

Memorandum

To: Professor Roberto Corrada

From:

Date: May 11, 2012

Re: Individual Contribution Report

Administrative Law: Legislation Regulating the Release of Dinosaur DNA

This memo briefly summarizes my contribution to the Regulatory Landscape and Details Team and, in the bigger picture, to the class as a whole in creating the federal statutory scheme for the release of dinosaur DNA.

The Regulatory Landscape & Details group worked very well as a team in which we communicated often, collaborated regularly, and divided tasks equally amongst ourselves to ensure the team was covering the procedural nuances that fell outside the purview of other groups.

When the Regulatory Details team met for the first time at the beginning of the year, we brainstormed what our work may look like over the semester and what we should tackle up-front to best aid the Policy Team in determining the best structure for our regulatory agency. I drafted a short "To Do Chart," which included some of the overarching issues we would likely be addressing over the next couple months (such as nonacquiescence, extraterritorial application, and current human/animal cloning regulation at the federal, state, and international level). We also brainstormed a list of agencies/acts from our own general knowledge and from those mentioned in class, which included CERCLA, the Clean Water Act, NEPA, Endangered/Exotic Species, Nuclear Regulatory Act, and NASA, that we began to investigate independently. We divvied up each of the aforementioned topics, acts, and agencies to spend time investigating and devising how we may best use this information to assist the class in creating our own regulations. I personally took charge of reporting to the group on NEPA, extraterritoriality, and current regulation of human and animal cloning both domestically and internationally.

On February 5, I completed and posted a memo regarding the current state of the law for extraterritorial application (see all postings included at end of memo). I spent the afternoon researching and writing a brief synopsis on my research. I found Jeffrey A. Meyer's article, *Dual Illegality and Geoambiguous Law: A New Rule for Extraterritorial Application of U.S. Law*,¹ and Andrew Smith's article, *The Extraterritorial Application of the National Environmental Policy Act: Formulating A Reliable Test for Applying NEPA to Federal Agency Actions Abroad*,² particularly helpful and insightful on the topic.

¹ Jeffrey A. Meyer, *Dual Illegality and Geoambiguous Law: A New Rule for Extraterritorial Application of U.S. Law*, 95 Minn. L. Rev. 110, 127 (2010).

² Andrew A. Smith, *The Extraterritorial Application of the National Environmental Policy Act: Formulating A Reliable Test for Applying Nepa to Federal Agency Actions Abroad*, 34 Nat. Resources J. 751 (1994).

The following week we again met as a group (with the plan to meet bi-weekly throughout the semester) to discuss the research we had conducted, post findings for the class (including memos and links), and to brainstorm and divvy up new tasks for the month of February. I discussed with the team the research I found regarding synthetic biology and the policy concerns and current regulation over the novel field. Although I had never heard of synthetic biology, once I started researching the current state of law regarding human and animal cloning, I found a wealth of resources on synthetic biology, which is very much related to the reintroduction of dinosaur DNA since it deals with the construction of new biological parts, as well as the re-design of existing, natural biological systems. There was so much information out there regarding cloning, synthetic biology and rDNA that it was a bit overwhelming for all of us, but I found a guide to U.S. and E.U. regulations regarding the regulation of synthetic biology, which was extremely useful in grasping a bigger picture of the field of regulation. I also found, and included in my memo, some of the policy rationales behind the Obama administration's decision to abstain from regulating synthetic biology further. I felt that all of this directly correlated with the Policy Team's work in attempting to articulate and determining how we wanted to structure and define our agency. Allie's research on the state level coalesced well with my federal and international findings on the topic.

The following week each member of the regulatory team was assigned to argue for the Chapter Two problem regarding delegation of power and possible violations of citizens' Seventh Amendment rights to a jury trial. Putting a lot of focus on these arguments was helpful in analyzing the policy team's drafts of language and comparing and contrasting our language to that provided in other Acts. I fell extremely ill during this week and had to put off presenting my oral argument on behalf of the U.S. Government, but I spent a considerable time thinking about deregulation and separation of powers arguments and how this plays into our own scheme while lying on what then felt like my death bed.

In early March I conducted research on the Court's decision regarding the Alien Tort Statute and couldn't stop thinking how it related to our simulation because of the extraterritorial application that we wanted our regulatory scheme to possess. Although purely speculative, I do not think it is a stretch that after a few decades of permitting regulated dinosaur attraction parks, tortious behavior by corporations may well take place. Indeed, in Crichton's Jurassic Park, it did not take much time at all before corrupt corporate behavior ensued. Although most cases under ATS deal more with human rights abuses, it still made me reflect on the importance of regulatory schemes that not only aim to, but achieve in, adequately ensuring that corporations cannot take advantage of, nor harm, aliens of another nation by skirting domestic laws.

Our Group also met in early March to discuss the ethical issues dealing with agency employees and possible conflicts of interest issues. I found the Department of Justice website very helpful in conducting research regarding conflict of interest rules pertaining to government

employees.³ The website contained brief synopses of what conduct would lead to a conflict of interest and referenced which statutes within the United States Code would govern the underlying impermissible conduct. As a group, we worked via a google document to create statutory language that we could include within the regulatory scheme that would govern conflict of interest issues (also included in postings below). Cameron found some great language from state agencies and I incorporated much of the language used in the United States Code to regulate improper behavior. Although the final version on the wiki was eventually amended, it was a good draft that got us all thinking about these issues and what the punishment for such violations should be. We upped the punishment for certain violations in order to deter government conduct. Thinking about the role of sovereign immunity and the inability to sue federal officials under the Courts' doctrinal limitations to *Bivens* actions, we thought it important to deter misconduct as much as possible considering the risks posed by this novel industry/field.

