UNITED STATES FOOD AND DRUG ADMINISTRATION

PREPARATION FOR THE 2018 INTERNATIONAL COOPERATION ON COSMETICS REGULATION (ICCR-12) MEETING

Thursday, June 7, 2018

2:05 p.m.

Food and Drug Administration

Wiley Auditorium

5001 Campus Dr.

College Park, MD 20740

Reported by: Natalia Thomas

A P P E A R A N C E S

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DEBORAH CAMPBELL, AMERICAN COSMETIC MANUFACTURERS ASSO.

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C O N T E N T S

P R O C E E D I N G

DR. KATZ: For those of you are here, we're just waiting a few minutes to see if some of the additional people who said they were going to attend will show up. Okay, good afternoon. Can everyone hear me? I'd like to take this opportunity to welcome everyone to our public meeting in Preparation for the 2018 International Cooperation on Cosmetics Regulation, or also known as ICCR-12, meeting that we're having in Tokyo next month.

Before I get started with my presentation, I just want to go over some general housekeeping rules. If anybody has any electronic devices that make sounds, please either silence them or turn them off now so that people won't be distracted during their talks. If you need to leave the room for any reason, please exit towards the back and someone will escort you to wherever you need to go. At the end of the meeting I'll come back and make some final comments.

The way we'll work things is that I will start off with the introduction and it will be followed up by public comments. The first one will be from David

Steinberg from Steinberg and Associates, the second from Deborah Campbell at the American Cosmetic Manufacturers Association, the third will be Janet Varnell at Varnell & Warwick, and the fourth will be Jay Ansell at the Personal Care Products Council.

I won't introduce each of you, but after the speaker before you speaks, if you could just come and plan to start your talk after they finish up, that would be helpful. As I said, I'll finish up at the end.

So let me begin and welcome you to our meeting in preparation for ICCR. In the time that I will be speaking, what I'll do is describe the ICCR and its process, do a summary of outcomes from ICCR-11 which was held in Brazil last year, and talk about some upcoming issues for ICCR-12.

So for those of you who have been here before, this is an old slide, but it really puts perspective onto why ICCR was eventually established. We look back into October 11, 1995 when the FDA policy was established on international harmonization. This policy was designed with the goals to

facilitate international trade, to promote mutual understanding, to facilitate exchange of scientific and regulatory data, to talk about further ways that we could be transparent to the extent permitted by law, to accept equivalent standards, compliance activities, and enforcement programs of other countries, again, if those are applicable to the FDA's level of public health protection. Finally, one of the major criteria was to avoid a lowering of public health protections. In other words, to avoid downward harmonization.

So initially CHIC was that entity that was established in the cosmetic realm. For those of you who have been around for a long time, people will remember CHIC, the Cosmetic Harmonization and International Cooperation. The first meeting was held in April of 1999 in Brussels, Belgium and the participants were Canada, the EU, Japan, and the United States.

The goals at that time, in keeping with the 1995 policy, was to talk about international regulatory schemes to seek areas of

commonality for development of regulatory alignment, and to develop a memorandum of cooperation. CHIC met three times. Its last meeting was in Canada in 2005. The reason why CHIC was disbanded was that the occurrence of the meetings were so infrequent that as a group we decided we needed something that would occur or meet on a more regular basis and where we could really try to accomplish the goals that were set out.

Rather than continue the same name which we thought might not be a positive thing, ICCR was developed. It was established in 2006 with its first meeting in 2007. The initial members were the same members as from CHIC, which were Canada, the EU, Japan, and the United States. And in 2014, Brazil was added to the ICCR steering committee.

The first things that we did were to establish terms of reference using the voluntary consensus model and it was modeled after ICH, VICH, and GHTF. We decided we would invite our industry partners, which was slightly different from the other international groups at the time.

This slide is here for reference to let you know where we've been over the last 12 years or so. As you can see, we meet pretty much the same time every year with a few minor exceptions, and this year's meeting will be held in Tokyo on July 10th through 12th.

