From: Henry Miller <henry.miller@stanford.edu>
Date: Fri, 13 Feb 2015 13:56:56 EST
To:
CC: "Drew L. Kershen" <dkershen@ou.edu>, Alan McHughen <alan.mchughen@ucr.edu>, Gary Marchant <Gary.Marchant@asu.edu>, Val Giddings <lvg@outlook.com>, "Thomas P. Redick" <tpr@geeclaw.com>, Guy Cardineau <Guy.Cardineau@asu.edu>, Yvonne Stevens <ystevens@asu.edu>, Steven Strauss <steve.strauss@oregonstate.edu>, "Kevin M. Folta" <kfolta@ufl.edu>, "Shane Morris" <shane.morris@nrcan-rncan.gc.ca>, Alison Van Eenennaam <alvaneenennaam@ucdavis.edu>, <jsax@cwsl.edu>, Gary Marchant <gmarchan@asu.edu>, Lauren Burkhart <Lauren.Burkhart@asu.edu>
BCC:
Subject: Re: Follow-up to Jan 14 Genetic Modification Workshop at ASU

Dear All,

I'm also interested in helping with #1, but not as the primary scientist-author. (Too much on my plate currently.)

Henry

From: "Alan McHughen" <alan.mchughen@ucr.edu>
To: "Drew L. Kershen" <dkershen@ou.edu>, "Gary Marchant" <Gary.Marchant@asu.edu>, "Val Giddings" <lvg@outlook.com>, "Thomas P. Redick" <tpr@geeclaw.com>
Cc: "Henry Miller" <henry.miller@stanford.edu>, "Guy Cardineau" <Guy.Cardineau@asu.edu>, "Yvonne Stevens" <ystevens@asu.edu>, "Steven Strauss" <steve.strauss@oregonstate.edu>, "Kevin M. Folta" <kfolta@ufl.edu>, "Shane Morris" <shane.morris@nrcan-rncan.gc.ca>, "Alison Van Eenennaam" <alvaneenennaam@ucdavis.edu>, jsax@cwsl.edu, "Gary Marchant" <gmarchan@asu.edu>, "Lauren Burkhart" <Lauren.Burkhart@asu.edu>
Sent: Friday, February 13, 2015 10:35:23 AM
Subject: RE: Follow-up to Jan 14 Genetic Modification Workshop at ASU

Hi Team,

I am most interested in helping with # 1 (as I've already sacrificed my professional reputation in advancing the 'product vs. process' approach to risk regulation) and/or either # 4 or # 5.

Cheers,
Alan

From: Kershen, Drew L. [mailto:dkershen@ou.edu]
Sent: Thursday, February 12, 2015 11:03 AM
To: Gary Marchant; Val Giddings; Thomas P. Redick
Cc: Henry Miller; Guy Cardineau; Yvonne Stevens; Alan McHughen; Strauss, Steven; Folta, Kevin M.; Morris, Shane; Alison Van Eenennaam; jsax@cwsl.edu; Gary Marchant; Lauren Burkhart
Subject: RE: Follow-up to Jan 14 Genetic Modification Workshop at ASU

Gary, Tom, Val,

Gary, you have stated well the five papers that I suggested in the telephone call.

As I envision the five papers, I agree with Gary and Val that paper # 1 is the "rethink" and "begin anew" paper on regulations. It is to propose and argue for a new approach to regulation of modern breeding. If I may be so bold, I would like to suggest Val Giddings (scientist) and myself (lawyer) for this Paper 1. As you know from my presentation at the ASU conference, my PowerPoint theme was on this "begin anew" approach. But I quickly add, that I think Gary Marchant would also be excellent for Paper 1, if this is his first preference.

As for Paper 2, I think this paper requires people with experience in the regulatory systems. People with experience can talk about the incremental, but real, changes that would have made their experiences much more fruitful and less stressful. I hope that those on this volunteer list who have this experience would take on this task.

As for Paper 3, proposal for legal strategies to defend GMOs. This is tough because it is so "nebulous." Many legal strategies are responses to immediate events. Legal strategies are rarely "strategic." But simultaneously, I think the opposition has been thinking much more strategically than agbiotech supporters. The Center for Food Safety has thought carefully about how and where to put their resources to use. Earthjustice has done the same. So, it is time for agbiotech supports to think strategically about the use of law and legal strategies. If I do not work on Paper 1, I am willing to volunteer for Paper 3. I need a scientist to help me think strategically.

As for Paper 4, I think this is the paper where Tom's proposed annex goes but with the theme of the paper being Val's comment that science and innovation are not predictable or known. In other words, the law assuredly will lag behind and, depending on what the law states and commands, the law will at present rule with a " dead hand and mind." ("Dead" is the operative word.) Joanna Sax made this suggestion and I would like to encourage her to volunteer for Paper 4. As Joanna is both a lawyer and a scientist, if she volunteers, she can state what she prefers as her co-author, either another scientist or another lawyer.

