patients or physicians, and I'll explain that in a bit more detail.

SPEAKER: Zoë Dunn

04:27 But multichannel, the difference between multichannel and omnichannel here kind of very simplified on the screen is in multichannel, all of the information we know about those interactions with those communications is very siloed.

MULTICHANNEL vs. OMNICHANNEL MARKETING

	MULTICHANNEL	▶	OMNICHANNEL
DATA	Data silod and managed separately		Integrated data offers single customer view
CHANNEL	Unconnected channels operate independently		Connected channels work together seamlessly
CONTENT	Static and repetitive content		Personalized, dynamic, and adaptive content



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For example, we have information about how you're engaging with us in email, right? If we send you an email it and when I say we, I mean the pharmaceutical manufacturers, when we send you an email, you can click through the links on that email, you can sign up for our newsletter, we have information about how you've interacted with that email. But that's it, that information doesn't inform any other marketing choices that we make. It's just about email, it doesn't help us to understand how you're going to interact with our TV commercial, or how you're going to interact with our website, or how you're going to interact when our rep walks into the office and talks to you. And that is multichannel.

5:17 Whereas omnichannel, we're really trying to get to an integrated data opportunity here. So we're leveraging the information across each of those channels to help serve up the most relevant content in other channels. And that's the first part of it. That's the data. That's the technology side. And we need to have a lot of technology in place to make that happen. You'll hear these terms like data lakes, companies are establishing a way to gather all those different communication points, all those different data points into one place. So we can make decisions based on that that are better.

The second thing is the channels. So right now, in a multichannel environment, those channels are not connected to one another. You know, sometimes on a TV ad, as Jason was talking about, you'll see a QR code and that QR code drives you to a website. That's a really great example of connecting your channels. And I think we have always in the marketing side, wanted to make sure that those channels are connected, but they don't really. So our move is to really make sure that they are integrated in a unique way. And so in an omnichannel environment, these channels will will work together much more seamlessly than they currently do.

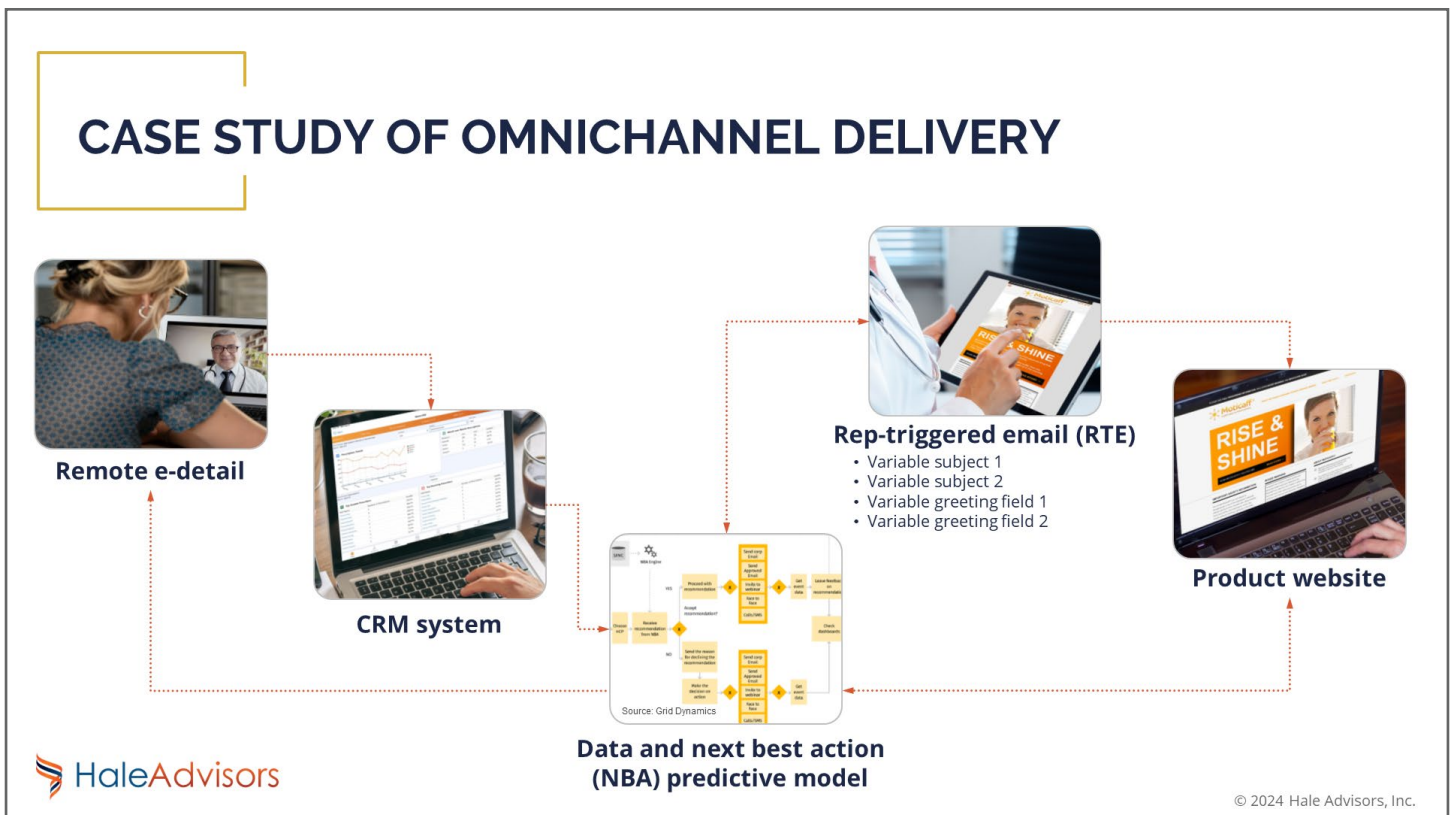
6:24 And then lastly, on the content side, and this is the big one, this is a big one for all of you and your promotional review teams. So right now in a multichannel environment, your marketing folks are developing content for each and every one of these channels independently. So they're writing emails, they're sending them through the promotional review process, and you're approving that email. Then separately, they're writing a television ad, and they're submitting that content and you're approving that television ad. There is no relationship, even though they will tell you that there is, between the content in the email and the content in the television ad.

