

# Rx-to-OTC Switch Challenges and Opportunities, A Conversation with Paul Wardle, Founder of Beacon Associates

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**Paul Wardle** 

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### Episode Highlights

- Paul has extensive experience in Rx-to-OTC Switches, and has worked with well-known brands like Viagra, Advil, Lipitor, and TUMS
- Rx-to-OTC switch allows consumers greater convenience and access to products, leading to improved public health benefits such as reaching underserved populations or improved adherence
- Switching a pharmaceutical product from prescription to non-prescription reduces barriers to access and has on average led to an approximately 30% increase in utilization
- The Switch process involves evaluating if consumers can appropriately self-diagnose, choose the right product, and follow the label instructions without the guidance of a doctor and requires studying behavioral patterns to be successful
- The FDA will determine if the benefits of increased access to a product without a healthcare practitioner outweigh the potential unintended consequences
- When an Rx product becomes an OTC consumer product, the focus shifts to brand building and guiding responsible self-directed care
- ACNU regulation aims to increase access to more therapeutic categories in the non-prescription market, including potentially chronic use categories
- ACNU shifts the approach from defining access based on the profile of the molecule to considering the characteristics of the individual – i.e. who should be able to engage in self-directed care vs others who may need the intervention of a professional. This opens opportunities for innovation and different models for product access

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## Episode Transcript



**Rusty Ray (00:06):**

Good morning. This is Rusty Ray with Alantra. I head up the US Healthcare Investment Banking Team here in New York, and you are listening to Crossroads by Alantra, our podcast that focuses on healthcare segment with a special series on content towards Consumer Health. Today we're joined by Paul Wardle. Paul is the founder of Beacon Associates, a strategic marketing consultancy. Paul has directed over 25 successful product and brand launches globally and has led numerous and well-known Rx-to-OTC Switches. We'll be focusing on the ability for Switch products to play a key role in enabling self-directed care and creating value for the brand owners. Paul's experience spans different therapeutic categories and many brands that we know and love and use every day in our lives such as Viagra, Advil, Lipitor, and TUMS to name a few. One of the topics we wanted to cover today was Switch, and that is the growth in self-directed care.

(01:05):

We've heard throughout the last 10 to 15 years that consumers more and more want to take control of their own healthcare decisions or doing more research on the internet for better, for worse, and coming to their GPs with an opinion about how they want to direct their care. And that's led in my understanding to people really paying attention to labels, paying attention to ingredients, and paying attention to what they're taking and what that impact would be and sort of taking responsibility for their own care.

(01:41):

Have you seen a similar trend, and I want to take this into the direction of talking about Switches and the importance of brand building, but just wanted to kind of set the stage of why there's so much impetus on Consumer Health and what's driving it, what's changed over the last 10 years and I guess maybe even what's changed over the last 2 or 3 years since COVID, so many new modalities of healthcare provision have come out and we're thinking about healthcare in such a different way. So, I'm just kind of curious to get your perspective on that before we talk about kind of diving into the brands.



**Paul Wardle (02:15):**

Rusty, firstly thank you for the introduction. That's a great question and it has a few different layers to it and I think the trends, whilst they, I'd say they've accelerated over the last few years, they've actually been in place probably since the 80s and 90s. You think about direct-to-consumer advertising for prescription products, which really came to be in the late 90s. The amount we now hear about medications you can ask, is there a benefit? Well, if you're not aware of a product, if you're not aware of your condition, it's actually hard to know should you do anything about it? If you layer onto that, the healthcare system in general, the barriers to getting to a doctor, the barriers, whether it's financial, physical, even psychological of engaging with healthcare practitioners means that there's a tough world if you've got to take time out of your day to get to the office.

(03:05):

If you're looking after someone, how do you get that time? So, what I see is there are roughly 250M searches on WebMD every month. People are out there looking for information that they're looking for the convenience. How do I help myself in a more efficient manner? Things like MyCharts. And what I see is that roughly 60% of people in the US access their data themselves. They're trying to figure it out and sometimes they get that information before the doctor. 30% of us have used a self-assessment tool. So, what you see is because the current methods are challenging, there's a desire to actually be healthy, and how do you actually get the products you need and want in a different manner.

