



from Amersham, leading some to suspect the accused intended to use the saponin in an attempt to weaponize the ricin.<sup>1</sup>

In the spring of 2005, the U.S. Commerce Department announced that EMD Biosciences, Inc. of San Diego, California had paid a civil penalty of more than \$900,000 for 67 shipments of biotoxins to Canada without the appropriate export licenses. The company had apparently missed an obscure change to the export regulations which added Canada to the list of countries for which a license was required for the export of such materials.<sup>2</sup>

These two seemingly different events actually do have a common element: they both relate to internal controls programs intended to ensure compliance with government export controls and to prevent the transfer of dangerous things to dangerous people. In today's environment of significant risk from small groups of bio- and chemical-terrorists, robust internal controls programs are increasingly necessary to protect biosciences companies from both government fines and possible criminal charges for export control violations, and from the potential liability arising from an incident where the company's product is used in a terrorist attack.

In order to be effective in mitigating the risks presented by both the Amersham and EMD situations, an internal controls program must do a number of things well:

- it must ensure that no product moves in international commerce without appropriate governmental authorizations;
- it must ensure that no sensitive technical data or know-how are released into international commerce or made available to foreign nationals who are in the United States without appropriate government authorizations;
- it must screen all customers, suppliers, and business partners against the

multitude of government lists of terrorists, drug traffickers, agents of governments designated as State Sponsors of Terrorism, and parties that have been penalized for violating U.S. export controls; and

- it must identify plausible misuses of the company's products so the company recognizes orders that simply don't make sense.

What follows is a brief description of the principal U.S. regulations that directly affect the international and domestic business model of biotech companies. It should be noted that although this discussion is limited to U.S. export controls, many other countries have similar regulations in place,<sup>3</sup> and many more will follow.<sup>4</sup>

### **U.S. Restrictions On Transfers Of Goods, Software, And Technology**

The principal U.S. export control regulations affecting biotech companies are:

- Export Administration Regulations ("EAR" – 15 C.F.R. Parts 730-774), administered by the Department of Commerce, Bureau of Industry and Security ("BIS"). These regulations control all items<sup>5</sup> of U.S. origin and certain foreign produced items with a defined amount of U.S. content. The EAR impose particular restrictions on dual-use items: those with both a commercial utility and a military utility. The EAR also treat the transfer of technical data to foreign nationals, who are not permanent resident aliens, located within the U.S., as an export to

---

<sup>1</sup> "Terror plot reportedly thwarted," [http://www.usatoday.com/news/world/2003-11-22-terror-plot\\_x.htm](http://www.usatoday.com/news/world/2003-11-22-terror-plot_x.htm).

<sup>2</sup> "California Biotech Firm Settles Charges of Unlicensed Exports of Biological Toxins," <http://www.bis.doc.gov/News/2005/EMDBiosciences.htm>.

---

<sup>3</sup> This includes, but is not limited to, all the members of the European Union, Canada, Australia, Japan, New Zealand, and Hong Kong.

<sup>4</sup> United Nations Security Council Resolution 1540 (April 28, 2004) requires all member states to implement export controls to combat the proliferation of nuclear, chemical and biological weapons and their delivery systems. (See <http://daccessdds.un.org/doc/UNDOC/GEN/No4/328/43/PDF/No432843.pdf?OpenElement>).

<sup>5</sup> For the purposes of this article, the term "item" is intended to include products, software, and technical data.

the home country of that individual. This "deemed export" rule can be a particular compliance problem for high-tech companies with a multinational workforce. Penalties for violations of the EAR can be criminal and civil (strict liability) and include a denial of export privileges.