And in an omnichannel environment, that content becomes modular, and that is really the money. That's what Jason is going to talk about in just a moment. Because when it comes through to OPDP, and it's submitted in your 2253, we're talking about a different opportunity here. We're talking about submitting content by channel, which is what the 2253 requires. But that content is modularized. That content is working across different channels. So does all of that, before we go forward, does all of that resonate with all of you and kind of make sense? Do you feel like you have a better handle now on what omnichannel means? You're going to go back and be like, "I know what omnichannel means. I am so connected." Okay, good.

SPEAKER: Zoë Dunn

07:44 Okay, so, so how does all of this work practically? So in terms of omnichannel delivery, as I mentioned, you know, there's there's kind of a flow-through of gathering these different data points. There's, let's say it starts out with maybe a remote edetail. And in the article, we kind of go through this in a literary way. So you can read through this this type of case study.

So let's say that there's a remote detail with a physician, we're going to capture some data based on that edetail, right, what they're interested in, what their questions are, what message resonated most with them. We're going to gather that detail into our CRM system, whether your rep is going to input it, or the actual engagement with the edetail is going to capture that—that information is captured together with all other information about other interactions that we're having with that physician. And it's going to serve up in what they call "next best action" in a predictive model, the data is going to serve up the next best predictive action. And that's going to happen in maybe the form of like a rep-triggered email, which has variable content in it. And this is really, Jason, when we talk about variable content. How would you define—I mean, like pause on this—how would you define modular and variable content for your purposes?



SPEAKER: Jason Cober

08:58 Yeah, so for us, when we look at module content, we're thinking I'm sorry, when we look at variable content, we're looking at a single piece, a single promotional piece with multiple variations. So think about the email example that we have. You know, you no longer have just one email. Based on the information you're getting back from your messaging platform or your email system where it may be. That's defining what the next email is going to look like. So your greeting, the claims that are in the body, the presentation risk in the body, the closing, any contextual information that you want to add based on those parameters coming from your

SPEAKER: Jason Cober

09:32 messaging system. That creates numerous different variations of a single email. That's what we call variable content.