So what is the ICCR work process? What does it look like? Well, we meet once a year and we rotate in the five regions so that the region who's in charge of the meeting, is responsible as being the secretariat for that year. We have an annual meeting and interim teleconferences. Usually we talk to each other quarterly, and ICCR may also establish subsidiary working groups to deal with specific issues that have arisen or topics that have come up.

In the United States, we hold a public meeting prior to the annual meeting, to obtain comments. Not all of the jurisdictions do the same thing.

So the structure for the meeting itself.

The first day is a regulators-only meeting; the second day is regulators plus industry; and the third day is a regulators-only meeting. On the third day, we go over the outcomes, we develop a press statement, and we develop other statements that we will put on our website.

We also have a stakeholder session on day two, and this allows stakeholders usually from a particular region to come and present topics of interest that they think ICCR might want to hear about and might be able to develop to put into our agenda in future years. The outcomes of the ICCR meeting are posted on our website and I have the website information here. I will show you a slide at the end again with this website info.

For those of you who've been around for a while you'll know that our website has changed. The deliverables and accepted documents are posted on the website.

So for ICCR-11, which met in 2017 in Brazil, the agenda items were microbiology standards, integrated strategies for safety assessment of cosmetic

ingredients, cosmetic product preservation, allergens, industry presentations, updates from observing regulators, and stakeholder presentations. The following slides will summarize what the outcomes were.

For the microbiology standards, ICCR adopted, and this is the title of the document, the "Review of ISO Microbiological Standards - Guidance for Cosmetic Preservation and Product Protection." This report was adopted, as well as the review of ISO standards embedded in ISO 17516 report, and both were published and posted on our website.

For integrated strategies for safety assessment of cosmetic ingredients, ICCR adopted the "Integrated Strategies for Safety Assessment of Cosmetic Ingredients, Part 1," and that report is also on our website.

For cosmetic product preservation, the ICCR agreed to develop new terms of reference since the previous terms of reference was no longer applicable, because the process, that it was related to, was completed.

For allergens, a similar situation. ICCR

agreed to develop a new terms of reference since the previous documents had been posted on the website.

With regard to industry presentations, we heard a presentation on e-commerce and cadmium levels in cosmetic finished products. A proposal is pending from industry regarding those presentations.

From observing regulators, we heard updates with regard to cosmetic regulations from representatives from Argentina, Chile, Columbia, South Korea, South Africa, and Taiwan. We also heard from stakeholders who made presentations on animal testing alternatives and talked about products whose claims and uses may not be compatible with cosmetic regulatory frameworks.

The ICCR Steering Committee is reviewing some of the proposals for consistency with ICCR objectives and the scope of work that's deemed by the terms of reference. Other new work items may also be submitted to ICCR at any time.

As I mentioned, ICCR-12 will be held in Tokyo. We've been holding quarterly teleconferences to discuss the outcomes of the work

group meetings and where they are at this point in time. Our last quarterly teleconference will be held later this month.

With regard to the agenda, you'll see some continuing themes that we're going to continue to talk about integrated strategies for safety assessment of cosmetic ingredients. We'll also continue to talk about cosmetic product preservation, allergens, analytic test methods, and communications will be somewhat new, as well as any new proposed agenda items that may come up during the course of that meeting.

This slide is really put here more for reference and it lists our website so that you can find the information that I've described in that website. You also can see who the regulators are from each of the different regions.

So thank you for your attention and now I'd like to welcome David Steinberg to give his presentation.

MR. STEINBERG: Just a very short speech. I have three suggestions. One, we've heard before many times and the whole purpose of this is when we're

talking about harmonizing or agreeing or doing things the same, it keeps coming up. And the whole concept behind it is to try having simpler, more uniform ingredient labeling for cosmetics, that there's a finite amount of space, and there are certain things because of different issues way before ICCR started, before CHIC. This goes back when I was born in Europe back in the '80s when we started doing ingredient labeling.

So the first one I'm going to talk for about one second, and that's water. The rest of the world uses the word aqua. We did studies. They were presented, I think it was 10 or 12 years ago, where American consumers know that water and aqua are the same thing. So why can't we just all have, and agree to have aqua as the INCI name or the ingredient name for water? It's something I think we really need to consider.