Around this time we also created a google document to draft language to include regarding extraterritoriality within the policy section of our statute. I drafted the language simply because the underlying issue seems to be whether congressional intent is clear with regard to extraterritorial application. I looked at the legislative history and current policy issues surrounding the Dodd-Frank Act to draw some language. I also conducted research regarding tribal sovereignty and the possibility of tribes implementing parks/research centers in Indian Country and arguing that the regulatory scheme does not apply to them.⁴ Although a huge supporter of tribal sovereignty, I understand the importance of regulating this industry and the fact that Congress would never create legislation regulating dinosaur DNA without the intention of it applying within Indian Country, too.

Within the final weeks of the course, our group focused on a few different details missing from the legislation, including advisory committees, an inspector general statute, offices of congressional affairs and administration, etc. We again split up tasks and I focused on advisory committees, which we created around Hermine's list of specific areas/topics that need be addressed by agency rules. I found a very informative, interactive website listing all advisory committees within each federal agency.⁵ It was helpful when drafting the language for the committees. Although in the end we had far too many advisory committees, it was fun thinking about the different areas in which expertise and a myriad of opinions may come in helpful for an agency attempting to regulate such a novel field. Over several emails and after amending the google doc, we finally combined and limited the number of advisory committees present within our regulatory scheme.

The final week and a half of the course involved my contributions in amending the statutory language for advisory committees and brainstorming on the Final Geeps discussion

³ <http://www.justice.gov/jmd/ethics/general.htm#27>.

⁴ Karen L. Lenertz & Sandra Glass-Sirany, *State Regulatory Authority in Indian Country: State OSHA Jurisdiction*, 17 Hamline L. Rev. 447, 448-54 (1994).

⁵ <http://www.gsa.gov/portal/content/248953>

page to some final changes to our regulatory scheme. While studying for the final I took notes of areas in our own scheme that should be amended or were lacking in appropriate language. This included suggestions pertaining to state law preemption, language granting the commission discretion as to whether to start the rulemaking process, and a post-promulgation comment period for emergency rules.

MY POSTINGS IN CHRONOLOGICAL ORDER **(Not Including my Wiki Postings and those made in Response to Others' Postings)**

February 5 posting on extraterritorial application:

Something that we must consider when creating our regulatory scheme is its extraterritorial application. Sure, we can regulate the heck out of something, but if we fail to take into consideration companies' ability to forum shop and skirt all regulation, then we have failed to fully prevent and/or regulate the action.

The National Environmental Policy Act (NEPA) offers good insight into the conundrum of extraterritorial application in administrative law. NEPA contains lofty environmental mandates to promote efforts that will "prevent or eliminate damage to the environment" and thus encourage "enjoyable harmony between man and his environment." Pub. L. No. 91-190, 83 Stat. 852 (codified as amended at 42 U.S.C. §§ 4321-47 (1988)). Thus, NEPA creates procedural duties requiring that all federal agencies create environmental impact statements (EIS), which examine fully the impact of their actions on the environment prior to taking such action.

Years of litigation, however, stem from the fact that Congress failed to express clearly its intent that NEPA have an extraterritorial statutory effect. In *Environmental Defense Fund, Inc. v. Massey*, the question before the D.C. Appellate Court was whether NEPA applied to agency action occurring extraterritorially in Antarctica. The court reasoned that "since NEPA is designed to regulate conduct occurring within the territory of the United States, and imposes no substantive requirements which could be interpreted to govern conduct abroad," NEPA regulates purely domestic decisions by agencies that occur within the boundaries of the United States. *Env. Defense Fund, Inc. v. Massey*, 986 F.2d 528, 532-33 (D.C. Cir. 1993); *see also Basel Action Network v. Maritime Admin.*, 370 F. Supp. 2d 57, 68 (D.C. Cir. 2005) ("Unless specified, there is a presumption that laws passed by the U.S. Congress have no extraterritorial effect."). The D.C. Appellate Court relied heavily on the Supreme Court's presumption against extraterritoriality doctrine set forth in *Aramco*, in which the Court reasoned that unless contrary intent is apparent, legislation promulgated by Congress applies only within the United States' jurisdiction. *E.E.O.C. v. Arabian American Oil Co.*, 499 U.S. 244, 248 (1991).

Nevertheless, it is important to realize that the Court has held numerous times that it is well within Congress' power to enforce its laws beyond U.S. jurisdiction through its power to

regulate offenses on the high seas or to regulate offenses against the law of nations. U.S. Const. art. I, § 8, cl. 10; *see Aramco*, 499 U.S. at 248 (holding that “Congress has the authority to enforce its laws beyond the territorial boundaries of the United States”); *Vermila-Brown Co. v. Connell*, 335 U.S. 377, 381 (1948) (finding that “Congress may regulate the actions of our citizens outside the territorial jurisdiction of the United States whether or not the act punished occurred within the territory of a foreign nation”); *United States v. Yousef*, 327 F.3d 56, 93 (2nd Cir. 2003) (“If a statute makes plain Congress’s intent (instead of employing ambiguous or ‘general’ words), then Article III courts, which can overrule Congressional enactments only when such enactments conflict with the Constitution, must enforce the intent of Congress irrespective of whether the statute conforms to customary international law.” (internal cites omitted)). “Congress is generally free to regulate conduct in foreign countries, and U.S. courts in turn are free to enforce and adjudicate congressional laws against individuals who are otherwise properly subject to their personal jurisdiction.” Jeffrey A. Meyer, *Dual Illegality and Geoambiguous Law: A New Rule for Extraterritorial Application of U.S. Law*, 95 Minn. L. Rev. 110, 127 (2010).[1]

Thus, we have the power to regulate extraterritorially, but we must do so with clear intent and plain language. Because NEPA is silent and there is a lack of legislative history on whether its provisions apply to extraterritorial agency actions, there is ambiguity and inconsistency amongst the courts in interpreting its application under such circumstances. Therefore, it is important to note that we cannot count on NEPA to regulate agency actions that occur extraterritorially when writing our own regulatory scheme, and we must also take into consideration the need for clear expression of legislative intent that sets forth how our regulatory scheme applies to extraterritorial activities and decisions by private companies, organizations and agencies. If we want the regulatory scheme to protect the world, let’s say so.