- International Traffic in Arms Regulations ("ITAR" – 22 C.F.R. §§ 120-130), administered by the Department of State, Directorate of Defense Trade Controls ("DDTC"). The ITAR control munitions items: weapons systems, weapons platforms, and any item that has been specially designed or modified for a military purpose.<sup>1</sup> Like the EAR, the ITAR also control foreign items with ITAR-controlled content; but unlike the EAR, the ITAR set no de minimis level for that content. Thus a foreign item containing any ITAR content, regardless of value, is subject to U.S. regulation. The ITAR also control technology transfers to foreign nationals, who are not permanent resident aliens, within the U.S. Penalties can be criminal and civil (strict liability) and can include debarment from government contracting.
- U.S. Economic Embargo Regulations (31 C.F.R. Parts 500-597), administered by the Treasury Department, Office of Foreign Assets Control ("OFAC"). The OFAC regulations implement the various U.S. economic embargoes (principally those against Cuba, Iran, Sudan, and Burma). They also impose prohibitions on dealing with designated terrorists and drug traffickers, and they prohibit the support of the proliferation of weapons of mass destruction and their delivery systems. Unlike the EAR and ITAR, the OFAC regulations do not address products or software directly; rather they prohibit "U.S. persons"<sup>2</sup>

---

<sup>1</sup> The "specially designed or modified" reach of the ITAR is comprehensive; even the slightest modification to a civil product, e.g., a change in color, to meet a military requirement will subject the item to ITAR control.

<sup>2</sup> Generally "U.S. person" is defined as a U.S. national or permanent resident alien, a U.S. corporation or any of its (continued...)

from engaging in certain types of transactions, including financial transactions and the export from any location of any form of service (financial or technical). Penalties can be criminal and civil (strict liability).

While both the EAR and the ITAR reach U.S. and foreign items, they do so in very different ways. The EAR contain a detailed list of products, software, and technology subject to licensing requirements. The more sophisticated the item, the longer the list of countries for which export requires a license. Some items require a license for export even to our closest allies, including the United Kingdom. Many of these very restricted items are chemicals, microorganisms, and toxins with a chemical or biological weapons use, items useful in the production of ballistic missiles and certain kinds of design and manufacturing technical data and know-how.<sup>3</sup> The Commerce Control List ("CCL")<sup>4</sup> contains ten categories of dual-use items. The most important for the biotech industry is Category 1 – Materials, Chemicals, Microorganisms and Toxins, which lists specific materials, production and test equipment, software, and technical data restricted for export. Not every export (or domestic transfer of technical data to foreign nationals) requires a license; the countries for which a license is required are identified in each entry in the CCL.

---

foreign branch offices, or anyone present in the U.S. The general definition specifically does not include the controlled foreign subsidiaries of U.S. corporations. The regulations implementing the embargo on Cuba, however, contain a different definition: they include any foreign entity owned or controlled by U.S. persons (31 C.F.R. § 515.330). Thus, the Cuba regulations reach the foreign subsidiaries of U.S. corporations, as well as joint ventures where a majority of the members of the board of directors are U.S. persons. The extraterritorial reach of the U.S. Cuba embargo has led Canada, the members of the European Union, and Mexico to enact blocking statutes which prohibit their domestic corporations from complying with the U.S. regulations.

<sup>3</sup> As a general proposition, technology is controlled more tightly than are products. This regulatory philosophy seems to originate in an old Cold War adage: if you sell your enemy products, you control your enemy; if you teach your enemy how to make those products, your enemy controls you.

<sup>4</sup> EAR Part 774.

The ITAR, on the other hand, do not provide specific technical descriptions of controlled items, rather items are listed in broad categories such as Category XIV – Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment. While Category XIV controls chemical and biological agents, it provides no prescriptive list of the items controlled. It provides an illustrative list of chemical agents, but no list of biological agents.<sup>1</sup>

An additional significant difference is that the ITAR contain no list of countries for which licenses are required: licenses are required for all transfers of ITAR-controlled items.<sup>2</sup> Thus all foreign-national employees who are not permanent residents, regardless of location, must be excluded from access to data systems and files containing ITAR-controlled technical data.

So what does all this mean?

