Message

From: GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=527246]
Sent: 4/22/2016 7:17:06 PM
To: HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=230737]; HEERING, DAVID C [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=RECIPIENTS/cn=68681]
CC: VICINI, JOHN L [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=56908]; REYNOLDS, TRACEY L [AG/1000] [/O=MONSANTO/OU=Na-1000-01/cn=recipients/cn=133378]
Subject: FW: Glyphosate and Medical Toxicologists in Europe
Attachments: Contemporary Concepts in Toxicology.docx

See below on SOT /CCT (College of Clinical Toxicology) glyphosate symposium and possible ideas for support via Consortium. The latter would be acceptable but direct Monsanto support would likely be a bad idea.

This could be very influential in the EU and globally. I do not have a specific dollar amount in mind at this juncture.

For Perspective- Sir Allister Vail is the premier clinical toxicologist in Europe at this juncture and is highly influential in Medical / Occupational as well as Military (chemical warfare directorate at Porton Downs) and governmental levels. He is a close friend of Sir Collin Berry.

Perspective: I have helped Allister with product data on several occasions for the UK emergency response system, and Allister saw my presentation on the clinical toxicology of surfactants in herbicide formulations when we were in Brazil and requested that I come and present it to the European toxicologists as he recognized the importance of the issue. It is a good relationship which long-predates my arrival at Monsanto. Allister Vale and Sally Bradberry wrote the last 2 major reviews on glyphosate along with Alex Campbell, also in the UK.

Dan

From: Allister Vale [redacted]
Sent: Sunday, April 10, 2016 2:06 PM
To: GOLDSTEIN, DANIEL A [AG/1000]
Cc: [redacted]
Subject: RE: Glyphosate and Medical Toxicologists in Europe

Dan

Please forgive the delay in responding but there are a multitude of deadlines this month and I have 2 weeks on clinical call as I am away for most of May either on AL or at EAPCCT. It was also important to submit our SOT proposal for 2017.

In addition, and more importantly, I wanted to discuss the matter informally (without any mention of your proposal) with key players. I did so because of the invitation I have had to organise an SOT CCT program on behalf of the CTTSS. The "controversies" you mention are ideal for this kind of program. You raise the idea of a joint meeting with EAPCCT/ACMT but neither has the financial resources to contribute actively. Moreover, the AACT, which is formally recognized by the SOT, is in the same financial boat.

Funding via the Glyphosate Consortium would be a way of taking this kind of meeting forward. Given the hands off arrangement you mention I am confident it would be possible to put together a team of clinical/medical toxicologists to be primarily responsible for the organization. However, to make this work, neither I nor they could be in receipt of direct funding from Monsanto or the Glyphosate Consortium.

If you think this approach is feasible please come back to me.

Best wishes

Allister

Professor Allister Vale MD FRCP FRCPE FRCPG FFOM FAACT FBTS FBPhS FEAPCCT Hon FRCPSG

Consultant Clinical Pharmacologist and Director, National Poisons Information Service (Birmingham Unit), City Hospital, Birmingham B18 7QH, UK; School of Biosciences, University of Birmingham, Birmingham, UK

Past-President, Clinical and Translational Specialty Section, Society of Toxicology;

Past-President, British Toxicology Society;

Past-President, European Association of Poisons Centres and Clinical Toxicologists

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From: GOLDSTEIN, DANIEL A [AG/1000] [redacted]
Sent: Friday, March 25, 2016 7:01 PM
To: Allister Vale
Subject: RE: Glyphosate and Medical Toxicologists in Europe

Allister;

My thanks, and apologies for ambushing you at the time of SOT.

At this time, the situation around glyphosate continues to be, frankly, bizarre. In Europe, we have the final EU re-registration from BfR/EFSA and are currently stalled on a final vote. This is largely the IARC issue of course, and as you probably know, IARC is out of alignment with EPA, EFSA, Japan, Canada, and AU/NZ as well as 3 other WHO organizations. Serious process issues surrounded this IARC assessment, including a scientific advisor from an anti-pesticide NGO and a hand-selected group of panelists chosen before the public announcement of the evaluation, so that no balance could be achieved.

The situation has deteriorated to the point where we have scientists from the various manufacturers facing criminal allegations in Germany, claiming that our dossier submissions contain fraudulent interpretations of studies (despite the fact that we provide raw data and that BfR and EFSA agree with us). There is also increasing activity around POEA surfactant. This is equally inexplicable as the whole series of events appears to have been triggered by a single case of "chemical pneumonitis" following roundup application in Germany several years ago (pathology report equally consistent with a viral illness) and disregarding entirely both the toxicity of all other surfactants and the fact that pesticide use is not a significant route of surfactant exposure for the general population.

Our only goal at this point is to create a larger number of medical toxicologists who know about glyphosate products. You have hit on the key problem of course- direct involvement of Monsanto is not going to be acceptable to experts in the EU. With Sir Collin, we used his assistance as a convener of a PhD toxicology group. This group is presently not active, but we would like to re-activate the effort. Funds were provided to Sir Collin (I believe via the university) and he served to do the selection, invitations, etc. While we could convene the medical toxicologists separately, our thought was that there may be a benefit in bringing at least some of the PhD experts into the conversation. This is largely due to the intensive role of epidemiology, genotoxicity data, and "inflammation and oxidative stress" in the IARC assessment (and in EPA, BfR, etc.). Med Tox folks are generally sophisticated in the areas of epidemiology, but less able to work with the vast array genotoxicity (approaching 100 studies) and the unclear relationship between oxidation/inflammation and cancer. (The data for the latter are essentially intra-peritoneal injection of formulated product….. Inflammation would not seem to be a terribly surprising outcome.