## Episode Transcript



**Rusty Ray (03:45):**

That's really interesting. In a prior conversation we had some months ago, you had sparked my interest when you told me in the last year or 24 months, I've probably changed some habits around my own healthcare consumption that I hadn't previously done. Be it having a telehealth visit or having a self-diagnostic or some other self-test or things of that nature. I guess talk a little bit about those trends because I thought that was really interesting because it really just dawned on me that you were correct. I hadn't even thought about it. The change happened so gradually and it felt natural.



**Paul Wardle (04:23):**

If you actually go back to March / April of 2020, we were all forced to stay at home for better or worse, but we still had healthcare needs. And so the advent of how do you continue to get access suddenly shot up telehealth as a mode of engaging pretty significantly to pretty high proportion of engagements with the healthcare professional. Now, as you look over the last three years, some categories, I'm going to say mental health is one of them, have remained very high in terms of how consumers engage or how patients engage. There are other categories that have returned to normal, but as you look towards the end of 2022, we're seeing roughly one in 10 visits to a doctor actually still in telehealth. That's a fundamental change because before it was less than 0.5%. Now is it all out of convenience?

(05:22):

Is it all kind of, hey, a preferred method of engaging? I think it's different by therapeutic area. Does that all apply to Consumer Healthcare or Switch? No, it doesn't, but what it tells you is every category and every product is slightly different in how we want to engage as you look more broadly. So, I think COVID really accelerated some of those trends. Also, as the regulations created barriers to access, the ways that consumers could engage with a healthcare practitioner also changed. So, you're seeing tools now where people can actually engage with their physicians via text. So, rather than a face-to-face conversation in the same moment of time, it's asynchronous. Those platforms have been growing. Oh, I'll do a questionnaire online. A doctor will review that, and then the product gets sent to me if it's appropriate. If it's not appropriate, then there's a consultation. So, it's a different kind of triage.



**Rusty Ray (06:21):**

So, I do want to focus on a conversation around Switch, but I think that's a nice segue into it because what I'm hearing about what you just said is access, and I think that's important. There are many communities in the United States that have been underrepresented in clinical trials. There are certain trust issues around medical professionals, et cetera, where people don't go to the doctor. So, hopefully these new modalities in able of that or foster an appointment or a consultation where maybe one didn't happen before.



**Paul Wardle (06:52):**

Can I just actually build on something you said there, Rusty? You used the word kind of in a way equity of access. I think we're very privileged that we can actually take the time out of our work to go to a doctor's office, even if it is only for a two-minute visit. But think of the number of people that their employment, their situation caring for somebody else. They can't get away from it. And if you think about the typical kind of journey to get to a prescription product. It's not just about the healthcare practitioners there, it's the ability even from your personal circumstances to be able to take the time to invest in your own. So, the trade-off is very real for many people.

## Episode Transcript



**Rusty Ray (07:35):**

For sure. We see it every day and more and more attention is being paid to it. And I think this is a nice segue into talking about what is a Switch and why are they important in the Rx / OTC landscape and brand building into companies both strategically but also to consumers. And I think one of the things that we've been talking about here at least initially is around adherence. I guess what's been your experience with the barriers to actually getting a pharmaceutical product and Rx product versus OTC Switches. Do you see an uptick in adherence and sort of consumer reception once something is more available in a grocery or pharmacy?



**Paul Wardle (08:20):**

That's actually a great question and I'm going to start on big picture. On average when something moves from prescription to non-prescription, about a 30% increase in utilization of that therapeutic category, what I'll say is some of it is purely the non-prescription sales and units actually growing. Some of it is actually increased use on the prescription side. That's driven by two factors. The barrier to access means more people can get it, but often when a product is generic, there's nobody promoting anymore, nobody driving awareness of that therapeutic condition. But when there's a consumer brand that's continued advertising the awareness, and to be honest, some of us would rather go to the doctor. I did some research with an organization last year and what we saw was about a third of people would rather do everything themselves. Whether they should is a different question. About a third would rather go to the doctor for everything. And in the middle depending on which category.

(09:20):

And so what that says is that access comes from, that increased utilization comes from a couple of factors. One is the barriers for getting the prescription product, but the other is the psychology and the convenience of being able to do it yourself. There's some categories I've worked in where I feel I should do it on my own, but if you think about your own household, most people in the US actually take a multivitamin or a supplement of some sort. We take it every day. That adherence in a non-prescription world when you don't have to get a refill, keep going back to the doctor for a prescription, actually can be a lot higher than it in this prescription world. And so when you reduce the barriers to getting the product, actually the usage can go up and responsible usage can actually be very good.