Modular is when you start going across multiple promotional pieces. When you have a library of claims, when you have blocks of text, imagery, you're trying to use the same imagery or text or to kind of like create this unified campaign and use the same blocks across different promotional pieces.

For us in OPDP, whether you're doing modular or variable, everything on the 2253 has to come back to a single piece, the specific channel that you're going to market on. So if you're doing, say, three social media platforms, let's say you're going to do Facebook, Instagram, and LinkedIn, you can do the same piece across those three channels. But that's going to be three separate pieces on the form 2253.

Where my team comes into play is talking about how do you get that onto the 2253? How do you assemble that submission, so that you can submit in a compliant manner, because at the end of the day, what our reviewers need to see is the total universe of claims, the total universe of text, that you're going to be submitting in those variations of your messaging. So.

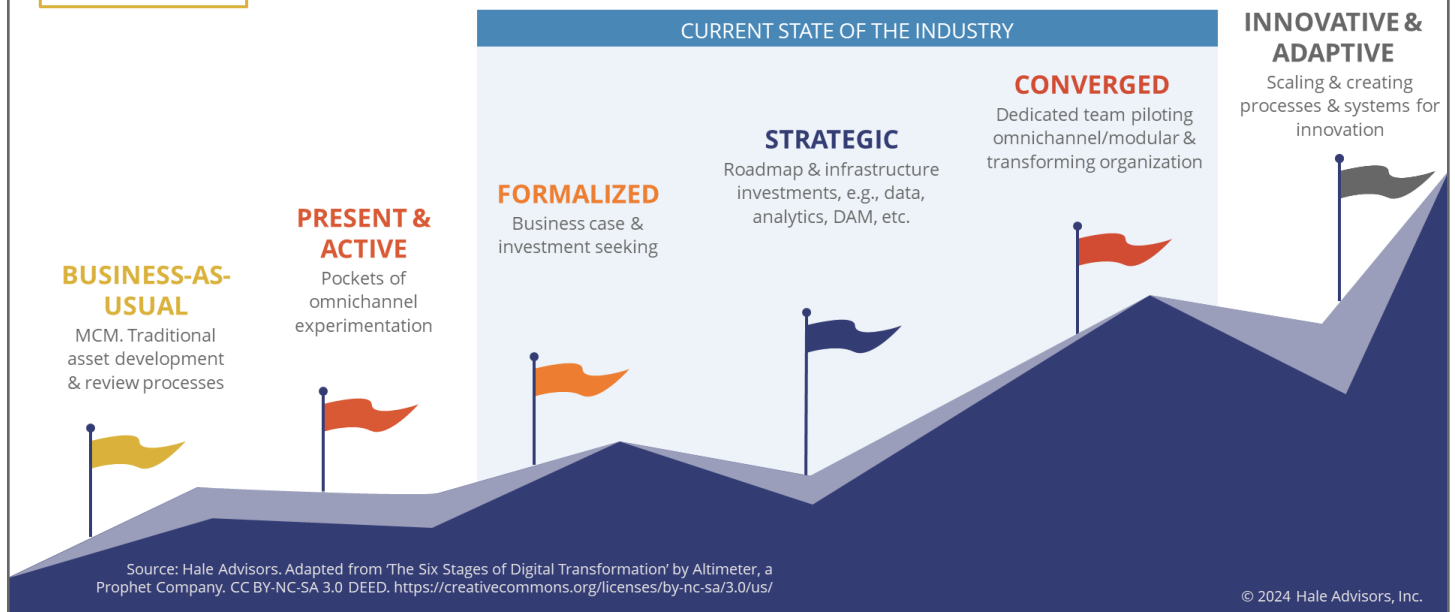
SPEAKER: Zoë Dunn

10:40 Perfect, excellent explanation. And the variable content, you know, when we talk about it right now, I think, people don't realize variable content is already in use, we have been doing that forever. That is not new. Variable content like the subject line, as Jason said, or you know, or the, the two headings, that is all content that we know is variable. We submit that through on the 2253. And we clearly annotate that this is variable content, here are the different variations in this content, and why, what the business rules are that are governing that variable content.

