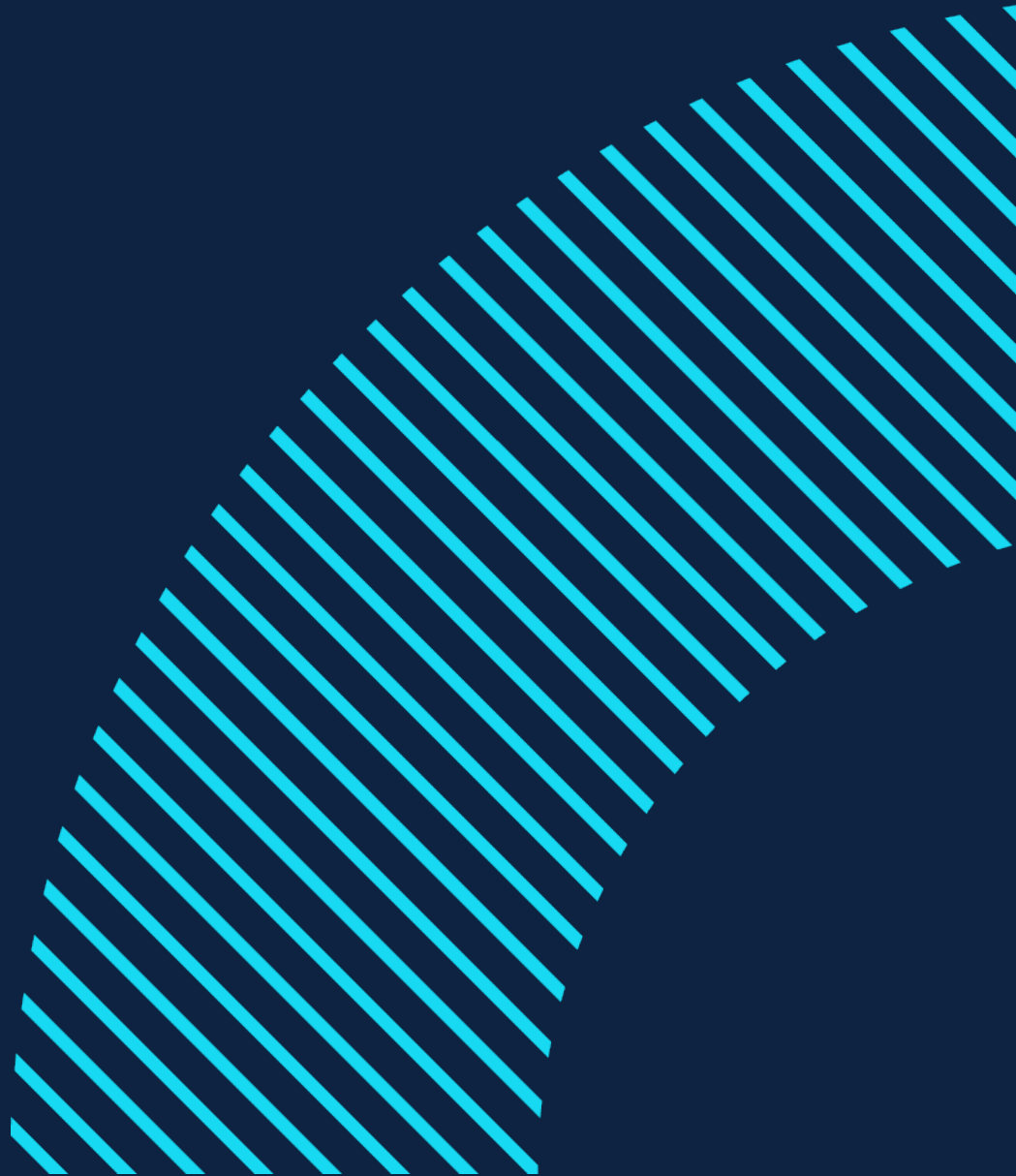


**REPORT**

# **REGULATION & INNOVATION**



# HOW THE RULES OF THE GAME ARE CHANGING FOR ANIMAL HEALTH FOUNDERS

The Director of the FDA's Center for Veterinary Medicine does not typically appear at industry conferences.

When Dr. Timothy Schell took the stage at AHNTI EU 2026 for a fireside conversation with Zoetis CEO Kristin Peck, his presence alone carried a message: the relationship between regulator and innovator in animal health is entering a new chapter, and both sides are ready to talk about it openly.