The second one is more difficult and this one is there's certain definitions which really need to be defined. They sound simple, but they're not. What I would like to recommend is a working

group from the five member countries of ICCR to come up with realistic, uniform definitions of what a leave-on cosmetic is or what a rinse-off cosmetic is. If you think that's a simple statement, I'm going to give you a real simple explanation. Some people have heard this 'cause I've said this before.

My wife came home from a hard day at work and she needed to relax. So she filled the bathtub up with warm water, took a bottle of bubble bath, which was preserved with methylchloroisothiazolinone and methylisothiazolinone preservative, dumped some in and soaked for 20 minutes. When she was done, she got out of the tub. She dried herself off. She never rinsed off. Is that a leave-on product or a rinse-off product?

Then she decided she needed a face mask. So she took a jar of this black clay, again preserved with the methylchloroisothiazolinone and methylisothiazolinone mixture, put it on her face and about a minute later washed it off with soap and water. Is that a leave-on or a rinse-off? Well, the answer is we don’t know.

And maybe we have with more and more restrictions on the use of ingredients from both Europe and from Canada as to these can be used for leave-on or for rinse-off, I think it would make sense to have a committee formed, a working group as ICCR does, to define these.

The last one is something which is far more complex and that's country of origin. This is something that again means different things in different countries and we really should have the same working group sit down and try coming up with a uniform definition understanding that there might be little questions in certain countries as to what they mean by country of origin.

That leaves me to the last topic, which I will scare you on. That's good. I'm going to try teaching you some chemistry. The FDA has approved the color years ago called yellow 10. Original name was D&C yellow 10. It's a mixture of the sodium salts of a mono- and disulfonic acid and you can see the long chemical name. I'm not going to go through it.

It is principally mono-substituted, which is

about 75%, if I remember correctly, from the Code of Federal Regulations. Europe calls this by the CI number, which is their way of determining nomenclature, and it's called the Colour Index 47005. This is principally a disodium substitution. Japan uses their nomenclature system, which is Ki203, and theirs, again, is principally disodium.

Now I'm going to teach chemistry very quickly. Push the right button. About 55 years ago I took inorganic physical chemistry and one of the things we learned, and it was equilibrium reactions and stuff I always forget 'cause I didn't like it. But if you take one mole of sodium hydroxide and one mole of a weak acid, and you racked them, you form a salt. When you take that and you put it in water, the pH is around nine or ten because you have a strong base and a weak acid.

This is no different when we have a disubstituted product. Yes, yellow 10 is chemically different than CI material from Europe and from Japan. Until you put them in water, and that's how we use them, these are water soluble dyes. When we put them

in water, they come to an equilibrium, and guess what. They're the same thing.

So if you start with the disubstitution here, it comes back to this level, and if you start with a monosubstitution here, guess what. It goes back to the same level and it all depends on the pH of your finished product.

So what I am suggesting is not changing anyone's specifications. That's ridiculous. What I'm saying is allowing a harmonized label and the harmonized label would allow you to say yellow 10, then CI 47005, or the reverse like they do in Europe, CI 47005, yellow 10, because that's what's in the cosmetic, not the name of what was started, but what actually appears when you make the cosmetic.

So there are my suggestions and I hope they have a successful meeting and I thank you for your time.

MS. CAMPBELL: Good afternoon. My name is Deborah Campbell and I am President of ACMA, the American Cosmetic Manufacturers Association. ACMA is a nonprofit trade association of cosmetic manufacturers

and distributors located in the heart of Washington, DC. We are a relatively new cosmetic trade association founded in 2011 and we have already developed a strong base of well-respected members.

US companies that manufacture and/or distribute cosmetic products in the US are eligible for membership in ACMA. Our members include new and established brand owners, manufacturers, distributors, ingredient suppliers, and retailers all supplying the American market. They are composed mostly of small to medium size entrepreneurial companies interested in breaking into the global market.

We continue to build our association and look forward to expanding our membership in the future. We represent the interest of American companies that wish to export their American and personal care products, and we support these companies with a broad array of services and resources. ACMA charges no annual fee for membership. Our services are funded by processing documents for our members at minimal fees.