It means that high-tech companies need to be aware of which of their products, software, and technology are controlled and under which set of regulations. This involves classifying all items under the various categories of the EAR. It means tracking customer-required design changes to identify those that are requested to meet a military requirement. These requests tend to come from defense contractors and their sub-tier suppliers, agencies of the Department of Defense, and the uniformed military. Any such change will most likely subject the modified item to ITAR controls and the resulting world-wide licensing requirements. It means identifying the

control status of all government-funded research before any activities are undertaken. The Defense Advanced Research Projects Agency ("DARPA") funds a significant amount of research in chem-bio terrorism. It would be advisable to treat all such research as ITAR controlled unless and until the funding agency, with the formal concurrence of DDTC, pronounces the research as civil, and therefore, subject to the EAR.<sup>3</sup>

Once a company has classified all of its products, components, software, and technology and identified the licensing requirements for all transfers, including domestic transfers, of technical data, it needs to develop its internal controls system. The greatest exposure for high-tech companies lies in their IT systems and the domestic transfer of controlled technical data to foreign nationals. The EAR, the ITAR, and their respective regulators take similar, but slightly different, positions with regard to the deemed export problem. The EAR restrict the release of technical data to foreign nationals. The EAR consider release to include visual inspection by foreign nationals and oral exchanges of information.<sup>4</sup> The ITAR restrict the furnishing of controlled technical data to foreign nationals. Furnishing is not a defined term, but DDTC takes the position that allowing a foreign

---

<sup>1</sup> Category XIV contains the following definition: "The biological agents or biologically derived substances in paragraph (b) of this category are those agents and substances capable of producing casualties in humans or livestock, degrading equipment or damaging crops and which have been modified for the specific purpose of increasing such effects. Examples of such modifications include increasing resistance to UV radiation or improving dissemination characteristics. This does not include modifications made only for civil applications (*e.g.* medical or environmental use)."

<sup>2</sup> The ITAR contain a few exceptions to this general rule, including very limited exceptions for exports to Canada. Most of these exceptions do not apply to many of the items controlled under Category XIV.

---

<sup>3</sup> Most such research and related equipment is probably already controlled under the ITAR. Category XIV specifically controls, among other things, (1) equipment for the testing identification, warning, monitoring, collection, processing individual protection, collective protection, decontamination, or remediation of chemical and biological agents; (2) antibodies, polynucleotides, biopolymers, or biocatalysts specifically designed or modified for use with the above-listed equipment; and (3) medical countermeasures, including pre- and post-treatments, vaccines, antidotes and medical diagnostics, specifically designed or modified for use with chemical agents and vaccines with the sole purpose of protecting against biological agents.

<sup>4</sup> This can get complicated because the EAR control technology for the use of equipment used in the production of certain chemicals, toxic gas monitoring systems, and equipment for the handling of certain biological materials. (See EAR Part 774 2E301).

national access to a data-rich environment constitutes furnishing.<sup>1</sup>

A final note on the export control exposure from technical data: any U.S. content in technology developed at offshore R&D centers may subject the foreign-origin technology to U.S. control. In other words, locating R&D facilities offshore will not necessarily isolate a company from the U.S. regulations. Neither the EAR nor the ITAR provide clear guidance on the nature or source of the U.S. content. It would therefore be prudent to consider any involvement by U.S. nationals or U.S. permanent resident aliens in an offshore research project, even if those individuals are not physically present in the U.S., as raising export control issues. As mentioned above, if any of the U.S. content is ITAR-controlled, then all of the foreign-origin technology would be tainted and subject to U.S. munitions licensing requirements. While the EAR contain de minimis thresholds which must be exceeded before the foreign technology would be controlled, the regulations provide no methodology for calculating the value of the U.S. content. Furthermore, the EAR require that all such calculations be expressly approved by BIS before the de minimis exception may be used for technology.