What followed was not a policy briefing. It was a candid, sometimes pressured exchange between an industry pushing hard for faster, more flexible pathways to market and a regulator navigating the real constraints of what reform requires.

Alongside a panel of global regulatory experts and a founder case study that puts the principles into practice, the picture that emerged from AHNTI EU 2026 is one of genuine momentum, tempered by an honest

account of what that momentum will and will not deliver.

For founders, the implications are direct. The regulatory environment shaping your timelines, your capital requirements, and your global market access strategy is changing faster than at any point in recent memory.

The question is not whether to engage with that change. It is how early, and how deliberately.



**NIAMH GALLAGHER**  
PROGRAMME DIRECTOR, AHNTI  
KISACO RESEARCH

# THE FDA SIGNALS A SHIFT

## WHAT IT MEANS FOR YOUR RUNWAY

Regulatory timelines sit at the centre of almost every strategic decision in animal health. They shape capital requirements, investor expectations, and the speed at which innovation reaches the market, yet they remain among the most uncertain parts of the journey.

For a long time, these timelines have been treated as fixed constraints. That is starting to change. Growing pressure to accelerate innovation, combined with advances in science and data, is prompting a rethink of what is possible within regulatory systems.

At AHNTI EU 2026, Dr. Timothy Schell, Director for the Center for Veterinary Medicine at the FDA, offered the industry a direct view into that rethink. What he shared were ambitions rather than confirmed commitments, but the direction of travel was clear, and for founders thinking about where the regulatory landscape is heading, the signal is significant.



Dr. Timothy Schell, Director for the Center for Veterinary Medicine, FDA

## REDUCING APPROVAL TIMELINE FROM TEN YEARS TO FIVE

Dr. Schell outlined a sequencing of approximately three years to build the right tools and capabilities, with the five-year horizon achievable from that point. For founders currently in early development, the near-term picture has not changed. For those modelling capital requirements over a longer horizon, it points to a meaningful shift in the cost and duration of the path to market.

The more immediate commercial opportunity lies in changes to the conditional approval pathway. Dr. Schell outlined a proposal to extend the conditional approval window from five to seven years, and potentially to bring certain Chemistry, Manufacturing and Controls (CMC) sections inside the pathway rather than requiring them to be resolved before approval is granted.

For founders working in areas of significant unmet need, oncology and chronic kidney disease among them, conditional approval already offers a route to earlier market entry. Expanding its scope and extending its duration makes it a more powerful commercial tool: earlier revenue, earlier validation for investors, and more time to build the post-approval evidence base that supports full licensure.

One concrete change already in motion is the stop-the-clock pilot, modelled on European practice. Under the current US system, when a reviewer requests additional data, the clock resets entirely on resubmission. The pilot introduces a pause-and-resume mechanism, allowing the review to restart from where it left off once the company has responded. For founders currently in review, this has practical implications for how they manage agency interactions and plan their timelines. The session also surfaced a sharper-edged

conversation about the CMC package. In animal health, unlike human health, CMC is consistently the longest and most resource-intensive part of an approval application, and one of the most significant contributors to overall timeline. Dr. Schell acknowledged the frustration directly, but was honest about the constraint: animal and human health share GMP regulations, and many manufacturing facilities produce both, meaning changes on the animal health side require alignment with human health counterparts. The opening is that the human side has recently signalled interest in reviewing CMC requirements as well, creating an opportunity for animal health to move in parallel. It is progress, but it is contingent. Founders facing CMC-related delays should treat this as a reform worth advocating for through industry bodies, while planning their timelines around current requirements.

On international data and foreign approvals, Dr. Schell made the economics explicit. Bringing a product to the US market costs between five and ten million dollars. For products targeting underserved species or niche diseases, the addressable revenue may be a fraction of that. The current risk equation, he acknowledged, simply does not work.

His proposed response is a move toward leveraging approvals from trusted regulatory partners as a bridge to US market entry: a structured evaluation of the differences between a foreign-approved product and US requirements, with a defined window to address any gaps. For founders whose products may reach international approval before the US, this represents a meaningful potential route that has not previously existed in any formal sense.

Finally, Dr. Schell outlined a voucher concept modelled on the human health rare disease programme. The proposed mechanism: bring products to market in underserved species or

disease areas, and receive a fast-track voucher applicable to a future standard approval. The proposal is still in development. However, for founders working in minor species or rare diseases, this could represent a meaningful structural shift. These areas have historically struggled to attract investment, mainly because of long approval timelines coupled with smaller market sizes.