As for Paper 5, I think this paper needs two authors with an excellent writing style and an impish (but kind) sense of humor. The article should be dead-pan straightforward but bordering on bizarre and satire. Just state the reality and let the reality sink in as absurd. Just give sufficient examples of the actual results and implications of the present system with a commentary that points out that this is the inevitable consequences, not the accidental misfires, of the present regulatory system. I do not know who feels that they have a "Jonathan Swift" alter-ego awaiting release, but if you do – please volunteer.

Best regards,

Drew

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http://ssrn.com/author=285854

From: Gary Marchant [mailto:Gary.Marchant@asu.edu]
Sent: Monday, February 09, 2015 9:34 AM
To: Val Giddings; Thomas P. Redick
Cc: Henry Miller; Guy Cardineau; Yvonne Stevens; Alan McHughen; Strauss, Steven; Folta, Kevin M.; Kershen, Drew L.; Morris, Shane; Alison Van Eenennaam; jsax@cwsl.edu; Gary Marchant; Lauren Burkhart
Subject: RE: Follow-up to Jan 14 Genetic Modification Workshop at ASU

Val – paper 1 is intended to be the blow the whole damn thing up topic. Its objective -- given everything we know about the flaws of the current system, as well as the changes coming from new technologies, what would a science-based regulatory system look like if we started again from scratch? As we discussed on the call last week, there are issues with the political feasibility of such an approach, but there is nevertheless value in putting the idea on the table and even if unlikely to be implemented in the next couple years, it is there for discussion and consideration, and if an opening should occur sometime in the future, there will be a vetted proposal available.

Gary

From: Val Giddings [mailto:lvg@outlook.com]
Sent: Monday, February 09, 2015 7:58 AM
To: Thomas P. Redick; Gary Marchant
Cc: Henry Miller; Guy Cardineau; Yvonne Stevens; Alan McHughen; Strauss, Steven; Folta, Kevin M.; Drew L Kershen; Morris, Shane; Alison Van Eenennaam; jsax@cwsl.edu; Gary Marchant; Lauren Burkhart
Subject: RE: Follow-up to Jan 14 Genetic Modification Workshop at ASU

Tom, Gary, All,

There is an alternative approach to what Tom suggests which, frankly, I would recommend be considered.

I would argue against an expansive or detailed appendix explaining the innovative technologies that are out there and/or emerging, on a number of grounds. First, it invites a detailed consideration of technologies qua technology, which is directly contrary to the focus we are trying to get folks to return to, i.e., hazards, per se, to which folks must be exposed in order for there to be any risk in need of assessment and management. Hazards, of course, are a function of the properties of a product and not of a manufacturing technology, and we need to remind people of this, as the present approach most regulators take is to presuppose a risk where there is in fact no hazard. I don't think it advances our cause to undermine our objectives with the way we structure and present our arguments.

Second, if we were to do such an appendix, it would rapidly be rendered obsolete. Such summaries done by others as recently as 1 or 2 years ago are a good example of this, which we should cite, but principally to make the point that process based regulations will inevitably lag far behind the evolution of novel technologies. We should use this to underscore the counterproductive nature of policies and regulations that focus on process rather than product qualities.

I think also that the 5 proposed papers as summarised below, while generally good topics, do not quite capture (unless I am mis-reading them) what I will call Henry's "Blow the whole damn thing up" argument, which is a case I do think should be made. It is possible that POV could be encompassed in the first paper, but I'm not sure if doing so only there would do it justice.

I'm also struck, when looking at the list of five, that to me these look less like separate papers than as essential elements of one single persuasive paper. This situation is, to me, a case perhaps of less is more. Do we really need to drill down so deeply on all these topics, or would it be more effective to fold these separate components of the argument succinctly into one?

I don't mean to re-litigate anything if folks are generally agreed on the 5 paper approach. But I am concerned that we risk weakening our overall impact if we are not brutally focussed on what may be most effective.

To my thinking, it might make sense to have perhaps 1, 2 & 4 folded into one paper, and 3 & 5 into another. Does that make sense to anybody else, or does such a suggestion create more problems than it would solve?

In any case, I stand ready to help with outlining and writing. I think I might have the most to add on 1, 2 and 4...