### **Elements Of An Internal Controls System**

These complex regulations reach virtually every aspect of a high-tech business model. In order to remain compliant, a comprehensive, robust internal controls program ("ICP") needs to be developed and implemented. The ICP should be risk-based and tailored to the particular business model of the company. The following are suggested elements of an effective ICP for a company with EAR- or ITAR-controlled product, software and technology. They are drawn in part from the elements of an effective compliance program as defined in the 2005 Federal Sentencing

---

<sup>1</sup> Indeed, DDTC recently charged General Motors with multiple violations of the ITAR for allowing foreign nationals theoretical access to electronic data files containing controlled technical data. The agency did not allege that GM's foreign employees actually gained access to the files, rather, the charges were based on the fact that the files were not protected to prevent unauthorized foreign national access.

Guidelines.<sup>2</sup> The list is comprehensive and addresses all export control risks, including those not specifically addressed in this article:

- Develop written policies and procedures; create a culture of compliance.
- Monitor and periodically audit compliance with ICP.
- Conduct periodic self-assessment of risk and audit results.
- Adopt appropriate incentive and disincentives to encourage compliance by employees.
- Establish internal mechanism for employees to communicate compliance concerns.
- Train and periodically refresh all employees on internal compliance program.
- Train and periodically refresh employees requiring expert level compliance training.
- Designate a single process owner to manage the ICP; staff appropriately.
- Designate an internal legal resource to support the process owner.
- Screen all transactions and business relationships for countries of concern.
- Screen all transactions and business relationships for involvement of individuals or entities subject to sanctions.
- Screen all transactions for possible nuclear, chemical, or biological weapons or ballistic missile connections.
- Classify all products (including spares), product design and development technology, product manufacturing technology, and product design and manufacturing software according to the EAR, ITAR, or other applicable local regulations – don't forget foreign export controls.

---

<sup>2</sup> See the United States Sentencing Commission website at <http://www.ussc.gov/>.

- Determine whether licenses are required for exports of product, spares, software, or technical data – identify countries for which licenses are required – ensure processes in place to prevent exports/transfers without appropriate authorizations.
- Ensure the global engineering enterprise is aware of applicable trade controls, both dual-use and sanctions. Ensure processes are in place to prevent transfers of technical data without appropriate authorizations.
- Ensure the global sourcing enterprise (supply chain) is aware of applicable trade controls, both dual-use and sanctions. Ensure processes are in place to prevent transfers of technical data without appropriate authorizations.
- If business has controlled technical data, coordinate with HR to identify all employees who are not either U.S. nationals or permanent resident aliens; ensure processes are in place to prevent transfers of or access to technical data within the U.S. without appropriate authorizations.
- Implement foreign visitors control program.
- Ensure all servers with trade controlled technical data are appropriately protected – file protection, system administrators are U.S. nationals, and all technical support/service is performed by U.S. nationals.
- Review all business operating processes and procedures for involvement of U.S. persons in transactions involving embargoed destinations.
- Ensure Internet marketing channel appropriately protected – screen all users at the transaction level and limit use of wizards or other technical services without appropriate screening.
- Ensure subsidiaries in Canada, the EU, and Mexico have mechanisms in place to address local blocking statutes.
- Conduct comprehensive compliance audit of all new acquisitions within 30 days of closing.

- Monitor changes to regulations and keep processes current.
- Review all business transaction documentation associated with government procurement at time of receipt for compliance with U.S. anti-boycott regulations.

The process of developing and managing an effective internal controls program can be challenging and expensive. In assessing the value of such an investment, however, corporate management needs to consider a number of related factors:

- 1) The cost of internal investigations of alleged violations can easily exceed any potential monetary fines, sometimes by several orders of magnitude;
- 2) The tort exposure from the failure to identify a problem customer (e.g., one with terrorist connections that appears on a published government list) could be almost unlimited; and
- 3) The reputational risk associated with any alleged violation could be significant; these regulations are maintained to protect U.S. national security and they are increasingly seen as a major tool in its war against terrorism.