Throughout the session, the exchange carried a productive friction worth noting. The questions pressed consistently on behalf of industry: on the gap between aspiration and timeline, on the limits of the FDA's labelling authority post-approval, on what stop the clock would mean in practice, on whether the CMC burden could be addressed now rather than deferred to a future reform cycle.

Dr. Schell was direct in return, acknowledging what was within his power and what was not, pushing back where the constraints were real, and inviting the industry to come in with proposals rather than waiting for the agency to arrive at solutions independently. That is perhaps the most important signal of all. The FDA is not offering to solve the problem alone. It is offering to solve it together, and the invitation to engage is genuine.

***"Please don't stop a product because you think we're going to say no. There are products that came in ten, fifteen years ago that are moving through our process very quickly right now, because we have evolved and we can look at risks differently."***

*Dr. Timothy Schell,  
Director for the Center  
for Veterinary  
Medicine, FDA*

## WHAT THE DIRECTOR OF THE FDA'S CENTER FOR VETERINARY MEDICINE WANTS FOUNDERS TO KNOW

### **Engage early, even with minimal data.**

CVM welcomes pre-submission conversations. Products have been revived after years of inactivity because the regulatory landscape evolved. Do not self-reject before the agency has had the opportunity to respond.

**Bring proposals, not just problems.** On CMC, on conditional approval, on international data: reform in these areas requires industry to come in with concrete risk management proposals. Waiting for guidance to arrive is a passive strategy in an active regulatory moment.

### **Plan for post-approval engagement.**

Approximately 60% of approved products carry a significant label change after approval. The transition from approval to post-approval surveillance is an area Dr. Schell identified as poorly managed today. Founders should expect label evolution as part of the commercial lifecycle, not as an exception to it.

## WHAT'S ON THE REGULATORY HORIZON

Three developments flagged by the panel as priorities for founders with EU market ambitions:

### **The Biotech Act**

EU legislation currently working through the policy pipeline includes a proposed 12-month extension to the Supplementary Protection Certificate for veterinary biotech products. An SPC extension adds exclusivity at the end of a product's commercial lifecycle, precisely the period when sales are at their peak before generic competition enters. The financial significance of even a single additional month of exclusivity at that stage can be substantial. Veterinary medicines were not included in the original proposal; industry associations pushed successfully for their inclusion. The legislation has not yet been enacted, but the direction is positive.

### **New approach methods and the 3Rs**

Reducing reliance on animal testing in the regulatory process is increasingly prominent on the EU agenda. A roadmap is in development. For founders in biologics and novel therapeutics, this has the potential to change both the cost and the timeline of the data required for approval.

### **AI guidance for regulatory use**

How AI-generated data and AI-assisted analysis will be treated in regulatory submissions remains unresolved across all major markets. The EU is actively developing guidance. For founders already using AI in drug discovery, dossier preparation, or post-market surveillance, clarity on how regulators will receive that work is both commercially important and, as yet, unavailable.

# THE GLOBAL MAP

## WHERE THE OPPORTUNITIES AND OBSTACLES ACTUALLY ARE

The shift in animal health's commercial centre of gravity over the past decade sets important context for any conversation about global regulatory strategy. Companion animals now represent 70% of the revenue base of the world's largest animal health company, up from 35% at the time of its IPO in 2013.

The demand for products that keep pets healthier for longer is growing steadily, driven by deeper owner engagement and rising expectations of care.

On the livestock side, disease outbreaks from highly pathogenic avian influenza to African swine fever to bluetongue continue to cross borders with no regard for the national regulatory frameworks designed to manage them.



*Jeannette Ferran Astorga, Executive Vice President, Corporate Affairs Chief  
Sustainability Officer, Zoetis.  
Roxane Feller, Director General, AnimalhealthEurope*

## A SINGLE-MARKET REGULATORY STRATEGY IS NO LONGER ENOUGH

Founders building products in animal health need to understand the global regulatory landscape as an active variable in their commercialisation planning, not background context to be addressed later.

The panel that followed Dr. Schell's session brought together perspectives from global regulatory consulting, a major pan-European industry association, and the corporate affairs function of a leading multinational, producing a candid assessment of where that landscape stands.