**Rusty Ray (10:08):**

That's fascinating. And I want to kind of maybe take one step back for folks that maybe aren't as fluent with the vocabulary. You mentioned a couple of things Rx, pharmaceuticals, generics as well as OTC and what is a Switch product, what is Rx-to-OTC Switch? How is that decided? Who decides it? Are there products that are more appropriate for Switch than others? And what's sort of the thought process that goes into that?



**Paul Wardle (10:36):**

Wow. Yeah, that's a great question. There's a few different pieces to unpack in that. I'll start at the first question. We're all familiar with prescription products. We have to go to the doctor in order to get that prescription, and then there is non-prescription. That actually is a categorization that was established in 1951. It governs all of the medicines in the US. And in theory, every product should be non-prescription unless a healthcare practitioner is necessary either for the diagnosis or for the use or some safety reason. In reality, almost every product starts off as a prescription product. The active Switch is a process working with

## Episode Transcript



the food and drug administration (FDA), to try and determine whether if you remove the healthcare practitioner from that engagement on the product, are the benefits of that increased access? Do they outweigh the unintended consequences of being able to just buy it off the shelf?

(11:37):

So, what does that mean? Can a person appropriately self-diagnose the condition? Do I know that I have a migraine? Do I know that I have pain in my knee? Can I choose the right product for myself? Will I choose the right strength, the right dose? Because what we don't want to have is people using it for the wrong condition. There's an element in thinking about what products are appropriate – is there potential for misuse so they may not understand the directions or potential for abuse. There's certainly some things that we wouldn't want everyone to have access. I just take a moment to talk about a prescription drug. Often the development is 10 years, multiple billions to actually try and bring a product to market. And most products actually never make it all the way through. But in that process of clinical studies, what we're looking at is how does the product work in a way that we hold the human constant and we're evaluating whether the product is effective for the indication, whether it's safe under this different situations.

(12:44):

So, we hold the consumer the same, we tell them what to do, how to take it, and that's essentially the prescription world. When we think about a non-prescription, we already know that the product is safe and effective in the people that should use it. So, now the question for Switch is what happens if you allow people access without the healthcare practitioner? Will the human behave appropriately with the drug? Now if there are things which a doctors should continue to monitor, it's unlikely to end up being in a non-prescription world. But these are some of the questions that we are asked to do and they're very much behavioral studies. Now, how do people interpret language on a label? You probably all looked at a drug facts label, your Advil box in the back, that's the labeling. Can you follow those instructions? That's what essentially Switches about. Understanding do you have the right words to guide people to use a product in the right way without having to talk to a doctor?



**Rusty Ray (13:41):**

That's interesting. It leans on so much more, in my opinion, subjective analysis of behavior as opposed to something that may be a little more defined in terms of clinical outcomes. So, lots of nuance there.



**Paul Wardle (13:54):**

I'm going to say something slightly different there. I think in the clinical world for a prescription product, we are holding the human constant and testing the product. But in reality, once a patient who's got a prescription from the doctor goes home, they are back to being a human again. They will do with it. So, what you see in clinical trials is actually different from what you see in real world evidence. And so there's a difference here that we approve drugs based on the clinical evidence, but the practice is real world evidence. And that sometimes can show the barriers to access can actually cause unintended consequences. And I'll give you an example, which was from a recent advisory committee. It was a prescription product and the question was looking at a prescription for an injectable product, is it as effective as a nasal spray?



## Episode Transcript



(14:49):

Giving an injection, it gets into the blood system quicker than the nasal spray did. So, there was a difference in the time for the product to work, but the discussion around that was, well people are afraid of giving themselves an injection. So, if you had the behavior of being able to use a nasal spray where there's less fear, would they use it sooner than the injectable product? And that to me was a great example of the clinical benefits when used exactly as it should. One is slower than the other, but when you start incorporating the behavioral aspects, they may be the same or you may come to a different conclusion. And so it's a level of confidence that the FDA expect before they will approve the drug that we've demonstrated that actually people will behave appropriately and there's a very in-depth evaluation of those behaviors in a very scientific way. It just happens to be a behavioral science rather than a lab science.