February 12 posting on Synthetic Biology and current regulation at the federal and international level:

Emerging Technology in Synthetic Biology

Synthetic Biology is a relatively new field of biotechnology, in which engineering, science and a variety of other disciplines coalesce with the underlying goal to design and construct new biological functions not found in nature. Although it is a new field, regulations for more traditional biological research also apply to synthetic biology.⁶ Notably, most synthetic biology research involves the use of DNA from existing organisms.⁷

A. *The Presidential Commission on Bioethical Issues: 2010 Report*

⁶National Science Foundation Synthetic Biology Engineering Research Center, *The Regulation of Synthetic Biology*, (Jan. 10, 2012), available at http://synberc.org/sites/default/files/Concise%20Guide%20to%20Synbio%20Regulation%20OYE%20Jan%202012_0.pdf.

⁷*Id.*

Recognizing the vast, uncharted territory that synthetic biology creates, in addition to the rapid development of technology in the field, the Obama Administration requested in May 2010 that the Presidential Commission for the Study of Bioethical Issues (PCSB) research and produce a report on the ethics and emerging science of synthetic biology.⁸ In December 2010, the Commission produced a 192-page report with recommendations to “ensure that America reaps the benefits of this developing field within appropriate ethical boundaries.”⁹ The report offers great insight into the issues we must think about in creating a regulatory scheme.

Although the Commission noted that synthetic biology “offers extraordinary promise to create new products and new economic opportunities,” it also admonished that such technology comes with the duty to assess potential risks and be responsible stewards with regard to implications to other humans, species and the environment in general. Remarkably, the Commission found “no reason to endorse additional federal regulations or a moratorium on work in this field” at that time, but noted that future developments may change its conclusion.” In its opening letter addressed to the president, the Commission stated that,

[I]t urges monitoring and dialogue between the private and public sectors to achieve open communication and cooperation. The Commission recommends that the government, through a coordinated process or body within the Executive Office of the President, lead an ongoing review of developments, risks, opportunities, and oversight as this field grows. This review should be in consultation with relevant scientific, academic, international, and public communities, and whenever possible its results should be made public.

We also recommend that reasonable risk assessment should precede any field release of synthetic organisms. We suggest support for public engagement, education, and dialogue to ensure public trust and avoid unnecessary limitations on science and social progress.

Thus, the Commission recommended a “process of prudent vigilance” to maximize “information, flexibility, and judgment” in regulating synthetic biology. An article from *Slate* printed a month after the Commission produced its report summarizes the 192-page report and offers insight into the Commission’s recommendations.¹⁰ The report focuses on many hot topics incredibly pertinent to creating our own regulatory scheme. The relevant portions of the article, which summarize the Commission’s statements into six categories, follow:

8 Presidential Commission for the Study of Bioethical Issues, *available at* <http://www.bioethics.gov/>

9 Presidential Commission for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*, 7 (2010), *available at* <http://www.bioethics.gov/documents/synthetic-biology/PCSB-Synthetic-Biology-Report-12.16.10.pdf>.

10 William Saletan, *Faking Organisms: How can we govern the garage biologists who are tinkering with life?*, *Slate* (Feb. 1, 2011), *available at* http://www.slate.com/articles/technology/future_tense/2011/02/faking_organisms.2.html.

1. If in doubt, don't interfere. The commission endorses "regulatory parsimony," i.e., "only as much oversight as is truly necessary." You might think that emerging technologies, because they're unformed and unpredictable, require particular restraint. That's the conservative view. The commission draws the opposite conclusion: The evolving nature of these technologies makes them "not well suited for sharply specified limitations."

This principle applies not just to technology, but to related fields such as law. "Intellectual property issues in synthetic biology are evolving," says the report. Accordingly, the commission "offers no specific opinion on the effectiveness of current intellectual property practices and policies in synthetic biology." Don't speak until you know what to say.

Why not err on the side of intervention? Because you might make things worse. Hasty restrictions, the report warns, "may be counterproductive to security and safety by preventing researchers from developing effective safeguards." Let the technology unfold, and see what happens. This might be the best way to learn what sort of regulation we'll need down the road. "The aggressive pursuit of fundamental research generally results in a broader understanding of a maturing scientific field like synthetic biology," says the report, and this "may be a particularly valuable way to prepare for the emergence of unanticipated risks that would require rapid identification and creative responses."

2. Change is the norm. The conservative instinct is to treat the status quo as natural and defend it against change. The commission rejects this idea. The notion that "synthetic biology fails to respect the proper relationship between humans and nature" misconceives the reality of that relationship. In biology, the panel argues, defining "nature" or "natural" is tricky "in light of humans' long history interacting with and affecting other species, humankind, and the environment." We've been messing with life all along.

The status quo, in other words, is change. Yes, modern genetic manipulation is more complex than old-fashioned breeding. But it isn't exploding. It's "proceeding in limited and carefully controlled ways." And while synthetic biology is at the cutting edge, it's just "an extension of genetic engineering" and "does not necessarily raise radically new concerns or risks."

3. Make the regulation as agile as the technology. The tricky thing about synthetic biology, according to the report, is that "the probability or magnitude of risks are high or highly uncertain, because biological organisms may evolve or change after release." And you can't gauge their future from their past, given the "lack of history regarding the behavior" of these organisms. So the commission keeps its judgments provisional. The words "evolve," "evolving," "current,"

"currently," "at present," "at this time," and "uncertain" appear 191 times in the report.

