

Neal Parker:

Thank you for inviting me here today. This is actually my first time in Brussels. I'm enjoying myself very much.

Interests of public health and commercial confidentiality can be reconciled. Companies like mine protect their business assets in order to maintain their ability to discover and treat new diseases and help patients and we believe strongly that this is itself a public health interest that has to be protected for the good of us all.

Balance – someone else said it but I agree – suggests compromise. And the extreme positions on transparency - disclose everything to everyone or disclose nothing - are both untenable and they are both not in the public health interest.

Current law and practice results in the release of extensive amounts of information in the marketing dossiers that we submit to regulators.

I have one slide but it's only one slide. It does build.

Here is a list, this graphic, of everything in our applications that is made public right now. This is a busy slide but it's supposed to be because there is a lot of information here including safety and efficacy approval documents that come straight out of our dossiers and safety reports and assessments. And our scientists also voluntarily present results and data at conferences and we publish the results in journals and so forth. And this means that there is a vast amount of information that gets released to both physicians and patients right off the bat without any controversy whatever.

Now, how we approach deciding how to release what is left over is the central question and it is very much a company specific product by product analysis. Each company must be permitted on its own to determine what information in which of its dossiers for which of its products it needs to protect in order to prevent competitive harm.

This is how we at AbbVie try to approach such disclosure issues. Here in yellow are certain categories of information which are present in marketing authorisation dossiers that may depending on the circumstances constitute confidential commercial information, what we call CCI.

There is a very good much more detailed description of this yellow information in the *Joint Pharma EFPIA* principles but briefly subject level data is information on individual study subjects like demographic data, lab results, adverse events. Study level data consists of the subject level data organised into data sets to be used in interpreting the outcome of a study.

Now the information in yellow may be considered confidential because it can be used by other companies to get competing products approved more quickly and that makes the information commercially valuable to us.

With this yellow information we recognize however that access to it can be central to advancing public health. So AbbVie is committed to giving others in the scientific community reasonable access to this information in order to replicate results, prove or disprove what's in the package insert right now, prove or disprove what we've tried to say is accurate before, generate new ideas and basically to move science forward. This is the

fundamental way that science advances and AbbVie is 100% behind it and in favour of advancing science for patients.

But there have to be reasonable controls put on the release of this information in order to maintain the appropriate balance, the centre position that we are talking about.

Information released without prohibitions on subsequent release to companies who want to exploit the information for their own commercial advantage undermines the public interest in release of the information in the first place.

Now here in white there is a third category of information I want to talk about. We may consider this CCI depending on the circumstances also. Interpretive analyses, judgements, these include a sponsor's characterisation, theories and conclusions regarding subject level and study level results. It also includes our individual, internal, tactical decisions on how we're going to run a study, how we are going to engage with the regulators, how we are going to confront and solve problems and challenges that we have uncovered during our clinical studies.

A good way to think about this white information is that it is subjective compared to the yellow which is more objective - it is more information of a factual nature. The white represents the intellectual output of our scientists which we consider among our company's most valuable assets.

The only way to protect this information is to protect it from disclosure as CCI. This information cannot be patented and it is not entitled to non-patent regulatory exclusivity. This sort of information can give other companies a tremendous competitive advantage by revealing our subjective, strategic thinking for proving the safety and efficacy of our products. And significantly third party researchers do not need access to this sort of information to conduct robust independent analyses of our data and our products.

So AbbVie's message for the panel to consider today is that the biopharmaceutical industry is committed to the scientific process and all that it entails including responsible data sharing to both replicate or challenge what's been done before or to spark new research and advance science.

We believe in a balanced approach to categorising and releasing information in our dossiers that is not already made public. So the objective study data and information needed by scientists, what I will simplify as the yellow stuff, should be released accompanied by appropriate conditions and safeguards. This balanced approach AbbVie suggests serves the public interest both by releasing information for responsible use by the scientific community and also preserving the incentives that my industry needs to keep researching, developing and getting approved new products that cure disease and help us all.