In the EU, the picture is genuinely improving but more complicated than the headline suggests. The veterinary medicines regulation now allows any company, not only those with highly innovative products, to apply for a centralised authorisation covering all 27 EU member state markets in a single procedure. Uptake of that centralised route is increasing.

The EU's aspiration toward regulatory unity and the practical reality of member state autonomy exist in genuine tension, and that tension has not been resolved by the current regulation.

The concept of mutual recognition drew significant attention from the panel. The post-Brexit experience in the UK human health sector was offered as a proof of concept: when the regulator pivoted to a recognition and reliance

model, accepting approvals granted by trusted counterparts as the basis for its own authorisation decisions, the impact on timelines was almost immediate. The equivalent shift in veterinary medicine, at both EU level and globally, remains largely unrealised. The panel positioned this as one of the most significant untapped commercial levers available to the industry, most likely to be activated through sustained coalition advocacy rather than through any single regulatory body acting alone.

The developing market gap represents a different order of challenge. Products already available to pet owners and livestock producers in North America and Europe can take years to reach markets in Africa, Southeast Asia, and Latin America, where the animal health burden is often heaviest. VICH, the international body that harmonises veterinary regulatory guidelines across major markets, was identified as the most viable existing vehicle for accelerating

developing-market pathways. But closing the gap will require the producer community to be brought into the regulatory advocacy conversation alongside industry and trade associations, not added as an afterthought.

On harmonisation more broadly, the panel offered a clear-eyed assessment that founders should carry into their planning. Full harmonisation across global regulatory frameworks is not a realistic near-term outcome. Progress is happening in specific, bounded areas: joint review procedures between national authorities, mutual audit acceptance for manufacturing quality inspections, and the gradual adoption of VICH guidelines by developing-market regulators. These are meaningful steps. But every major regulatory jurisdiction retains the instinct to maintain its own requirements, and that instinct will not be overcome by goodwill or advocacy alone.

The practical implication for founders is to build regulatory strategy that accounts for fragmentation as a durable feature of the landscape, not a temporary condition awaiting resolution. That means sequencing market entry decisions against a clear understanding of where pathways are most developed, where mutual recognition agreements may create shortcuts, and where the cost of compliance in a given market is proportionate to its commercial opportunity.



*Chris Boyle, Partner, Sidley Austin LLP (Left) and Kimberly Simmons, VP Regulatory Affairs & Consulting, Clinglobal (Middle)*

# ELIAS ANIMAL HEALTH CASE STUDY

## WHAT IT ACTUALLY LOOKS LIKE TO BUILD A COMPANY AROUND REGULATORY STRATEGY

Ten years ago, Tammie Wahaus co-founded ELIAS Animal Health around a lead product that had no clear regulatory home. The therapy was autologous: manufactured individually from each patient's own tumour tissue and immune cells, it could not be produced in the large, standardised batches that existing veterinary biologics regulations were built around. Stem cell transplantation, a loosely analogous category, was largely exempt from regulation at the time.

A lower-resistance path existed. ELIAS did not take it.

The decision to pursue full USDA licensure as a regulated product, on the basis of prospective controlled clinical trials and a manufacturing discipline that would establish a scalable, consistent process, was not made out of caution. It was made out of a specific commercial conviction: that regulatory approval would create market trust, that trust would drive veterinary adoption, and that adoption was the only thing that would unlock scale. Without that sequence, the therapy might work in a handful of academic centres and go no further.

What that decision required, in practice, was a fundamental reframing of what the product actually was. The product was not the cells. It was not the treatment protocol. The product was the controlled manufacturing process,

operating under a unified quality system. That reframing mattered enormously: once the product is defined as a process and its controls, it becomes transferable, scalable, and legible to regulators and commercial partners alike.

The path that followed was neither smooth nor quick. ELIAS deliberately held back from commercial launch until they had clinical trial data in dogs, because, as Wahaus put it plainly, you cannot sell a product to a veterinarian if you cannot tell them what it is going to do.

Their pivotal trial ran from 2019 to 2020, through the early months of a global pandemic, enrolling 101 dogs across sites that had never run a trial of this kind. During that period, ELIAS paused its commercial activity entirely to maximise enrolment.

ELIAS also had to build its entire commercial infrastructure from the ground up: from apheresis site access to cold-chain logistics, none of the systems required to deliver a personalised therapy at scale existed when the company started. Many people, including some within the regulatory process, thought it was too complicated to be commercially viable.