How can we manage such fast-moving, adaptable targets? With a fast-moving, adaptable regulatory system. The White House must "direct an ongoing review of the ability of synthetic organisms to multiply in the natural environment," says the commission. It must "identify, as needed, reliable containment and control mechanisms." This means constant reevaluation. A system of prudent vigilance will "identify, assess, monitor, and mitigate risks on an ongoing basis as the field matures." The word "ongoing" appears 73 times in the report.

4. Make the regulation as diffuse as the technology. The commission notes that synthetic biology "poses some unusual potential risks" because much of it is being conducted by "do-it-yourself" amateurs. Top-down regulation of known research facilities won't reach these garage experimenters. "It is at the individual or laboratory level where accidents will occur, material handling and transport issues will be noted, physical security will be enforced, and potential dual use intentions will most likely be detected," says the commission. Therefore, the government should focus on "creating a culture of responsibility in the synthetic biology community." The phrase "culture of responsibility" appears 16 times in the report.

5. Involve the government in non-restrictive ways. Given the complexity, adaptability, and diffusion of synthetic biology, the report suggests that the government "expand current oversight or engagement activities with non-institutional researchers." This "engagement" might consist of workshops or educational programs. By collaborating with the DIY research community, the government can "monitor [its] growth and capacity," thereby keeping abreast of the technology and its evolving risks.

The best protection against runaway synthetic organisms might come not from restricting the technology, but from harnessing it. "Suicide genes" or other self-destruction mechanisms could be built into organisms to limit their longevity. "Alternatively, engineered organisms could be made to depend on nutritional components absent outside the laboratory, such as novel amino acids, and thereby controlled in the event of release."

How can the government encourage researchers to incorporate these safeguards and participate in responsibility-oriented training programs? By funding their work. This reverses the Bush administration's approach to stem cells. Bush prohibited federal funding of embryo-destructive research so pro-life taxpayers wouldn't have to support it. The Obama commission does the opposite: It recommends "public investment" to gain leverage over synthetic biologists. If the

government subsidizes your research, it can attach conditions such as ethics training or suicide genes.

6. Revisit all questions. Occasionally, the Obama commission forgets its own advice and makes a risky assumption. For example, it brushes off "the synthesis of genomes for a higher order or complex species," asserting, "There is widespread agreement that this will remain [impossible] for the foreseeable future." But if this prediction or any other turns out to be erroneous, don't worry. The report builds in a mechanism to correct them: future reevaluations of its conclusions.

This is more than a matter of reassessing particular technologies. It's a commitment to rethink larger assumptions, paradigms, and ethical questions. "Discussions of moral objections to synthetic biology should be revisited periodically as research in the field advances in novel directions," says the report. "An iterative, deliberative process ... allows for the careful consideration of moral objections to synthetic biology, particularly if fundamental changes occur in the capabilities of this science." Arguments against the technology will surely continue as the field matures, as well they should. The question relevant to the Commission's present review of synthetic biology is whether this field brings unique concerns that are so novel or serious that special restrictions are warranted at this time. Based on its deliberations, the Commission has concluded that special restrictions are not needed, but that prudent vigilance can and should be exercised. As this field develops and our ability to engineer higher-order genomes using synthetic biology grows, other deliberative bodies ought to revisit this conclusion. In so doing, it will be critical that future objections are widely sought, clearly defined, and carefully considered.

That's the way good scientists think: subject your work to peer review, seek falsification, and revise hypotheses as we learn more. Every question is open to reexamination. Even the commission's rejection of a moratorium on synthetic biology "at this time" implies the possibility of reversal. Who knows what the future will bring?

I count three specific restrictions in the commission's interpretation of prudent vigilance. First, "Risk assessment should precede field release of the products of synthetic biology." That's more than monitoring. It's a precautionary hurdle. Second, "reliable containment and control mechanisms" such as suicide genes "should be identified and required." Third, "ethics education ... should be developed and required" for synthetic biologists, as it is for medical and clinical researchers.

Beyond those three rules, prudent vigilance seems to be a matter of humility, open-mindedness, keeping an eye on things, constantly rethinking assumptions, and finding creative ways to influence an increasingly diffuse community of scientific entrepreneurs. It's a lot of work. But it's what we'll have to do if we don't want to restrict technologies preemptively or leave them unsupervised. Eternal vigilance is the price of liberty.

Many individuals, activists and organizations made clear their disagreement with the Commission's 2010 report. Shortly after the report went public in December, 58 organizations from 22 countries signed onto a Civil Society Letter addressed to the Commission on Synthetic Biology to critique the Commission's recommendations, finding that the recommendations fall far short of properly protecting the environment, workers' health and public health. Specifically, the Civil Society Letter criticized the Commission, stating that the recommendations are "an inadequate response to the risks posed" because they, (1) ignore the precautionary principle, (2) lack adequate concern for the environmental risks of synthetic biology, (3) rely on the use of "suicide genes" and other technologies that provide no guarantee of environmental safety, and (4) rely on "self regulation," which means no real regulation or oversight of synthetic biology.

B. Current Regulations of Synthetic Biology

The National Science Foundation Synthetic Biology Engineering Research Center (SynBERC) produced a useful guide to United States and E.U. regulations of synthetic biology, as well as their applicability and penalties.¹¹ Under U.S. regulation, the National Institute of Health regulates the research involving DNA while agencies such as the EPA, USDA and FDA regulate the use and production of genetically modified microbes, plants, food and drugs. A short summary of Federal U.S. regulations follows, but we urge everyone to read this guide in full.

Relevant US Federal Regulations mentioned by SynBERC Guide:

National Institute of Health: Guidelines for Research Involving Recombinant and Synthetic Nucleic Molecules

- set forth safety practices and containment procedures for the creation and use of organisms and viruses containing recombinant DNA
- funding from other federal agencies or private sources may be contingent upon compliance with these guidelines
- the guidelines classify experiments into six categories and specify regulatory hurdles that must be overcome prior to receiving approval (including approval by an Institutional Biosafety Committee, approval by a Recombinant DNA Advisory Committee and/or review and approval by the NIH director)

¹¹SynBERC, *supra* note 1.