What is new when we're talking about omnichannel, as Jason said, is folding that into modules that can be used in different ways and the business rules that go along with stacking those modules of content together. And we're going to talk more about that in just a moment. But that's perfect.

So this rep-triggered email with that variable content within it is going to go, that that data, you know, how people engage with that data, that's going to feed back into that database as well. And it's going to serve up, you know, some new content that is going to be more related to, it's going to gather the inputs from the remote edetail from the rep-triggered email. And then perhaps that physician has also gone to the website, and they've taken an action on the website, that information is also going in. And so what we're hoping is, that we're serving up the most relevant content to that person, in that moment, that we possibly can. And that's really making the strength out of omnichannel.

INDUSTRY CURRENT STATE



SPEAKER: Zoë Dunn

12:08 As you can imagine, and we talk about it in the article, there's a lot of things that are going to have to change in terms of the way that we do business in order to make this a reality. And right now, the state of the industry is truly at its infancy. So I have spent the last three years supporting companies in this transition. And I've seen a lot of variation, from the biggest of the big companies who have really invested heavily in this, to these tiny little companies who are more nimble, who are really trying to invest in this as well.

And I can tell you that the majority of the industry is kind of somewhere in that middle range—we identified that this is important, we want to be much more personalized in our communications, as an industry. But we haven't really invested appropriately to be able to get there. And when I say invested, I mean technology. I also mean people and people in serving in the right roles to facilitate this. And process. And the process part is the trickiest part because this is going to really take some transition as an entire industry. And I'm going to explain that in just a moment.

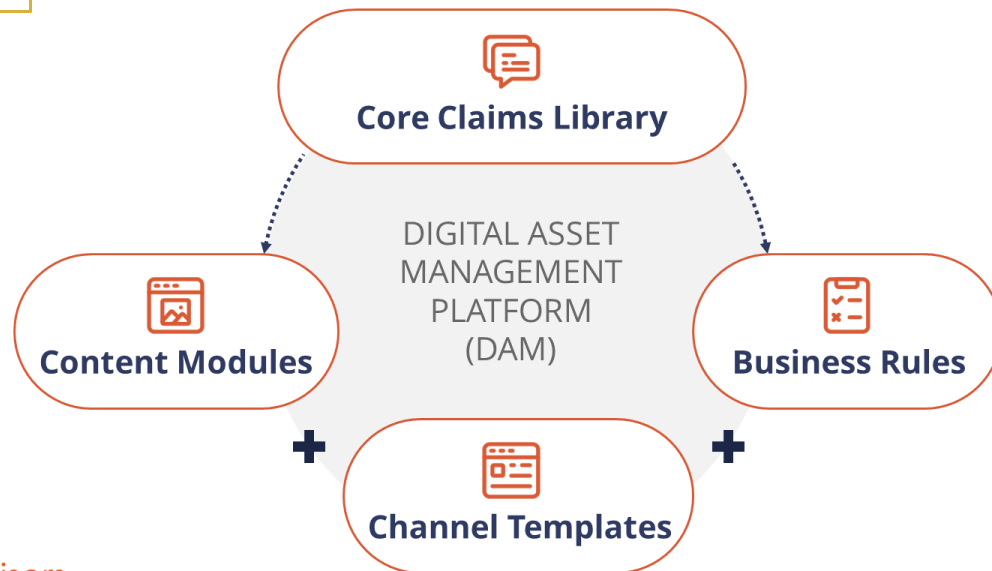
SPEAKER: Zoë Dunn

13:15 The components that we need, in order to set the stage for the process part are kind of represented here. And again, we explain this more in the article. But it really to me all starts with this idea of a core claims library.

So how many of you, right now, feel that you have active, well-used core claims libraries at your companies? Not many. Holy moly. I mean, how many companies do we have represented in this room? 30 companies, 40 companies?

So we can't get, let me go back a slide. I don't know exactly how we're going to get to the upper right corner if we don't even have core claims libraries. And why is this important?

COMPONENTS TO SUPPORT REVIEW PROCESS FOR MODULAR



14:04 Well, as Jason said, these modules have to be based on these core claims and the references that support those core claims. Marketers need to know and take ownership and this is the tricky bit. They need to know and take ownership over these modules, these core claims, and the communications that they make, the representations that they make, in order to be able to create content that is then going to work across channels. And without that, forget it.