*Bill Clements is a Partner in the Washington, DC office of Foley & Lardner LLP. He specializes in compliance issues related to U.S. international trade controls and the Foreign Corrupt Practices Act. He agreed to write this article as a follow-up to a presentation he made at the Biotechnology Committee's annual meeting in Chicago in August 2005.*

---

## **Evaluating the Case Against Pet Cloning**

**Autumn Fiester, PHD**

The cause that opponents of pet cloning support is indisputably a worthy one: namely, the protection of animal welfare. And because this type of animal cloning appears, at least at

first glance, to have no noble ends,<sup>1</sup> the public and most animal ethicists have been content to let the cause, rather than the arguments, carry the day. There is an overwhelmingly negative view of companion animal cloning among the lay public, animal advocacy organizations, and professional ethicists. But how sound are their arguments against pet cloning? Can they withstand careful scrutiny?

There are three ethical objections given by pet cloning opponents: 1) the plight of unwanted animals; 2) the exploitation of grieving clients; and 3) the suffering of the animals involved in the cloning process (the donors, the surrogates, and the clones). An analysis of the various arguments given by opponents of pet cloning shows, however, that only one argument can survive critical reflection, and that argument – the concern about the suffering of the actual clones – is the issue on which the moral justification of pet cloning hinges and around which the moral debate ought to be focused.

Let's start with the plight of unwanted animals. The US pet overpopulation problem has been cited repeatedly as a central objection to companion animal cloning. For example, the animal advocacy organization American Anti-Vivisection Society writes, "While pet cloning firms currently are charging customers up to \$50,000 for a cloned cat and as much as \$2,995 to 'bank' a dog's or cat's DNA for future cloning, millions of homeless animals of the same species are available in US shelters for a round \$100, which is used to cover costs. However, most animals in shelters are euthanized for lack of adopting homes."<sup>2</sup> Says Humane Society President Wayne Pacelle, "The Humane Society of the United States opposes pet cloning because it is dangerous for the animals involved, it serves no compelling social purpose, and it threatens to add to the pet overpopulation problem. It doesn't sit well with us to create animals through such extreme and experimental means when there are so many animals desperate for

homes."<sup>3</sup> Bioethicists agree. David Magnus, Director of the Stanford Center for Biomedical Ethics, argues, "The idea that somebody would spend \$50,000 for a cat when they can go to any shelter and rescue one is absurd."<sup>4</sup>

What these arguments certainly get right is the staggering problem of unwanted animals in the United States. The National Council on Pet Population Study and Policy found that in 1997 alone, 2,329,978 dogs and 1,759,743 cats entered shelters, and between 50-70% of these animals were euthanized.<sup>5</sup> By ASPCA estimates, 8-12 million companion animals enter shelters, and 60-70% are euthanized.<sup>6</sup> A similar number is cited in the 2001 Humane Society report on the state of animals in the US. According to that report, 4-6 million dogs and cats were euthanized in shelters in 2001.<sup>7</sup> These figures do not include the millions of stray animals in the country: the ASPCA estimates that 70 million stray dogs and cats live in the US.<sup>8</sup>

The connection between the pet overpopulation problem and pet cloning seems obvious: there are many wonderful pets ready to adopt, and adopting instead of cloning saves one animal from euthanasia; therefore, one ought to adopt rather than clone. When we add to that argument the fact that each cat clone currently costs \$30,000, which – if redistributed – could save thousands of animal lives, we appear to come to the conclusion that the money ought to be donated to shelters rather than devoted to the purchase of just one animal. But there is a serious problem with this argument against companion animal cloning. If we interpret the

---

<sup>1</sup> I have argued elsewhere about the potential benefits to companion animals in general. Fiester, "Creating Fido's Twin: Is There Moral Legitimacy in Pet Cloning?," Hastings Center Report, 35, No. 4, 2005, pp. 34-39.

<sup>2</sup> AAVS, Pet Cloning: Separating Facts from Fluff (February 16, 2005).