- noncompliance with NIH guidelines may result in penalties for both the violator and the institution that supports the violator, even if the violator is not a recipient of NIH funding.
 - penalties include: suspension, limitation or termination of financial assistance
 - penalties are not enforceable against researchers not affiliated with an institution receiving NIH funding
 - stringency of enforcement varies on locale because it is left to local biosafety committees to enforce NIH guidelines

Environmental Protection Agency

- regulates the development and production of “new” microbes “for commercial purposes” created by using DNA
- EPA gets its authority from the Toxic Substance Control Act (TSCA) (15 U.S.C. 2615)
- anyone attempting to “manufacture, import, or process” microorganisms for commercial purposes must satisfy numerous regulatory hurdles; these regulations also apply to “substances produced coincidentally during the manufacture, processing, use, or disposal of another microorganism”
- companies may be subject to civil penalties of up to \$25,000 for each violation of regulations

US Department of Agriculture – Animal and Plant Health Inspection Service

- regulates genetically engineered organisms (including plants insects or microbes) that may pose a risk to plant or animal health by requiring permits/notifications prior to their introduction
- if there is a “high risk for a new plant variety to outcross with a weedy relative,” it may not be authorized or heightened regulations may be put into place to ensure it is handled properly/safely
- Federal courts have on occasion reversed USDA approval of GM plants
- Civil penalties for violations include fines up to \$500,000 and the possibility of criminal liability

Food and Drug Administration

- See posting by Cameron for details

Department of Commerce Regulations

- not science savvy enough to know whether this applies

Select Agent Rules

- not science savvy enough to know whether this applies

March 6 Post on Alien Tort Statute Ruling:

This is a recent article I wrote for a blog posting. It is somewhat relevant to our simulation (and extraterritoriality) in that it deals with corporations and their tortious behavior abroad. In its

subsequent term, the Supreme Court may well determine federal courts lack jurisdiction to hold corporations accountable for violations of human rights occurring in foreign countries under the Alien Tort Statute specifically. This jurisdictional stripping is just another reminder why we must ensure, as Lee suggests, that our agency regulations apply not only to the actions occurring abroad but also ensures adequate enforcement and agency review of those actions.

After oral arguments last Tuesday, the U.S. Supreme Court issued a short order stating that it would hear arguments in its subsequent term as to whether the Alien Tort Statute, a law promulgated in 1789, can be used to sue multinational corporations in U.S. federal courts for alleged human rights abuses committed abroad.

The Alien Tort Statute allows Article III courts to hear “any civil action by an alien for a tort . . . committed in violation of the law of nations or a treaty of the United States.” The law was largely dormant until the last two centuries, when federal courts began to apply it to international human rights cases. For example, the U.S. Supreme Court left open the possibility of holding corporations accountable in *Sosa v. Alvarez-Machain*, so long as the alleged violations dealt with international norms with “definite content and acceptance among civilized nations.” Since the 1980’s, more than 120 lawsuits have been filed in the United States against 59 corporations for alleged violations of international law in 60 foreign nations.

The Supreme Court’s short order this week stems from issues arising from *Kiobel v. Royal Dutch Petroleum Co.*, a lawsuit involving 12 Nigerians alleging that Royal Dutch (“Shell”) aided and abetted the Abacha dictatorship by cracking down on citizen protests against oil exploration through acts of torture, executions and crimes against humanity. Last Tuesday, the Court heard arguments on the narrow issue of whether aliens can sue corporations under the U.S. statute, an issue reminiscent of the Court’s renowned *Citizens United* opinion. The argument follows that if corporations are people for the purpose of rights secured by the U.S. Constitution, per *Citizens United*, they ought to be treated as such, and held accountable, when it comes to violations of international law abroad, too.

Although some Justices seemed ready to rule on the narrow issue, Justices Alito, Breyer and Kennedy questioned whether the Court and U.S. federal courts had jurisdiction to hear such lawsuits for genocide and war crimes occurring abroad at all. Justice Alito asked, “What business does a case like that have in courts of the United States?”, while Justice Breyer followed by stating, “There is no United States Supreme Court of the World.” Many agree that the U.S. judiciary should not meddle in foreign affairs or police the actions of foreigners abroad. Human rights activists counter, however, that if U.S. courts do not have jurisdiction over U.S. companies’ actions abroad, as a practical matter, victims lack any forum where justice may be served.

Briefs on the issue of whether and under what circumstances Article III Courts have jurisdiction to hear cases arising from violations of international law under the Alien Tort Statute are due in May and June, and the Court will hear oral arguments in its next term, which is to begin in October. Corporations will nervously twiddle their thumbs in anticipation of the Court’s ruling, which could very well lead to time-consuming and costly litigation if corporations are to be held accountable in U.S. courts for their alleged roles in foreign abuses that violate international law.

March 6: Research on Ethical Issues of Agency Employees:

The “revolving door” is a term used to describe the movement of personnel between roles as regulators and the industries that are ultimately affected by their involvement in the drafting of legislation or regulation. The purpose of this posting is to determine the applicable standards and statutes that regulates conflict of interest issues that arise in the government employee context.

The Code of Federal Regulation sets forth uniform standards of ethical conduct for employees of the executive branch. 5 C.F.R. Part 2635. These standards mandate rules to be followed with regard to the following:

1. gifts from outside sources;
2. gifts between employees;
3. conflicting financial interests;
4. impartiality in performing official duties;
5. seeking other employment;
6. misuse of position; and
7. outside activities.