**Rusty Ray (15:50):**

Interesting, very interesting. I want to switch gears for a second because we've talked a lot about the patient and all the good things that come with providing easier access to medications or even care for that matter and all the benefits around there, whether it's pricing or just increased accessibility. Those are all good things, but obviously, there's a manufacturer involved. As I think of an Rx product moving to become an OTC or consumer care product, I think often about brand. I know as you referenced a few moments ago that advertising around Rx products has been around for quite some time and we've all seen the drug commercials and the wonderful lifestyles that people lead as a result of those drug commercials. But I often don't think of the brand, I think of the indication and the solution that it's providing. That's just me.

(16:50):

Whereas when I think of a consumer care OTC product, I'm really all thinking about brand. I mean, of course I'm still thinking about problem solution, but that's the problem solution that becomes inherent in the brand. So, I'm just kind of curious, how does a big corporate that's going through one of these Switch processes, is that part of the strategy to sort of brand build? Are they truly brand building? Are they leveraging what has been done in the Rx world and in terms of awareness or how does that mind shift take place within a corporation that's actually developing these things for the consumer care market?



**Paul Wardle (17:26):**

I would actually think about a few things. One is how many barriers are there for a consumer to even get to the doctor to get to treatment? Now we actually even see in heart disease, which is the leading cause of death in the US – roughly 50% of people who should be on a statin, one of the cholesterol lowering kind of medications actually aren't. In hypertensive products, many people who start them actually stop taking them. So, there's barriers for adherence and continuation and there are also psychological barriers. I feel, well therefore I don't need to it. But actually when I think about taking a supplement every day, I don't have those barriers because I can just go and buy it. I'm not sick if I'm taking a supplement, but if I'm on a prescription, I'm sick. So, there are psychological components here. And so as I think about Switches, I think I is there a reason for the consumer, are is there increased access you could get?

(18:17):

Are there more people you can get to treatment? And that access benefit results in a public health benefit. So, there's a benefit for doing, it's not just a financial one. From a financial standpoint that the lifecycle of a prescription product as a brand tends to be 7 to 10 years. Now, how long do you have left before the patent

## Episode Transcript



expires? For a consumer product, the examples I'll give you, Aspirin has been a consumer product for over a hundred years. Advil Switched to move to non-prescription in 1984. It sells over a billion dollars every year. And that continued investment in the consumer with education, that relationship allows that brand to live on indefinitely. And so when you think about the lifecycle of a prescription product, one of the questions is can you get more life out of it by thinking about non-prescription? Is there continued value?

(19:11):

Is there increased utilization that can be had? Is there an improved healthcare benefit? If there's no healthcare benefit, there's probably not a reason to switch it. If there's more downside risk, the FDA, we should all be thinking there's probably not a reason to switch it. But when the incremental benefits to society are increased with Switch and they outweigh the unintended consequences, then we should be thinking about it for public health reason, but also for as manufacturers for elongating the lifecycle of these brands.



**Rusty Ray (19:44):**

That's very interesting. Because one of the last points I wanted to cover today – love to continue the conversation on a couple of other topics that you've touched on here, but maybe for another session – is really around value creation associated with brands. And I'm thinking about this more in the realm of portfolio management. Portfolio management is an active process, buying, selling, developing products. I think Switch is a key component to that management for sure. But I also wonder if you could think about and maybe address the audience in terms of just general portfolio management and how Switch sort of fits into that in terms of brand building and value creation.

(20:30):

But maybe also to get your thoughts on the current spin outs we've seen with Haleon and Kenvue and probably another couple more that are rumored to happen. Does that put a hindrance on Switch because you now no longer have Rx and OTC coupled? I certainly see some advantages of having the businesses separated, but in this case, does that create some complexities because it almost, it becomes more difficult to think about portfolio management because now you're taking something that's Rx moving into OTC, you no longer have that capability or even that thought process that now resides at a different company. So, how does someone manage kind of the value of Switch in portfolio, now that they're separated?



**Paul Wardle (21:17):**

Just to think about Consumer Healthcare today, the majority of the leading non-prescription products, OTC products, were once Switches. As you look over different periods of time, there have been more or less Switches, but there are periods where over 50% of the growth in the industry has become because of non-prescription Switches. So, the question for me is less about should we Switch or if we do it is. It's how we Switch because the value has clearly been shown that there is an investment, there is a development risk, there is a commercial value when the parameters of risk are right for the molecule and that the parameters of safety are there. Now thinking about the question you just asked. We talked earlier about there are other products and can you Switch? If you can Switch, should you Switch?