The conviction that carried ELIAS through those years was not that the regulatory process would be straightforward. It was that engaging with it rigorously, and early, was the only way to convert the uncertainty of a novel technology into the commercial structure needed for scale. Clinical trials were designed to answer regulatory questions rather than simply

to generate scientific publications. Manufacturing was treated as core intellectual property. Demonstrating consistent, controllable production to the USDA's satisfaction was the work that made everything else possible.

The result is a USDA-licensed manufacturing facility, the first of its kind for this category of therapy, with manufacturing success rates that exceed those reported for comparable FDA-approved human products. ELIAS launched commercially in 2021, marketing aggressively only after receiving full regulatory approval. At the time of AHNTI EU 2026, the company was preparing to release data from a post-marketing combination therapy study with the potential, in Wahaus's words, to represent the most significant advance in veterinary cancer treatment outcomes in thirty years.

The trade-offs were real and the timeline was long. But the regulatory discipline did not

constrain the innovation. It created the conditions for it to survive contact with the market.

**"Regulation is not the opposite of innovation. It just lags innovation. We must invent it before they can determine how to regulate it."**

*Tammie Wahaus, CEO and Co-Founder, ELIAS Animal Health*

## LESSONS FROM ELIAS: PRINCIPLES FOR FOUNDERS IN NOVEL THERAPEUTIC CATEGORIES

**Define your customer broadly, and early.** Veterinarians, regulators, and pet owners are more aligned than they initially appear. Designing for all three from the outset is more efficient than retrofitting for each sequentially.

**Design clinical trials for regulatory approval, not just scientific publication.** The questions a regulator needs answered are different from those a veterinary journal requires. Both matter, but if you can only design one trial, design it for the regulator.

**Treat manufacturing as core IP.** Particularly in cell therapy and novel biologics, the manufacturing process is the product. Protecting and documenting it with the same discipline applied to scientific IP is both a regulatory necessity and a commercial asset.

**Lean in early to evolving regulations.** Waiting for the regulatory framework to be fully formed before engaging is itself a strategic choice, and one with costs. Regulators are more receptive to early dialogue on novel technologies than many founders assume, and early engagement shapes the framework rather than simply responding to it.

**Be honest with your stakeholders.** ELIAS built veterinary trust by reporting outcomes transparently, including those that did not go as hoped. In an industry where trust drives adoption, the long-term value of that transparency compounds.

## THREE SESSIONS, ONE ARGUMENT

The sessions at AHNTI EU 2026 covering regulation and innovation arrived at the same conclusion from three different directions. The FDA is signalling a genuine openness to reform, with specific mechanisms in development and an explicit invitation to industry to come in with proposals rather than complaints. The global regulatory landscape remains fragmented, but the direction of travel, toward mutual recognition, centralised procedures, and international data acceptance, favours founders who build their regulatory strategy proactively rather than reactively. And the most compelling evidence that regulatory engagement is a commercial discipline rather than a compliance overhead came not from a regulator or a policy expert, but from a founder who made the harder choice a decade ago and is now commercialising the first adoptive cell therapy approved for the treatment of cancer in companion animals.

The common thread is timing. The founders who will extract the most value from the regulatory shift currently underway are those

already treating it as a strategic variable: engaging with agencies before their dossier is complete, sequencing international market entry against a real understanding of where pathways are most developed, and designing their clinical and manufacturing programmes with the regulator as a named customer alongside the veterinarian and the pet owner.

The regulatory landscape for animal health is not fully formed. In many of the most exciting therapeutic categories, it may not be fully formed for years.

That is not a reason to wait. As ELIAS demonstrated, and as the Director for the Center for Veterinary Medicine confirmed from the stage at AHNTI EU, the founders who engage with an evolving regulatory environment early and deliberately are not taking on additional risk. They are converting uncertainty into structure, and structure into scale.

# JOIN US AT AHNTI EU 2027

AHNTI returns to London from 1 to 3 March 2027, at the Royal Lancaster Hotel.

Now in its twelfth year, AHNTI EU brings together the founders, strategists, and investors driving the next generation of animal health innovation, from novel therapeutics and diagnostics to nutrition, technology, and the regulatory pathways that connect them all to market.

Whether you are building a company, sourcing your next investment, or shaping the strategic direction of an established organisation, AHNTI EU 2027 is where the conversations that matter happen.

**FIND OUT MORE AND REGISTER YOUR INTEREST AT [AHNTI-EU.COM](https://www.ahnti-eu.com)**