Id. Failure to abide by the uniform standards of ethical conduct and similar regulations by statute can lead to reprimand, suspension, demotion, or even removal from office. *See* U.S. DOJ, Department of Ethics Department, *available at*: <http://www.justice.gov/jmd/ethics/generalf.htm#27>.

Additionally, numerous federal statutes regulate the conduct of government officers. *See* 18 U.S.C. §§ 203, 205, 207-08. For example, with regard to conflicting financial interests, an employee is prohibited from participating personally and substantially in an official capacity in particular matters in which, to his knowledge, the employee has a financial interest. 18 U.S.C. § 208(a). Notably, the amount of any gain or loss is irrelevant in establishing a conflict of interest. *Id.* Additionally, ethical issues also arise when an agency’s actions are likely to affect the financial interests of an employee’s household. *See* U.S. DOJ, Department of Ethics Department, *available at*: <http://www.justice.gov/jmd/ethics/generalf.htm#27>.

The following, however, is a notable exception this statute regulating conflict of interest with regard to financial interests:

[I]f the officer or employee first advises the Government official responsible for appointment to his or her position of the nature and circumstances of the . . . particular matter and makes full disclosure of the financial interest and receives in advance a written determination made by such official that the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such officer or employee.

18 U.S.C. § 208(b)(1). Thus, if we do not want the “official responsible for appointment” to have this discretionary power to determine whether an employee’s financial interest is “so substantial” to affect one’s employment with the agency, we should add a supplemental regulation to our enabling act to dispose of this discretionary power or, at the very least, place it in the hands of more than one individual. This would ensure an additional check on any financial interests having an effect on this regulatory agency’s actions.

An additional criminal statute prevents former government employees from “switching sides” by placing a permanent ban on an individuals from representing clients or organizations before a federal department, agency, or court on certain matters in which the former employee participated personally or substantially while working for that government agency. 18 U.S.C. § 207. Additionally, the statue places a two-year ban on Government employees in representing individuals and organizations before the agency on matters that were pending during the employee’s supervision. 18 U.S.C. § 207(a)(2). It further restricts aiding or advising others postemployment when the employee had access to information that is exempt from disclosure for a period of one year after employment with the U.S. government. 18 U.S.C. § 207(b).

Punishment for conduct constituting violations of the aforementioned statutes includes possible criminal and civil penalties. 18 U.S.C. § 216(a). The Attorney General may bring action in the appropriate federal district court upon proof of such conduct by a preponderance of the evidence. *Id.* Whoever engages in such conduct may be fined and imprisoned for up to one year, while those who willfully engage in such conduct may be imprisoned for up to five years. *Id.* Notably, this statute does not “preclude any other criminal or civil statutory, common law, or administrative remedy, which is available” *Id.* Hence, we may impose additional penalties if we so desire.

Google Doc: Collaborative Effort to create Statutory Language pertaining to Conflict of Interest

§ X Conflict of Interest

Members of the commission and employees of the agency are declared to be in positions of public trust. In order to ensure the confidence of the people of the United States in the integrity of the agency, its employees, and the commission, the following restrictions shall apply:

(A) Acceptance of fees, commissions, gifts, or other considerations prohibited

No officer, attorney, or other employee of the agency shall, directly or indirectly, be the beneficiary of, receive or solicit any fee, commission, gift, or other consideration of monetary value for or in connection with any transaction or business under this chapter other than such salary, fee, or other compensation as she may receive as such officer, attorney, or employee of the agency.

(1) Notwithstanding any other provision of this statute, the following exceptions shall apply to the rule against acceptance of gifts:

- (a) Unsolicited gifts with a monetary value of \$20.00 or less;
- (b) Gifts clearly received on behalf of a familial or personal relationship;
- (c) Free attendance to an event or function at which the officer, attorney or employee is speaking or presenting on behalf of the agency; and
- (d) Gifts given as an award or honorary degree for work conducted on behalf of the agency.

(B) Acquisition of interest in a regulated entity by certain officers or employees of the Commission for GEEPs prohibited; 3-year period

Except as otherwise provided in this subsection, no officer or employee of the Agency who acts on or reviews applications, investigates or enforces regulations set forth under this statute may acquire, directly or indirectly, any financial interest in such regulated entity for a period of three years after the date on which such officer or employee ceases to be employed by the Commission.

(C) Prohibitions

(1) Any officer, attorney or employee of this agency, including but not limited to Commissioner, Commissioner member, Advisory Committee member, Inspector or Enforcer, shall not—

- (a) carry out any inspections of any operation in which such certifying agent, or employee of such certifying agent has, or has had, a financial interest, including the provision of consultancy services; or
- (b) accept payment, gifts, or favors of any kind from the business or entity inspected other than prescribed fees; or
- (c) be financially interested (directly or otherwise) in any business entity falling under regulation by GEEPs; or
- (d) be in the employment of, or accept gratuities from, any such entity; or
- (e) be engaged in any other kind of activity specified by regulation of the GEEPs Commission as involving a conflict of interest; provided, however, that the GEEPs Commission may by regulation provide exceptions to the restrictions of this section as the GEEPs Commission determines are consistent with the purposes of this section.

(2) Prohibition with respect to personnel of official or Federal agencies and business or governmental entities related to such agencies; substantial stockholder; use of official inspection service; authority delegation; report to Congressional committees

- (a) No official agency or a Federal agency delegated authority under this chapter, or any member, director, officer, or employee thereof, and no business or governmental entity related to any such agency, shall be employed in or otherwise engaged in, or directly or indirectly have any stock or other financial interest in, any business involving the commercial transportation, storage, merchandising, or other commercial handling of grain, or the use of official inspection service; and

no business or governmental entity conducting any such business, or any member, director, officer, or employee thereof, and no other business or governmental entity related to any such entity, shall operate or be employed by or directly or indirectly have any stock or other financial interest in, any official agency or a Federal agency delegated inspection authority. Further, no substantial stockholder in any incorporated official agency shall be employed in or otherwise engaged in, or be a substantial stockholder in any corporation conducting any such business, or directly or indirectly have any other kind of financial interest in any such business; and no substantial stockholder in any corporation conducting such a business shall operate or be employed by or be a substantial stockholder in, or directly or indirectly have any other kind of financial interest in, any official agency.