New Person:

When you talk about the yellow section and we take a clinical study report, if you talk about interpretive analyses and results do you refer to the discussion and conclusion? And if this is what is meant doesn't that enter into your labelling?

Because if I look at what typically we write in a clinical study report conclusions and discussion generally reflects in the label. So I wonder what you are driving at here.

Neal Parker:

This is the right approach. I mean, it's not constructive to look at categories of documents and say we're going to release this – we'll release Annex 1, 7 and 8 and a clinical study report. Because all three categories of information are interspersed throughout all of these documents and it takes a very fine analysis which it is the burden by the way of the company to do to identify what's sensitive.

You are right that a lot of summary information in the label which is the product of all our work is in the blue stuff, it's in the label, it's in the ?e bars? it's in the summaries that FDA releases, it's all out there, it's enough to give independent researchers the end product of our conclusions.

But the detail of the give and take, of the problem solving which is reflected in the narratives of some of these clinical study reports is internal sensitive information which is nowhere reflected in the label.

The process of getting these products approved with the regulatory agencies is a give and take of issues, challenges, re-working of data in response to regulator's concerns or concerns that we have identified and raised ourselves which needs to be explained and articulated in documents that we submit to regulators to get products approved.

And if I'm a competitor to AbbVie and I'm in a competitive landscape where there are a lot of products on the market and I want to enter that market the first thing I want is AbbVie's clinical study report because I want to know what problems I'm going to have to confront when I try to get a product approved. And that is a competitive advantage and that's why we consider this information, depending on the circumstances, CCI.

Aginus Kalinus:

Did I understand it correctly that when you were talking about the yellow stuff you were mentioning adverse events? You think that adverse events might be commercially confidential information?

Neal Parker:

It is commercially confidential information because if adverse events are reflected in either patient level data or in study level data that information can be in one instance photocopied and taken to - I heard a country, I'm just going to use this as an example that was raised before, Bangladesh – I can photocopy that data including the adverse events and perhaps do a bioequivalent study and I can get a product on the market. That steals my company's data.

Aginus Kalinus:

That means, yes. You say, yes. Adverse events might be commercially confidential.

Neal Parker:

Yes, but it's very important to understand that does not mean that it can't be released.

Aginus Kalinus:

You are aware that you are working in the health care industry? With patients and human beings?

Chairman:

This is descending into discussion points and we'll come back to that...

Hans-Georg Eichler:

I'm sorry I've been a regulator for many years. But I'm totally flabbergasted. What exactly is in that white field? If we ask your company - give an explanation for a signal for carcinogenicity or whatever and there is a public health concern and then you respond to that, is that what you mean in the white circle?

Neal Parker:

There are internal deliberative processes, thoughts, product of our scientists that are used to frame data, present data, organise data and argue or present that data to the regulators in a fashion that we believe supports the safety and effectiveness of our products.

That information, including adverse events, to respond to the previous question, is confidential commercial information because if released other companies could use it to help them get products approved.

Now again, I want to make sure I am crystal clear on this, that does not mean that we believe the public interest does not outweigh the release of that information. In fact for all the yellow information we think it should be released. We think that the public interest if it is released under the appropriate conditions – the main condition being I promise not to share it with your competitors – then that information can be released. (25.43)

Chairman

So, it's open. We've heard that IP is not the problem. If IP is not the problem, then is it the solution. Or if it's not the problem, what's the answer. I mean you tried to raise that question with Richard Bergstrom. So Richard do you want to respond now to that question.

Richard Bergstrom:

Yes, IP is never a problem. It's rather the lack of IP which is the problem.

We're looking here at here, if I connect this question with the debate that Neal initiated, when I talk to my members, most of them are quite relaxed about all of this. Because for most products people have no issues. We're going to put out these CSRs, we'll redact a little bit. Maybe something, maybe nothing in there.