## Episode Transcript



**Rusty Ray (22:12):**

One of the things that we haven't covered today that I'd like to ask if you talk about in a next session, because I think it could be its own conversation, is some of the new FDA proposed rules around Additional Conditions for Non-prescription Use (ACNU). I know that's going to be a game changer, but maybe spend one minute just describing that and how that might fit into the conversation we're having here today, and then perhaps we could invite you back and we could dive deeper into that.



**Paul Wardle (22:46):**

That's great. One of the really interesting things to me about the proposed ACNU regulation that the FDA introduced in June 2022 is how they're thinking about the products that should be non-prescription. Within the proposal, various members of the FDA have talked about this over the last 10 years. It's been in development. They talk about how do you increase access to more therapeutic categories, including potentially chronic use categories. Most of the categories today that are non-prescription are acute usage. If you actually think of many of our healthcare needs in the US, they're actually chronic conditions, whether heart disease, whether diabetes, I'm not suggesting all of them should be non-prescription. The ACNU rule actually starts to think about those conditions differently. We talked about prescription and non-prescription a little earlier today, black and white, you can either be one or the other.

(23:40):

You can either be prescription or you are non-prescription. What the ACNU actually does is rather than define access based on the molecule, so if it's not safe for some people, it's not going to be non-prescription going to be prescription for everyone. So, today's model is prescription or non-prescription based on the molecule. What the ACNU in a way does is says access should be defined by the individual. If the characteristics of you are such that you can take it appropriately, et cetera, then you should have access. If potentially you have concomitant medications or other conditions which make this medication inappropriate, you shouldn't get access.

(24:24):

And the FDA are opening up the door for innovation in very novel ways to change how we access products in very different categories. I would encourage anyone thinking about an ACNU not to think about it as a Switch. I would think about it as a completely different type of product. What is the business model associated with a different method of access? It may be only an online business. It may be something where there are other steps you have to go through, but it means we can look at far more therapeutic categories than we traditionally have, but look at it on the individual benefit versus the benefit for everybody.



**Rusty Ray (25:02):**

Thanks again for joining us today, Paul. This was a fascinating conversation. It was frankly really eye-opening on hearing your perspective on how Switches enable market access and adherence. The thought process behind initiating a Switch process, the key factors in determining if a Switch is worthwhile and the execution of the marketing plan post-Switches can be real value drivers for brand owners as they continue to think about their portfolio management. Paul touched upon it at the very end, but hopefully we can have him back for a full episode to discuss the regulatory framework around Switches and the future. Really interesting to take a deep dive today on the considerations behind Rx-to-OTC Switch. If you'd like to learn more about our thoughts on where we're headed within the Consumer Health space as well as some of the work that we've done, please feel free to reach out to us at [www.alantra.com](http://www.alantra.com). Thank you.