---

<sup>3</sup> HSUS, "Cat Cloning is Wrong-Headed States the Humane Society of the United States" (February 14, 2002), available at: <http://hsus.org/ace/13214>.

<sup>4</sup> P. Fimrite, "Cat Has 10 Lives, Thanks to \$50,000 Cloning," *San Francisco Chronicle* (December 23, 2004).

<sup>5</sup> National Council on Pet Population Study and Policy, "Shelters Statistics Survey," 1994-7, available at: <http://www.petpopulation.org/statsurvey.html>.

<sup>6</sup> ASPCA, "Annual Shelter Statistics," available at <http://www.aspc.org>.

<sup>7</sup> P.G. Irwin, "Overview: The State of Animals in 2001," in *The State of Animals 2001* (D.J. Salem and A.N. Rowan, eds) (Washington, DC: Humane Society Press, 2001).

<sup>8</sup> ASPCA, "Annual Shelter Statistics," available at <http://www.aspc.org>.

above argument as the claim, "There are too many cats in the world, therefore we shouldn't be cloning more," then the flaw in the argument might be called the "Hangnail vs. Hemorrhage" problem. In terms of cat "production," cloning represents a tiny hangnail, while we're currently hemorrhaging to death from intentional and unintentional breeding. According to the Humane Society of United States, there are currently 77 million cats owned in US households, and only 11.5 million were adopted from shelters.<sup>1</sup> In other words, 66 million cats were either purchased from breeders or bred by owners (again, either because they wanted to breed their cats, or because they didn't spay or neuter them). To date: there have been 6 cats cloned. If there are too many cats in the world, and the quantity needs to be reduced to cure the unwanted animal problem, then we should focus on breeders and owners who don't spay. After we have made a significant impact on the main source of the problem, then we can focus on the trivial contributors to the companion animal numbers.

One additional irony of this argument against companion animal cloning is that the only firm currently cloning cats commercially buys its donor eggs in the form of ovaries that have been procured at spay clinics. The money that those spay clinics receive for the ovaries is used to spay other cats. So, at least while pet cloning production remains extremely low, a pet cloning firm that indirectly supports the spaying of cats from this method of egg procurement reduces the future pet population

The second objection to pet cloning fares no better, namely, the exploitation of grieving clients. On this argument, opponents argue that buying a clone necessarily means being deceived because without deceived clients there wouldn't be clients. The idea here is that it is irrational to want to have a later-born genetic twin of a beloved pet, and if a client had an accurate understanding of what cloning was, he or she wouldn't want one. For example, Lawrence Hinman, Director of the Values Institute, University of San Diego, argues, "We can produce a genetically identical copy of our pet, but we delude ourselves if we think we have somehow accomplished something by the

substitution."<sup>2</sup> But this is not true. For pet owners, cloning a pet is an expression of profound grief and loss of intrinsically valuable entity; therefore, having the identical twin of beloved animal is closest they can come to having some part of that animal "live on." There is nothing irrational about this.

That leaves opponents with only one remaining objection: the suffering of animals involved in the process. But there are problems here as well. Opponents cite three groups of animals that suffer in the process of pet cloning: the donors, the surrogates, and the clones. But the only firm cloning pets to date uses eggs procured from spay clinics, so there is no suffering of the donors – their owners had their ovaries removed to prevent future pregnancies (a cause pet cloning opponents fully embrace), so no procedure was performed on these animals for the enterprise of pet cloning. As for the surrogates, again in current practice, they are adopted after one pregnancy, so their suffering is equivalent to what a human woman goes through in a successful cycle of in vitro, but then they are adopted into homes. This turns out to be, then, the equivalent of feline kidney transplant, to which no one seems to raise objections.

That leaves the health status of the clones, and here the opponents raise a serious moral issue. The public does not have access to the data about the number of stillbirths and early neonatal losses in this process, and there certainly are no long-term data on the health status and long-term outcomes for the actual clones. Here is where the opponents should focus their energy in making sure that these legitimate animal welfare concerns are addressed.