Our mission is to support cosmetic manufacturers and distributors to expand into the

international marketplace by focusing on international regulations. ACMA's goals are twofold. One, to provide assistance to cosmetic companies to understand expert regulations, and two, developing partnership with the FDA to provide guidance on requirements of the international cosmetic market for our members, which brings me to the subject of my talk today, breaking into the global market.

Many of our members already export some products to Europe and other countries. We are, we are dedicated to helping our members expand and thrive, not only survive in the international marketplace. There are many things to consider when marketing cosmetics abroad.

The major consideration is that the standards of composition and manufacture of the receiving country can vary very much from US standards, or sometimes not that much. Products that are manufactured and sold freely in the US may not have been manufactured or produced according to the required standards of the importing country or may contain ingredients banned, banned by these other countries.

For this reason, the accepted practice of requiring a Certificate of Free Sale as it now exists may be inappropriate. For instance, according to the Official Journal of European Union 2009, Annex 2, there are greater than 1,000 listed substances that are prohibited to be used in the manufacture or production of cosmetics. According to the FDA website, there are 11 ingredients prohibited from being used in the cosmetics in the US; although, it is against the law to use any ingredient that makes the cosmetic harmful when used as intended.

The accepted industry practice of requiring a CFS for US products being exported to Europe may be insufficient 'cause there is no indication of the ingredients used in the manufacture of the products listed on the certificate.

To solve this matter, we propose that the CFS as it now exists should be updated to include a statement that the composition of the listed product complies with European standards. Companies must also ensure that their products have been manufactured within the regulations of the receiving country, which

brings us to the Good Manufacturing Practice Certificate, or GMP. Many new cosmetic exporters face difficulty obtaining a GMP for their products because they're not manufacturers. They develop their product composition and packaging and contact a large manufacturer to produce their product and package it for them, making it market-ready.

We advise our new companies using this strategy to request a Good Manufacture Practice Certificate from that manufacturer. With this GMP certificate for their product, they can reissue the GMP certificate under their own company name based upon what the US manufacturer produced for them.

Another way we are assisting our members to break into the global market is by encouraging them to participate in our new Customer Connect registered distributor program. This program brings manufacturers, distributors, and importers together for mutual benefit. ACMA members manufacture some of the finest cosmetic and personal care products available in the US today and are already exporting these American made products to a number of foreign countries. Our

members have the merchandise and expert experience that international cosmetic distributors and importers are looking for in a partner.

This innovative program is a forum where contacts can be made and developed into long lasting business relationships. Our members participating in the Customer Connect program make their contact and product information available for interested distributors or importers.

Distributor and importer information is available to all ACMA members interested in locating an export partner. Manufacturers are always looking for new markets and partners to help them develop a foothold in the, foothold in the international marketplace.

ACMA is in the process of developing other programs and providing more resources to assist our members to expand their businesses. ACMA is dedicated to help our members break into the global market while ensuring that they produce safe products compliant with all existing regulations of the United States and the importing countries.

Thank you for allowing ACMA to participate today and be part of this planning meeting. Thank you.

MS. VARNELL: It's a pleasure to be here. Thank you for letting me come. I know the last thing anybody wants to do is listen to lawyers, but I have, I'm in good company here with other lawyers. But my name is Janet Varnell. I'm a private practitioner and I come to you from Florida, and I want to talk about post market surveillance in the hopes that it will assist you in preparation for the ICCR meeting.

I'm going to begin by saying, asking you who is Jessica Deetz and why do you care who Jessica Deetz is? Jessica Deetz is a stay-at-home mom in Indiana. She has two young children, a little boy who's nine and a little girl who is two.

Jessica saw posts on Facebook by her friends who were marketing their hair care products and said that these hair care products could regrow your hair and that they were so safe they could be used for things like pregnant women to lower hormonal levels to help with hair loss. They also said they had a safe junior line that was good for children that are ages

one to nine.

Since it's sold via a multilevel marketing company, she purchased the products from her friend. She paid more than $300 and after a few months using them on both herself and her children, Jessica realized that she was experiencing hair loss and other adverse reactions. Worse yet, her son had horrible head sores on his head and had began to develop bald patches, which he ultimately was ridiculed about when he went to school.