(b) A substantial stockholder of a corporation shall be any person holding 2 per centum or more, or one hundred shares or more, of the voting stock of the corporation, whichever is the lesser interest. Any entity shall be considered to be related to another entity if it owns or controls, or is owned or controlled by, such other entity, or both entities are owned or controlled by another entity.

(c) If a Federal governmental agency is delegated authority to perform official inspection, or a Federal governmental agency is designated as an official agency, the GEEPs Commission shall specify the officials and other personnel thereof to which the conflict of interest provisions of this subsection (2) apply.

(D) Penalties

(1) Any persons violating any provision of this section shall, upon conviction thereof, be punished by the following:

(a) Whoever engages in the conduct constituting the offense shall be imprisoned for not more than two years or fined in the amount set forth in this title, or both.

(b) Whoever willfully engages in the conduct constituting the offense shall be imprisoned for not more than five years or fined in the amount set forth in this title, or both.

(2) The Attorney General may bring a civil action in the appropriate United States district court against any person who engages in conduct constituting an offense under any provision of this section and, upon proof of such conduct by a preponderance of the evidence, such person shall be subject to a civil penalty of not more than \$200,000 for each violation or the amount of compensation which the person received or offered for the prohibited conduct, whichever amount is greater. The imposition of a civil penalty under this subsection does not preclude any other criminal or civil statutory, common law, or administrative remedy, which is available by law to the United States or any other person.

(3) If the Attorney General has reason to believe that a person is engaging in conduct constituting an offense under any provision of this section, the Attorney General may petition an appropriate United States district court for an order prohibiting that person from engaging in such conduct. The court may issue an order prohibiting that person

from engaging in such conduct if the court finds that the conduct constitutes such an offense. The filing of a petition under this section does not preclude any other remedy which is available by law to the United States or any other person.

(E) Review of Advisory Committee Members' Outside Interests

The Designated Federal Officer or alternate for each GEEPs advisory committee and the General Counsel or designee shall review the interests and affiliations of each member of the Designated Federal Officer's advisory committee annually, and upon the commencement of the member's appointment to the committee, for the purpose of ensuring that such appointment is consistent with the laws and regulations on conflict of interest applicable to that member.

(G) Nothing in this section prevents an individual from giving testimony under oath or from making statements required to be made under penalty of perjury.

(H) This section is to be considered supplemental to all other criminal or civil statutory, or common law regulations and penalties set forth under federal or state law including, but not limited to, the Standards of Ethical Conduct codified at 5 C.F.R. § 2635, and the following federal statutes: 18 U.S.C. §§ 203, 205, 207-09, as enforced under 18 U.S.C. § 216.

Our google doc discussion regarding extraterritoriality:

(KS) (a) It is the affirmative intention of Congress that this statute has extraterritorial effect.

(i) This Act therefore applies to, but is not limited to, all conduct by persons, companies, and entities occurring:

(A) within the United States;

(B) within Indian Country; and

(C) outside the United States but within the jurisdiction of the United States Federal Courts.

(ii) This Act gives Federal Courts extraterritorial jurisdiction over actions brought by GEEPS or by the United States for conduct in violation of, or constituting significant steps in furtherance of a violation of, this act, notwithstanding whether said conduct occurs within the territorial jurisdiction of the United States.

(Cam) (b) Any person, company, or entity that has suffered damages as a result of another person's, company's, or entity's violation of GEEPS either within the territorial jurisdiction of the United States or abroad, shall have the right to bring suit in the appropriate Federal Court of the United States.

(i) such person, company or entity bringing suit shall be entitled to a percentage reward as an "informant" under this Title in addition to damages.

(ii) if such person, company, or entity bringing suit is unable to prove damages, they may still be entitled to the reward as an "informant" under the Title if a violation of GEEPS is proven.

Notes – (KS)

***DO WE WANT TO CREATE A PRIVATE RIGHT OF ACTION, TOO?**

I posted this draft to the wiki since the formatting was messed up from my previous post. We can certainly amend it before tomorrow.

(Cam) I like the idea of private right of action because it could help get these companies to police themselves, especially if a the party bringing the action gets a cut of civil penalties as provided for under the “enforcement” section of the Wiki dealing with informants. I took a very amateurish hack at it above in green. What do y’all think?

(AS) I think both sections work well - In part (b) do we need to say “Any United states individual, company or entity that has suffered....”

Cam- what do you mean by “informant” do we need to define this in the statute?

(KS) I fear we may want to think more about the private right of action before throwing it on there, especially because this will be the final version before the midterm. Should we save that as a question/issue we can research and talk with Corrada about post-mid term?

First Draft of Advisory Committee/Offices Language sent to Kyler, 4/22

The Office of Congressional Affairs--

- (a) Advises the Chairman, the Commission, and GEEPS staff on all GEEPS relations with Congress and the views of Congress toward GEEPS policies, plans and activities;
- (b) Maintains liaison with Congressional committees and members of Congress on matters of interest to GEEPS;
- (c) Serves as primary contact point for all GEEPS communications with Congress;
- (d) Coordinates GEEPS internal activities with Congress;
- (e) Plans, develops, and manages GEEPS' legislative programs; and
- (f) Monitors legislative proposals, bills, and hearings.