I am open, at this point, to all suggestions and models. It will be important to have this group be public-facing as the issues are now far more political than technical. If you believe that a joint EAPCCT/ACMT and SOT effort would be the best approach, I agree. If this is something that the SOT and Med Tox community see as sufficiently important to be done using general funds or other (non-industry) resources, I am perfectly happy to back away altogether. I assume that the cost will be considerable. SOT is sufficiently large and well supported that it might be able to carry the load- especially if done in conjunction with existing SOT events, but ACMT and EAPCCT have more limited resources. At this point, I certainly understand the need for Monsanto (and the other manufacturers) to stand back from proceedings and to participate as observers at most (if at all). Funding can perhaps come from the Glyphosate Consortium which is conducting the EU re-registration or via ECETOX or CEFIC, for example, and be routed via SOT or one or more academic institutions. At that point, we can be "hands off" altogether.

In the current environment, I am not foolish enough to think that anything will entirely prevent allegations of undue influence. Rather, I am hoping that with appropriate mechanics, the medical toxicologists can convene (with or without the additional expertise on the PhD side) and learn the science underlying the ongoing debate and discussions on glyphosate. As important resources for their respective national agencies, we are of course hopeful that they can support a balanced and scientific approach in the EU.

My thanks- Dan

From: Allister Vale [redacted]
Sent: Thursday, March 24, 2016 6:51 AM
To: GOLDSTEIN, DANIEL A [AG/1000]
Cc: [redacted]
Subject: RE: Glyphosate and Medical Toxicologists in Europe

Dear Dan,

My apologies that I was unable during SOT to respond further to your email of the 10th March. The programme is always very busy and I was still fine-tuning my lecture. Immediately I landed I was on call and so have only now been able to respond in some detail to you.

The issues you raise in regard to glyphosate are of course of considerable professional interest to me, not least because we have grappled with them in completing our chapter for our new book on the *Clinical Toxicology of Pesticides*. Furthermore, we have proposed a symposium for next year's SOT which will include a discussion of the carcinogenicity of glyphosate.

Your email does not expand on the role that you expect these medical/clinical toxicologists to play. Whether it is possible to recruit such individuals will depend very much, I believe, on what you have in mind. As I understand it, you currently have a panel of PhD/animal toxicologists who are advising you privately under Colin Berry's convenorship. An alternative approach, at least for the medical/clinical toxicologists, would be for the group to be more public facing and be responsible for organising one or more symposia to deal with these issues, which could be convened, for example, in association with the SOT, both in the US and Europe.

I believe it would be easier to bring together a group of medical/clinical toxicologists for this kind of activity than to get together a group to advise you directly, particularly as this would require the payment of an honorarium, which would have to be declared and could make more difficult participation in independently organised academic programmes in the future. Of course, it could well be that participation in such symposia would encourage individual medical/clinical toxicologists to consider a direct advisory role.

I would be grateful for more clarity on what you are hoping to achieve.

Meanwhile I look forward to receiving the in press recent expert review or at least a note of where I can find it.

With kindest regards,

Allister

Professor Allister Vale MD FRCP FRCPE FRCPG FFOM FAACT FBPhS FEAPCCT Hon FRCPSG

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From: GOLDSTEIN, DANIEL A [AG/1000] [redacted]
Sent: 10 March 2016 19:59
To: [redacted]
Subject: Glyphosate and Medical Toxicologists in Europe

Allister;

I hope all is well with you.

Undoubtedly you are aware of the increasing controversy over glyphosate safety, carcinogenicity (IARC) and renewal in Europe.

In support of the molecule, we would like to open a dialog with a number of Medical Toxicologists in Europe. This is of course a difficult challenge (as we have discussed in the past) given the reluctance of European academics to be associated with industry in any manner.

Historically, we have a panel of PhD/animal toxicologists dealing with product safety issues, convened by Sir Colin Berry. It would make sense in our mind to use a similar model for Medical Toxicology and, in fact, to join these efforts together and have the Medical and PhD toxicologists and other experts (oxidative stress/genotoxicology) working together. You seemed the most logical choice to help convene the Medical Toxicologists given both your stature in the EU Medical Toxicology /academic community and your long term knowledge of glyphosate products.

In the interest of pursuing this, I contacted Sir Colin a few days ago, and he is interesting in "reincarnating" and facilitating a panel and is enthusiastic about the idea of working with you as a Co-Convenor if you are amenable to considering this. He suggested that I contact you myself and forward to you his editorial in the subject (attached) and a recent expert review (in press and I will need to get final copy and send it to you).

Obviously, this is just a preliminary inquiry and any final decision to participate will require that many details be addressed. Cost (including honoraria) will be picked up by Monsanto via an appropriate granting mechanism which allows for a proper degree of academic independence, and we can provide (or provide support for) logistical assistance so that this does not become an undue draw on your time and that of Sir Collin.

Please let me know if you would be willing to consider such a role, assuming of course that remaining details can be worked out to meet your needs.

Thanks, and my best regards

Dan

Daniel A. Goldstein, M.D.

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