So one company that I spoke to a few weeks ago, a top five pharma company, said to me that they have a core claims library established, and about 10% of their marketers—this is a huge company, dozens and dozens of products—10% of their marketers are implementing or using that core claims library. Now why? Some of the brands that are using core claims have three or four core claims in that library. Some of them have 150. Why you need 150 core claims? I don't know. Do you know why you need 150 core claims?

SPEAKER: Jason Cober

15:15 That's above my paygrade.

SPEAKER: Zoë Dunn

15:16 Yeah, I know it's above your paygrade. It's above my, like, conception, I don't even understand why people would need that.

So here's the sea change that we need to make in terms of the process here. First, we need to really help our marketing teams understand what the heck core claims are. I mean, do you feel any confidence that your marketers understand them?

SPEAKER: Audience

15:36 They do, but it's...

SPEAKER: Zoë Dunn

Tell me, Mark, go ahead.

SPEAKER: Audience

But there's a commitment required, not just to establish a core claims library, but to maintain it, to do that, it takes investment, it takes marketers to support it and resource it.

SPEAKER: Zoë Dunn

15:49 Right. So Mark just said, you know, in order to set up and maintain that core claims library, it takes resources. You have to be able to set it up, you have to manage it, you have to maintain it. And things do shift. I mean, that's the problem with claims, right? As new research becomes available, as competitors come to market, there's pressure on the shifting of those claims. And we also want to change the way that we're engaging, you know, marketers, they don't want to stay static. They want to constantly try to figure out better ways to communicate with their audience. And so that shifts the way that those claims are being used, and the way that that content in that library uses. And then when it comes time to submitting it, you know, those submissions—we're going to talk about that matrix approach to submissions in just a moment—but those may shift as well. So now, we're trying to keep track of an enormous volume of content. And that is not easy.

Technology can help. There's a bunch of different technology partners who are out there in the marketplace. And they want to help you set up and manage and maintain that core claims library. But you have to have internal folks who are really going to do it. It can't be an external thing. So now you have folks like coordinators on your teams, right? You have coordinators. And those folks, I can tell you right now, having worked in the industry for 30 years, they spend most of their time as basically admin assistants.

Would you all agree with me? Yes, everybody is nodding.

SPEAKER: Zoë Dunn

17:10 Is that fair? Do we really want to make our coordinators into admins? I think they're, they're smarter than that. So could we really evolve that role? And this is where the people part of this comes in. Could we evolve the role of our of our coordinators, into really library managers? So they're not just scheduling, like, have you ever seen what a coordinator does all day long? They just schedule meetings. Like they have this calendar that has like 1,000 meetings across all the different review teams in different color-coded blocks, it's a nightmare.

And instead, if we made that more efficient by setting up core claims libraries, that's less meetings. That's less to review. And that's getting and expecting more out of your marketing teams to actually create and understand the content that they're submitting and reuse it and repurpose it across these channels. That's less money we spend with our agency partners—not trying to take work away from agency partners—but what I'm suggesting to you is, the entire system becomes more efficient. So it's a bit of garbage in, garbage out.

If we don't set up these core claims libraries well, and manage and maintain them, then we're not going to be able to accomplish omnichannel. End of story. End of story. Those submissions to OPDP become like chaotic. And that's not what we want. Do you want chaotic submissions, Jason? Preferably not? Absolutely not? Absolutely not. So that's the first part about this.

18:33 The second part about this that I want to point out is those content modules, I want to talk about what goes into those. So there are core claims, there are claim statements, but there's also marketing

messaging in there that drives those core claim statements, right. We're making a claim. We're representing that claim. We're serving up that content. And we want that to be really tailored to the different people we're speaking to. So we want that to be tailored to one type of HCP versus another, a specialist versus a general. We want that to be focused on one type of patient population, or another, or a caregiver population, or whatever that that information is set up for it.

Those are the different modules, then there's the business rules, and the business rules are the interesting part, right? We need to submit those for 2253 purposes, how we get together with that content, because we need to be able to show how these modules work together. Sometimes a module cannot appear with another module because it makes that claim misleading. Critical. Sometimes it has to appear with another module, because it supports that claim statement with additional research. Sometimes they can be independent. And when we support them on 2253, what's your preference, Jason, about those business rules and those content modules appearing together?