The Office of Administration--

- (a) Develops and implements agency-wide contracting policies and procedures;
- (b) Develops policies and procedures and manages the operation and maintenance of GEEPS offices, facilities, and equipment;
- (c) Plans, develops, establishes, and administers policies, standards, and procedures for the overall GEEPS security program; and
- (d) Develops and implements policies and procedures for the review and publication of GEEPS rulemakings, and ensures compliance with the Regulatory Flexibility Act and the Congressional Review Act and provides translation services.

ADVISORY COMMITTEES:

(A) This provision grants the GEEPS Commission the power, in accordance with The Federal Advisory Committee Act (5 U.S.C.A. Appx. 2 §§ 1 et seq.) (FACA), to establish advisory bodies, within the purview of GEEPS' regulatory responsibilities, to provide advice, make recommendations, and render expert opinions as requested by the Commission, inter-agency departments, and GEEPS staff.

(i) Advisory Committees shall consist of a maximum of fifteen members appointed by the Commission for terms of four years each.

(ii) One member shall be designated by the Committee as its Chairman.

(iii) The members of the Committee shall receive a per diem compensation for each day spent in meetings or conferences, or other work of the Committee, and all members shall receive their necessary traveling or other expenses while engaged in the work of the Committee.

(iv) The members of the General Advisory Committees established may serve as such without regard to the provisions of section 281, 283, or 284 of title 18 of the United States Code, except insofar as such sections may prohibit any such member from receiving compensation from a source other than a non profit educational institution.

(B) There is hereby established an Advisory Committee on Construction Licensing Review. The Committee shall provide expert opinion on the design, geographic location, development, and operation of facilities seeking or currently in possession of license(s) issued by GEEPS. The Committee shall review safety studies and facility license applications referred to it and shall make reports thereon, shall advise the GEEPS Commission and other GEEPS staff with regard to the hazards of proposed or existing facilities and the adequacy of proposed safety standards, and shall perform such other duties as the Commission or other inter-agency departments may request.

(C) There is hereby established an Advisory Committee on rDNA Licensing Review. The Committee shall provide expert opinion on the design, development, and operation of rDNA research and experimentation requiring licensure under GEEPS regulatory scheme. The Committee shall review safety studies and license applications referred to it and shall make reports thereon, shall advise the GEEPS Commission and other GEEPS staff with regard to the hazards of proposed or existing experimentation with rDNA and the adequacy of proposed safety standards, and shall perform such other duties as the GEEPS Commission or other inter-agency departments may request.

(D) There is hereby established an Advisory Committee on International and Indigenous Programs. The Committee shall advise the Commission, the Chairman and GEEPS staff on pertinent international issues, recommend policies concerning GEEPS exports and imports, international safeguards, international physical security, and international cooperation and assistance in safety and protection. Additionally, the Committee shall

(a) Plan, develop, and manage international genetically extinct prehistoric species safety information exchange programs and coordinate international research agreements;

- (b) Obtain, evaluate, and use pertinent information from other GEEPS and U.S. Government offices in providing opinions on GEEPS export and license applications;
- (c) Establish and maintain working relationships with individual countries and international GEEPS organizations, as well as other involved U.S. Government agencies;
- (d) Assure that all international activities carried out by the GEEPS Commission and staff are well coordinated internally, Government-wide and internationally and are consistent with GEEPS, U.S. policies and international customs; and
- (e) Ensure that international activities carried out by GEEPS will, to the furthest extent possible, uphold the rights of Indigenous peoples as recognized by international human rights law and custom.

(E) There is hereby established an Advisory Committee on the Security and Containment of GEEPS. The Committee shall advise and render expert opinions on the materials, design, power resources, engineering and the development behind containment of GEEPS in all stages of reproduction involving rDNA of GEEPS. Additional details regarding this Committee will be provided in the regulations.

(F) There is hereby established an Advisory Committee on Animal Health. This Committee shall provide the Commission with advice regarding the treatment of GEEPS, including, but not limited to the birth of GEEPS, proper procedures when a GEEPS suffers an illness, use of euthanasia, feeding, care, treatment, and transportation of GEEPS.

(G) There is hereby established an Advisory Committee on the Protocol of Emergency GEEPS Procedures, facility shutdowns, and emergency medical procedures for humans injured by GEEPS. Additional details regarding this Committee will be provided in the regulations.

(H) There is hereby established an Advisory Committee on GEEPS waste management. The Committee shall provide advice and render expert opinions on all aspects of GEEPS waste management, within the purview of GEEPS' regulatory responsibilities. The primary emphasis of the Committee is disposal of, but will also include other aspects of GEEPS waste management such as handling, processing, transportation, storage, and safeguarding GEEPS waste. In performing its work, the Committee examines and reports on specific areas of concern referred to it by the GEEPS Commission or a designated representative of the GEEPS Commission, and undertakes studies and activities on its own initiative as appropriate to carry out its responsibilities.

(I) There is hereby established an Advisory Committee on Facility Placement. The Committee shall consider geographic placement, geological effects, and environmental impact of GEEPS and GEEPS facilities. This Committee shall provide the Commission with advice and expert opinions on appropriate geographical locations to establish facilities regulated by GEEPS, the geological effects of GEEPS, and the environmental impact of GEEPS on the natural habitat.

(J) There is hereby established an Advisory Committee on Emergency Medical Services. The Committee shall take into consideration the access and routes available for medical care in the event of injury to facility staff or patrons. The Committee shall collaborate with the Advisory Committee on Emergency GEEPS Procedures and the Advisory Committee on geographic placement before making recommendations to the Committee.

(K) There is hereby established an Advisory Committee on the Reproduction of GEEPS. This Committee shall advise the Commission on reproduction of GEEPS, including proper methods of reproduction. Additional details regarding this Committee will be provided in the regulations.

(L) There is hereby established an Advisory Committee on Prehistoric Species. The Committee shall advise the Commission on the different prehistoric species, including, but not limited to the species size, weight, predator status, and natural aggression tendencies. Additional details regarding this Committee will be provided in the regulations.