Val

> Date: Mon, 9 Feb 2015 09:17:20 -0500
> Subject: RE: Follow-up to Jan 14 Genetic Modification Workshop at ASU
> From: tpr@geeclaw.com
> To: Gary.Marchant@asu.edu
> CC: henry.miller@stanford.edu; guy.cardineau@asu.edu; ystevens@asu.edu; alan.mchughen@ucr.edu; steve.strauss@oregonstate.edu; kfolta@ufl.edu; lvg@outlook.com; dkershen@ou.edu; shane.morris@nrcan-rncan.gc.ca; alvaneenennaam@ucdavis.edu; jsax@cwsl.edu; gmarchan@asu.edu; lauren.burkhart@asu.edu
>
> Gary et al,
>
> I think one of the papers -- perhaps the first? -- should have a succinct discussion, perhaps in an appendix, of what technologies are out there and what they are called. This field has shown a prolific number of terms to describe technologies. New terms are being coined all the time, like the "GRO" below in item 1.
>
> Also see the article on Cibus and regulation by Breyer et al, which has ten different names for the technology used by Cibus.
>
> I'll offer to co-write whichever paper has this appendix, which I assume to be the first.
>
> All the best,
>
> Tom
>
> ITEM 1
>
> GROs for Creating Safer GMOs
> Section: Beyond Crop Biotech
> Environmental safety of the release of genetically modified organisms (GMOs) has long been an issue affecting its public acceptance. With this, Yale University researchers developed a new way in producing GMOs that are safer for the environment. This was done though the use of synthetic amino acids not found in nature. This synthetic amino acid is inserted in the DNA of a bacterial strain when the DNA has been rewrote to activate the important genes for growth. Researchers refer to it as genomically recoded organisms (GROs). GROs also contains a new genetic code that connects the growth of bacteria to synthetic amino acids.
>
> The development of GROs will be essential in restricting the spread and survival of organism in a natural environment. The researchers believe that the use of GROs consisting of a new genetic code and synthetic amino acids will be important to scientists in making safer GMOs.
>
> Details of the story can be read at: http://news.yale.edu/2015/01/21/synthetic-amino-acid-enables-safe-new-biotechnology-solutions-global-problems or http://www.nature.com/nature/journal/vaop/ncurrent/full/nature14095.html.
>
> ITEM 2
>
> Oligonucleotide-mediated mutagenesis (OMM) is a technique
> used to correct or to introduce specific mutations
> at defined sites of the genome. OMM is a generic term
> covering several approaches and applications. It is referenced
> in the literature under other names such as
> targeted nucleotide exchange,
> chimeraplasty,
> oligonucleotidemediated gene editing,
> chimeric oligonucleotidedependent mismatch repair,
> oligonucleotide-mediated gene repair,
> triplex-forming oligonucleotides induced recombination,
> oligodeoxynucleotide-directed gene modification,
> therapeutic nucleic acid repair approach,
> targeted gene repair
> http://www.cibus.com/pdfs/EU_Belgium_report_ebr0910_100709.pdf
>
>
> -----Original Message-----
> From: "Gary Marchant" <Gary.Marchant@asu.edu>
> Sent: Sunday, February 8, 2015 10:32pm
> To: "Henry Miller" <henry.miller@stanford.edu>, "Guy Cardineau" <Guy.Cardineau@asu.edu>, "Yvonne Stevens" <ystevens@asu.edu>, "Alan McHughen" <alan.mchughen@ucr.edu>, "Steven Strauss" <Steve.Strauss@oregonstate.edu>, "kfolta@ufl.edu" <kfolta@ufl.edu>, "lvg@outlook.com" <lvg@outlook.com>, "dkershen@ou.edu" <dkershen@ou.edu>, "Shane Morris" <Shane.Morris@NRCan-RNCan.gc.ca>, "Alison Van Eenennaam" <alvaneenennaam@ucdavis.edu>, "jsax@cwsl.edu" <jsax@cwsl.edu>, "tpr@geeclaw.com" <tpr@geeclaw.com>

> Cc: "Gary Marchant" <gmarchan@asu.edu>, "Lauren Burkhart" <Lauren.Burkhart@asu.edu>
> Subject: Follow-up to Jan 14 Genetic Modification Workshop at ASU
>
> Thanks to all of you who joined the conference call on Thursday, and I know the couple of you who could not join that you are interested in continuing to be involved.
>
> To recap, we agreed to work on up to 5 different publications, listed below (Drew – correct me if I did not accurately capture the 5 ideas). These would like be submitted for publication separately in probably more than 1 journal, but would cross-reference each other. We agreed that one scientists and one lawyer would take the lead on each article.
>
>
> 1. Big Picture – need for a new science-based product-focused regulatory system, including statutory changes
>
> 2. Incremental Fixes – some non-statutory regulatory changes (eg fixed review periods) that could smooth regulatory approval
>
> 3. Legal strategies – a roadmap for defending GM products against unreasonable opposition and delays
>
> 4. Aligning Law with Science – law must do a better job to stay apace with new scientific understanding and knowledge; has failed to do that with GMOs
>
> 5. Loopholes – critique of current system that relies on series of loopholes and exemptions to try to minimize regulatory unreasonableness.
>
> Please let me know if you are willing to take a lead role on one of the topics listed below. Draft manuscripts will be circulated to this group for editorial comments and with the lead authors approval, sign on.
>
> Thanks,
>
> Gary
>
>
>
>

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