SPEAKER: Jason Cober

19:48 So for us, what we like to do is, we like to have a conversation. So this is something as you're designing either multichannel or an omnichannel campaign, we'd like you to reach out to us, well in advance, you know, don't call us the day before, say, hey, I need a 2253 we're going to disseminate tomorrow. I can't help you. We want you to engage with us. And usually a few weeks in advance.

We have come across variable content submissions for several years, I think our first one was back in 2018. What we like to do is get a better understanding of exactly what you're doing in your campaign, what your business rules are, what promotional pieces you're going to be running in your campaign, and how all these building blocks fit together.

2253 AND CLAIMS UPDATES



**Preparing for
OPDP Consult**



**Traceability
Matrix**



**Variable vs.
Modular Content**

20:26 From there, we can give you specific instructions for how to submit the 2253. I think one of the big things that we see right now is the result of variable and module content submissions is that it produces a lot of different variations. When we started in 2018, we were doing banner ads with maybe five to 10 different variations of a banner. Today, RSA [responsive search ad] is a good example. If you max out your ad manager configuration for responsive search ads, you have like 54,000 different combinations of a single promotional communication. It gets even larger when you go across omnichannel.

So, what we're looking for on our side is, how do you present to OPDP all of the claims, all the content that you're going to be presenting in your marketing communications in a way that our reviewers can see in a matter of pages, right? Because if you drop 100,000 promotional pieces on us with all the different variations of text and images, we're not going to be able to go through all that, right?

SPEAKER: Jason Cober

21:20 So what we have are different procedures for different types of promotional communications. We can talk to you about your campaign, talk about how you can submit those in a compliant manner. And really, what we try to do is, we handle this on a one-on-one basis. We don't have published guidance right now on how to do this. The landscape is changing rapidly, okay, there's just too many changes year by year for us to really put out a guidance that says, do this at this point, going forward. Next year, who knows what the next big thing is going to be. For us, we want to address this on a case-by-case basis.

But the big thing is reaching out to us in advance, and we'll give you instructions on how you get your 2253 in. I do want to emphasize though, the 2253 does have to be submitted, we have seen especially in the RSA world, where companies aren't 100% clear, you know, especially when you're loading up your ad manager, do I need to submit all these different variations? The answer is yes, that has to be submitted on 2253. I just want to reiterate that.

SPEAKER: Zoë Dunn

22:11 That's excellent. And the channel templates also figure into this as well, because you really, when we were talking a lot about this, Jason, I mean, the 2253 is really designed to, to understand the communication by channel. And that's so in an omnichannel environment, if we're looking at the same content across different channels, it is really important that you are submitting that content for each channel, even if it's the same content. That sounds really repetitive. But we're going to talk in a moment about a submission matrix, so that we can follow the codes for that content and how that content appears in different places and different channels. But the channel template is really important as well.

When we're talking about the same content, in a different channel, then we need to think very carefully about how that content will appear in that channel. And it is not always the same. Why? Because TikTok is different than an email. And an email is different than a webinar. And a webinar is different than your website. So these are all different places that that content can appear. We were talking about short-form video as a great example. And how that short-form video, the captions on that short-form video in one channel might look one way, and another channel might get covered up because of the way the channel works. And these channels don't work together. They don't care. TikTok could care less about your obligations to communicate effectively, I can guarantee you, right now.

23:40 Okay, so this is kind of the last bit that I wanted to make sure. So we started talking about, Jason started talking about preparing for that OPDP consult. In that article, you will see the email address. Poor Jason is going to get deluged I'm sure now, but you want to be deluged, right?

SPEAKER: Jason Cober

We'd rather talk first. Yeah.

SPEAKER: Zoë Dunn

23:58 That's a really nice way of saying, sure, send me an email. I mean, the nice thing about email is you can choose who you want to respond to and when, right? You can, you can stack those up in your to do list. But um, but we do really want to make sure that you are preparing effectively. So again, what I'm concerned about is the process here. I'm concerned about your marketing teams, getting ready for omnichannel, putting together all this modular content, and not considering the pathway through your promotional review process.