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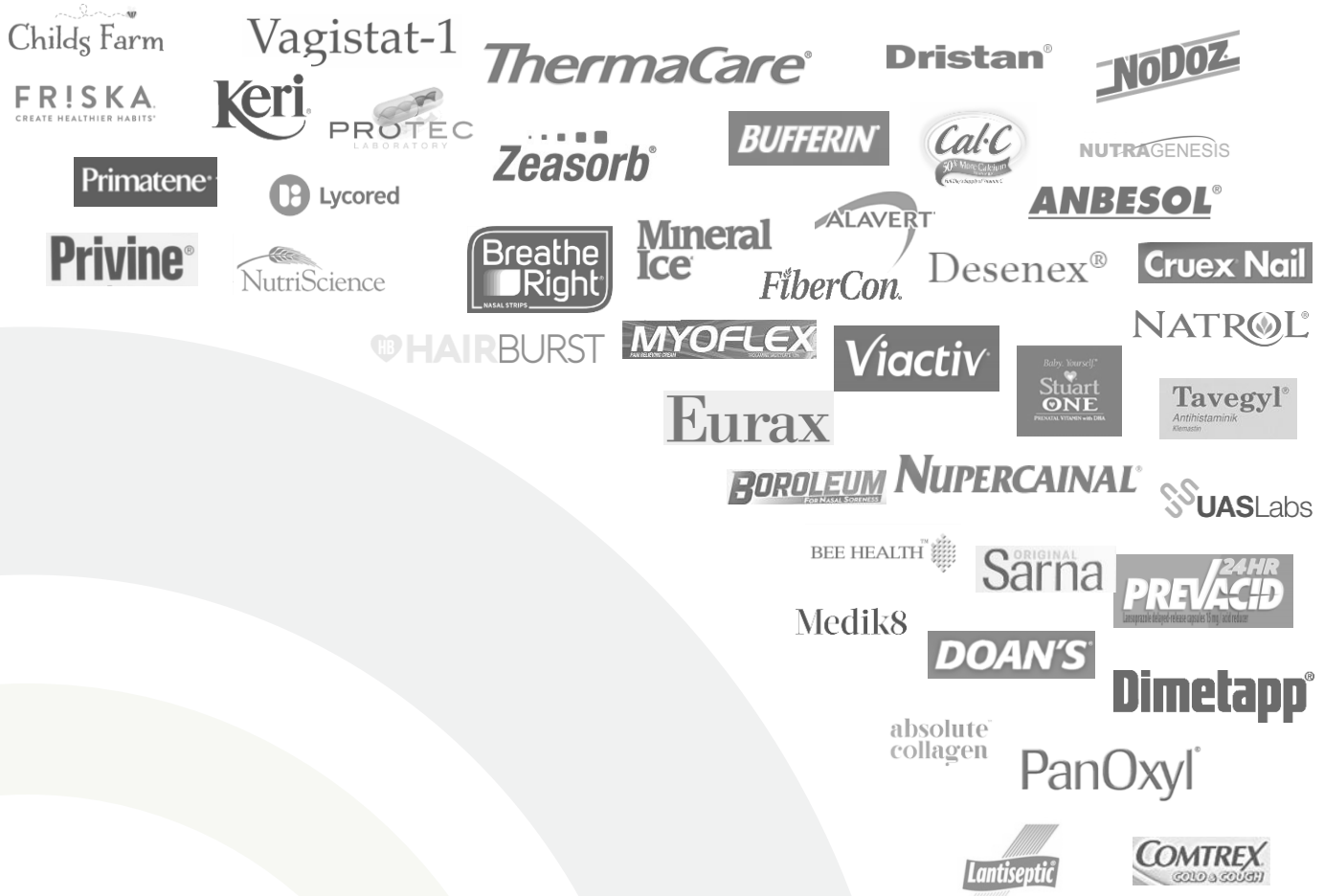
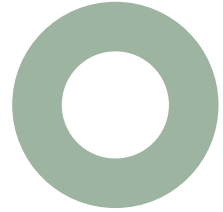
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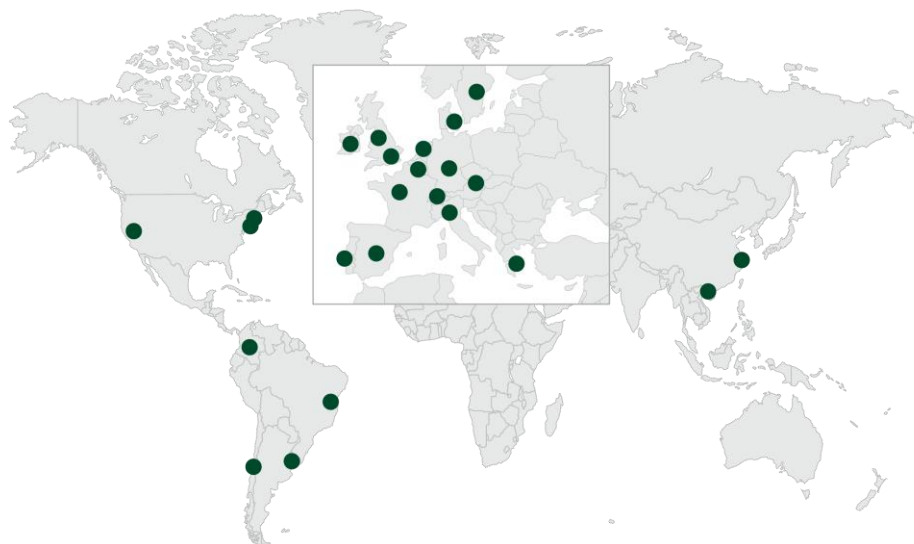


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25

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Clients Advised<sup>2</sup>

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