Some companies are quite relaxed about this because of the way they write the document, the type of products they have. Others have more issues because they may be in a very competitive field maybe particularly in the biologics field where you do a lot of bridging and you have to argue, to persuade the regulators to take the totality of the data and approve it. I guess that's what you're after, Neal. So there it becomes a bit more sensitive.

You look at the global scope as well. You may have some companies from Korea or China breathing down your neck trying to copy your technologies. Then you get a bit extra sensitive about putting things out there.

We are trying to build a model here which works for 100 per cent of the products and for most of them we have good patents and they work and we enforce them and no problem. But maybe for one tenth of the pipeline we rely on other incentives.

If I may use an example Lundbeck – this is in the public domain – recently got a product approved for alcoholism Nalmefene. This is publicly known. The investors know it that there is no patent on that use. So Lundbeck has developed this and is commercialising it. It's a pity they only commercialise it in Europe and countries with data protection - all the citizens of the world should get the medicine. Nevertheless, the point being this, that would never have been developed if they did not know they had some kind of protection.

Now with the new definitions that are emerging in Europe, in Europe even Hans-Georg, we are told that that is a known substance, it is not a new active substance and therefore it is not subject to data protection which means that a generic producer can come day one and file an application for approval. There is no protection, no patent, no data protection. No market exclusivity.

It's not all products, maybe one in ten or maybe even less, it doesn't matter, but we need a model that works for that and we need to have a model that works for Neal's product, which is subject to a legal case right now that EFPIA is supporting, where it is extremely competitive in the biologic space, the new indications, and everyone's trying to learn from one another and so on. So we need to find a model where also these one out of ten there is a possibility actually to blacken out a bit more than is the normal case.

But again under these commitments that we have put forward today this data all of it including that white spot there will be available for legitimate researchers. So a scientific organisation coming in saying that we would like to have this information, provided there are safeguards for patient privacy and commercial confidential information, we are willing to

share the information. All the CSRs, all the arguments we put forward to the regulators. But it's just that we don't want it out there for everyone.

Jim Murray: Open Medicine EU.

Two quick questions for Mr Parker. The first one is very short. Disclosure to certain recognised scientists is envisaged but they can't share this data normally with somebody else. Does that mean they can't share it with clinicians?

Second question. The EMA in the policy they are following are following an independent assessment by the European ombudsman who set out a series of criteria which does recognise by the way the possibility that some information may be commercially confidential and may properly be withheld from any disclosure the agency might make. The real question though is that you seem to say that you won't accept anyone else's judgement, it is only the company's judgement which matters, not that of the ombudsman, not that of the EMA, not that of anybody else and it seems also, if I'm not mistaken, that that principle very much underlies the EFPIA roadmap.

Neal Parker:

Let me comment on the second question. The general idea of confidential commercial information - there is a worldwide definition - it was repeated earlier by my colleague here - Confidential commercial information is information that a company keeps internal, protects, because if it were to release it, it would give a competitive advantage to another company. That by its nature is a subjective decision. So you are correct that in the first instance that decision is up to the company. The company is best positioned to know the competitive environment within which it operates. Now I believe that that judgement deserves some respect.

Now, it can be rebutted. It can be rebutted by a factual assertion that you say it's confidential but you released it in a report or in a poster at a symposium last year. Or it can be rebutted by going and getting experts to talk about the competitive environment within which the product exists. But absolutely the judgement is the company's because that is what the definition of CCI goes to - the subjective belief of the value by a company of its information.

JM: Who arbitrates between you and your rebutter?

NP:

Ultimately a judge does. But there should be a process when a request comes in to a regulator for a clinical study report - a clinical study report is given to a company and AbbVie will treat it according to these circles perhaps depending on can we release it with controls.

But at AbbVie we will go through and the first thing we will do is circle everything in that clinical study report that we know is already out in the public domain. All the adverse events that are reported in PSURs. All of that information which is already in the blue just goes, it's not even in dispute.