Then she goes into her daughter's crib and finds lumps of matted hair falling out of her two-year-old daughter's head to the point that the child lost over half of the hair on her head.

So I've come to ask you all that, to pay attention to people like Jessica Deetz and the thousands of other consumers who are experiencing serious reactions, not only to Monat products, but others. And I think that if we had properly working, working mechanisms for better post market surveillance, then we would be able to do a better job to help people like Jessica Deetz and all of the other thousands of

consumers that I end up running into.

Everyone here is either in industry or working for the FDA and then ultimately you all are going to have this opportunity to work with the ICCR. This is a real legitimate plea. I've come to you all the way from Florida, flew up here just because by chance if there's somebody here who can have an impact on the, the tools that we use to try to monitor what's going on with people.

For instance, like the FDA complaint system, we need to do something that will promote big consumers' use of those mechanisms and track that data a little bit better because it's, as a lawyer I can tell you that it's damn near impossible to help these people.

Their claims are small. Even when, even in the case of Jessica Deetz. This is not a case that most lawyers could ever take to court. It's only going to be successful if it's a class action. I've been a consumer protection lawyer for over 20 years and I'm here to tell you I may have been able to bring, bring the Wen hair care settlement to, together last year,

but it is no easy row to hoe and these cases should not ever happen and they should never be tried in our court system. This is something that we can get the manufacturers to do a better job on and get the FDA and the other ICCR members to do a better job of policing.

So let's talk just for a second about the feedback that I've gotten from these thousands of consumers 'cause I've specifically asked them. I want to know how we're actually accomplishing this post market surveillance. You know, you get it from three sources, right? You get it from physicians. You get it from consumers. And you get it from the company, the manufacturers themselves.

So I only really know very much about what I find in the records of the manufacturers and what I find when I see the records that are handed over from the FDA at some point, but I really know what the experience of a consumer is who's trying to give information back to regulators, whether it's like, for instance, with Monat, which is also sold in Canada, the UK, two of our other partners in the ICCR, as well as here in the US. I know that, that they give me

feedback that when they try to make the claim or a complaint, the, the system is too onerous.

If we truly, whether you're a manufacturer or you're a regulator, if you truly do want to know what's going on with the product in the market, scientifically we know you have to try to gather that data about what's going on in the market. What whether there's an unusual number of adverse reactions.

So I find from my folks that when they go to make a complaint, they are asked questions that they don't, that are very intimidating and they don't know how to answer. They're frequently asked questions that they don't have an answer to like you're not allowed to register this complaint unless you can tell what batch number or, you know, specific items on pikes that they may not have retained the product to enter the information.

So they don't know it, but can't they at least say, hey, I only know this? I used a shampoo. It was this general type and it was made by Monat. Why can't they just tell you that so that at least you will know,

hey, we have maybe 250 very unscientific reports, but we have 250 additional people where we have very little information that are complaining about, about having severe adverse reactions.

You want that information. If you don't have it, if the manufacturer doesn't have it, they can't do anything to prevent it in the future. So the first element being simplify the complaint process. The second is I implore you to talk with ICCR and here at the FDA to consider better communication with the clients.

You know, I don't have very many industry reps here, but I'm glad to have you here because you're certainly in a position with the manufacturers to talk about the importance of communicating with your customers. If you have a tremendous number of people complaining, it can be a curse, I know, but it can also be a blessing.

It's also a resource for you to find out what's wrong, identify it quickly, deal with it. I know, I noticed a firm-generated recall of shampoo just this past week by Paul Mitchell. I applaud that when I

see that. I don't know how on earth Paul Mitchell knew to do that or how much, who brought pressure to bear on it, or whether it was all, it's Paul Mitchell's culture that they decided we're going to deal with this problem of a contaminate in our shampoo or not. I don't know, but that is a stark contrast to what I see.

But there are real victims and I can't help most of them. I need for you all to find a way to capture what people are trying to tell you. They don't feel like they can tell you what's going on. They don't feel like they're listened to and they're not feeling like you communicate with them about what's going on. And if all the FDA does and if all ICCR does is send an e-mail back that says we are continuing to gather information, that's something.