I would like you all to become advocates, when you go back to your office for, hey, before you just ask us about like processing all this omnichannel content, what are we doing to ensure that we are receiving this content in a way that's going to make it easy for us to work with OPDP to get it submitted in a way that's going to not, not, you know, halt this process of getting this material to market? Because I do think your marketers want to get their communication pieces into market. And I do think they don't want to drive you crazy in the process, because it doesn't help them. Right? So that's the first thing, is really preparing for that consult.

25:01 The second is, let's talk for just a moment about that traceability matrix and those codes on that variable and modular content for just a moment, if you would, Jason. Do you mind telling us a little bit about how you guys prefer to receive that content in that matrixed approach?

SPEAKER: Jason Cober

25:15 Yeah, so what we're going to look for in a variable content submission is basically the total universe of text and imagery that you're going to put in your pieces. So all the content that you're going to put in your header, all the content you're going to put in, say, the core claims, all the content, you're going to put in the closing of this email. We want to see the total universe of the text, and we want to see that in a traceable matrix.

Traceability, though, is an idea that came out of another discussion with a company several years ago. And it's the idea of, traceability is basically an extension of your promotional material ID. So if you think about your 2253 has the material ID for every piece. Take that to an extension where every combination has a traceability number. So if you're doing say an email, for example, you should have a way to trace back the total combination of you know, header, introduction, main body, closing. And if you find that number, say in the footer of the email, you should be able to look and make sure, on my traceability matrix, this matches the configuration. If it doesn't, you know you might have a problem. It's an audit practice, right?

26:14 This isn't always practical, it's not really easy to do this for things that are configured through ad managers, whether we're talking about Google or the social media platforms where you mix and match these different claims. In that situation, we recommend you have some kind of audit procedure in place with your ad agency. The ad agencies can do auditing, they can do monitoring to make sure your claims are going out in a compliant manner.

But in situations like email, or text-based communications, we strongly encourage the use of this traceability so you have a way to make sure that, whenever you introduce automation into the equation, you want to make sure that you know that automation is working correctly. If you find that your traceability doesn't look right, if the automation isn't working right, put a pause on it, fix it, and then restart it. That's what we recommend.

SPEAKER: Zoë Dunn

26:56 And this, you know, some of this can be really helped, depending on the technology that you've implemented to help in this process. I know Veeva is kind of the elephant in the room in a good way. I don't mean that to be a disservice to Veeva at all, you know, they are, they are the big ones, right? Who tend to be really trying to amend their, their software to be able to support this and to be able to support this traceability, and they're constantly enhancing that software. And there are others as well. Most companies that are managing this, this part of the review process, are trying to augment their software to be more skilled at this.

The other thing too, about that variable and modular content and making sure that that's organized in an efficient way within your system, that it can be amended, it can be changed very easily, it goes back to you know, the process of who's managing it, who's maintaining it.

27:49 I think all of this puts a lot of pressure on your marketers and your agency partners, as Jason just mentioned, there needs to be some better accountability as we get ready for omnichannel on how they are creating, managing, developing these these communication pieces. And, and we'll continue to see this evolution. But know if your company is saying we got to get this done today, that very few companies are really, really ready for this. Most companies are still piloting these techniques. They're starting small. They're starting with things like email, like next best action emails or banner advertising, where they can really play with this and set those processes in place.

Do we have, I know we're kind of out of time. But if we have any questions, we could probably take one question. No, did we blow your minds? Are you confused? Yes.

SPEAKER: Audience

28:40 I have a question about the traceability matrix. So is that looking like one submission that can have multiple combinations, but somehow you need to identify each potential combination?

SPEAKER: Jason Cober

28:53 That's correct. That's the recommendation, it's not required for the 2253, but at a minimum, we do recommend that companies maintain traceability. So this will tell you if your system is—especially with these automated email systems—it will tell you if the configuration is working correctly, and you can identify errors early in the process. But yeah, you're correct, it is tracking all the combinations.

SPEAKER: Zoë Dunn

29:11 Excellent. And I think the business rules are a really important part of the 2253 submissions as well, so that they can understand how you how you're going to use this information in conjunction with one another. Thank you so much for coming, everyone.



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