And then we will look at information which is not in the public and we will assess whether under the circumstances releasing this publicly without any conditions is going to hurt us competitively. We should be able to go back to the regulator and present that version of the document. The regulator in his expertise, or the ombudsman or any other objective or third party who has the legal authority should be able to challenge that. And if an agreement, a compromise, a settlement can't be reached, then ultimately we live in a world where there are courts and sometimes you have to go to courts.

We believe that those instances if we can implement a responsible compromise along the lines of the joint principles that I've talked about here should be very few and very far between.

Jim Murray:

The difficulty about challenging this in court is one must have standing and a set of principles, independent principles, by which they will be judged, by which the court will arbitrate. And where are they to come from?

Neal Parker:

There's a law right now which gives you standing immediately. The Transparency Regulation allows any member, any person of the public to submit a request to the EMA for data, for information. And if ultimately the EMA denies that because they have been provided with a redacted copy by the company then you can challenge that decision not to get the data. Now if the EMA decides to give you the data and to disregard the company's explanations about what is confidential, then the company has to sue the regulator and that happens sometimes too.

Chairman:

And Jim's first question about sharing with medics?

NP:

I'm sorry I don't remember your first question.

JM: Can recognized scientists share material with doctors.

Neal Parker:

There are two issues going on here. Number one as a matter of law if I have confidential information and I decide to give it to you and I don't make any sort of accommodation or agreement that says you won't give it to your neighbour then I've lost the ability to protect it as CCI. Because a test is something that a company protects. So we need, when we release it, to ensure that Scientist A is not going to be a conduit of my CCI to Journalist B.

Flaminia Macchia:

Flaminia Macchia, European Public Affairs at Eurordis, which is the European Organisation for Rare Diseases. I'm really trying to understand what you're saying. It's difficult but...can you give an example of an adverse event that would be commercially confidential, so

commercially confidential not to have to be shared with the patients? But maybe this is commercially confidential.

Neal Pearson:

Let me answer your question because it was raised before. I cannot come up with an example of an adverse event that we would not share. Because AbbVie is going to share all of its yellow stuff under appropriate conditions that maintain the public health.

Now stepping back from this, and I will talk to my regulatory people, but if there is adverse event information which is not released in PSURs, which is not released normally and made available in adverse events databases worldwide, if there is discussion of adverse events perhaps in the narrative of clinical studies which doesn't fall into any of those categories, I suspect it would fall into the yellow and it would be released under the conditions that we would be sure would ensure the advancement of public health.

But also remember in the blue – I think it's in the bottom right of my graphic – companies can choose to release anything that they want to. That's part of the definition of CCI.

Personally from Abbvie's perspective I cannot imagine any circumstance where my company would not release voluntarily adverse event information that was relevant to one of our products on the market. That's just not the way we do business.

Flaminia Macchia:

But this has happened in the past, in the history, no?

Neal Pearson:

I can only speak for AbbVie here. I don't know what you're talking about...the specific examples. But again, this idea, this construct that we're putting together here. It is a big picture of trying to ensure that we recognise the different kinds of information that appear all throughout these marketing authorisation dossiers. A lot of stuff can be released, a lot of stuff is confidential commercial information but a lot of that CCI, notwithstanding that it's confidential and can help competitors, we can release provided that the proper conditions are met.

Aginus Kalinus

I heard you say the company is the best judge of its environment in which it operates.

Neal Pearson

Competitive environment

Aginus Kalinus

Yes but I hope it goes further than just the competitive environment. Because you are working in healthcare. That's my question – do you have any idea that you are working in healthcare with patients?

Neal Parker



Of course that's our whole reason to be in existence – to research and discover new patients, new drugs.

AK

The only reason I have heard is that you have commercial considerations

Neal Parker

Our reason for being in business is to continue to research and discover new products to help patients and all of us. The question and considerations of commercial value - a commercial environment - when we consider whether something is CCI has to center on the commercial value of that information in our marketing authorization dossier to our competitors – because that's what the definition of CCI is. That is separate from the determination of whether than is publicly releasable in the interests of public health.