But I am sick and tired of having people parade across my e-mail or call me on the phone and tell me tragic stories and I cannot help them. There's just no way for me to bring a lawsuit for everybody who has a small amount of harm, but I'm seeing it by the thousands.

So you have to do something to get those

complaint processes in your post market surveillance to do a better job of that and capture that data. Thank you.

DR. ANSELL: Good afternoon. My name's Jay Ansell and I'm vice president for cosmetic programs at the Personal Care Products Council. I'd like to thank FDA for holding this meeting and showing its interest in soliciting the viewpoints on the ICCR process from its stakeholders.

Briefly, the Personal Care Products Council is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, our more than 600 members include manufacturers, distributors, and suppliers of a vast majority of the finished personal care products marketed in the United States. While our members represent some of the most well-known products in the world, we also include many medium and small size company as part of our membership.

For the 125 years, regulators and policies, makers have relied on our organization to deliver honest, credible, and accurate scientific information

about cosmetic and personal care products. We take this responsibility very seriously. We're pleased to represent our industry in the International Cooperation on Cosmetics Regulation initiative.

Cosmetic and personal care products industry is a truly global industry dependent on open markets and transparent and consistent regulatory environments around the world. Our member companies continually strive to exceed the most stringent regulatory and product integrity standards worldwide and to provide consumers with safe, innovative, and high-quality cosmetics that they have come to expect with ingredients that are imported from around the world.

We understand international harmonization is a critical component to the success of our industry and significantly contributes to our ability to expand manufacturing and employment, as well as to provide other industries, such as advertising, packaging, and transportation.

The globalization of our industry also promotes continual technological innovation which contributes significantly to the application of these

scientific advancements benefiting consumers around the world.

For all these reasons, the Personal Care Products Council is actively engaged in international efforts to align global safety and regulatory standards for consumer products to eliminate trade barriers and to assure a level playing field for member companies while at the same time reenforcing consumer confidence in product safety.

Now the stated mission of ICCR, to maintain the highest level of global consumer protection while minimizing barriers to international trade, underscores the important role of FDA and the other regulatory, regulators in a global environment. We believe that the ICCR serves as an important forum for alignment of regulation, policy, and guidelines affecting our industry, and as a resource for other companies, countries looking to align their regulatory approaches around common guidelines.

We're very encouraged that ICCR's dedicated website, which was formally launched in 2014, will continue to serve as the important vehicle for the

public and private sector to review the results of ICCR work.

We're looking forward to the results of the ICCR-12 meeting, especially endorsement of a report on applications of an integrated strategy for safety assessment of cosmetic ingredients, as well as endorsement of the ISO analytical methods, and continuing work items in the areas of preservation, assessment of allergies, and many of the other topics.

Further, the important work undertaken by ICCR has been recognized by industry and regulators in other countries who have reviewed the ICCR documents and have expressed interest in participating in the meetings. We're particularly pleased this year to welcome representatives from Columbia, Israel, Korea, South Africa, Taiwan, and Thailand to participate in ICCR-12 as observers.

Our industry fully supports the participation of other countries in the ICCR process. We're also interested in exploring other avenues to promote the work of ICCR globally and to continue the synergies between ICCR and other forum such as ISO. As

international trade on cosmetics and personal care products continues to expand, achieving the goal of global regulatory alignment becomes more critical. We look forward to working with FDA and the other regulators to enhance the ICCR process in the months and years ahead. Thank you.

DR. KATZ: Thank you all for your presentations and comments and for making the trip here to tell us what you think. The information that you provided I will bring back with me to ICCR-12 in Tokyo. I would also, before I finish up, would like to thank several people from my staff and others in the FDA for helping us today. Jonathan Hicks, who helped to organize this meeting, as well as Kate Thrieschman and John Gasper, who you may have met when you walked into the building, and Juanita Yates, who was at the welcome desk.

So with that, I'd like to conclude this meeting. Again, thank you for coming.

CERTIFICATE OF NOTARY PUBLIC

I, Natalia Thomas, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

Natalia Thomas

Notary Public in and for the

State of Maryland

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I, Penny Knight, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

June 19, 2018

DATE Penny Knight