*Dr. Fiester is a senior fellow at the University of Pennsylvania Center for Bioethics. She specializes in the ethics of animal cloning. She agreed to write this essay for the Biotechnology Committee as follow-up to the presentation she gave at a program on pet cloning sponsored by the Section of Science & Technology at the annual meeting in August 2005.*

---

<sup>1</sup> HSUS, available at <http://www.hsus.org>.

---

<sup>2</sup> L.M. Hinman, "Rover is Not Replaceable – Forget Cloning," *Los Angeles Times* (August 28, 2004).



---

## **State Funding of Embryonic Stem Cell Research: Is Florida Next?**

**Julie Fleming Brown**

In 2006, Florida may provide funding for embryonic stem cell research either through a constitutional amendment or through legislation. The campaign to get a constitutional amendment on the ballot was started by Burt Aaronson, a commissioner for Palm Beach County, where the first satellite branch of the Scripps Research Institute will open in the summer of 2006. Funded by a \$310 million commitment by the state and a \$200 million pledge by Palm Beach County, the location of the new Scripps Institute is expected to kick off a wave of life sciences development in Florida. And as if the Scripps Institute isn't enough to put Florida on the life sciences map, the group Floridians for Stem Cell Research and Cures is determined to encourage embryonic stem cell research.

The proposed constitutional amendment would provide \$200 million in funding for stem cell research over the next ten years. The amendment would provide that "the Department of Health shall make grants for embryonic stem-cell research using, or using the derivatives of, human embryos that, before or after formation, have been donated to medicine under donor instructions forbidding intrauterine embryo transfer." Scientific experts would evaluate grant applications, which would be awarded to universities and nonprofit organizations with money from the state's general fund. Notably, the provision specifies that the embryos used in such research would be donated with instructions that would prevent them from being implanted; in other words, the research would be accomplished only with cells that would never have the possibility of maturing into fetuses or live-born human beings.

Supporters of the proposed amendment seek to avoid the problems that have beset California's stem cell research efforts, which started with the passage of Proposition 71. The California Institute for Regenerative Medicine, a state agency created by Proposition 71, has been tasked with granting \$3 billion for stem cell research over the next ten years. The Institute has been unable to make the anticipated grants, however, because a lawsuit challenging the

constitutionality of the referendum has made it impossible for the state to sell the long-term bonds intended to fund the grants. The lawsuit, filed by lawyers at the Life Legal Defense Foundation, claims that the Institute's finances are not under "exclusive state control" as required by the California Constitution. A trial is expected to begin in that case on February 27, and the ability of the fruition of Proposition 71 hangs in the balance. Proponents of the Florida amendment suggest that a similar challenge in Florida would be fatal because of the specified oversight by the Department of Health, which necessarily means that Florida would exercise control over the grants made from the state's general fund.

In a state governed by Jeb Bush, President Bush's brother, embryonic stem cell research is controversial, and Governor Bush has publicly opposed the technology on the grounds that the destruction of the blastocyst constitutes destruction of human life. Florida permits ballot initiatives to amend the state constitution. An initiative will be placed on the November ballot if supporters gather 600,000 petition signatures by the end of the preceding calendar year. "When the governor says that he will not support it, there's only one way to do it - get it in the constitution," Aaronson said. At the time this essay was written, it was not clear whether supporters would gather the 600,000 signatures required by the end of 2005, in order for the measure to appear on the ballot on November 6, 2006. Petition signatures are valid for four years, however, and proponents have promised to continue their campaign forward if they're unsuccessful in 2005.

Following Aaronson's efforts - and notwithstanding Gov. Bush's opposition to stem cell research - two Florida legislators announced a plan to introduce the Florida Better Quality of Life and Biomedical Research Act, which would provide \$15 million a year for 10 years in state seed money for embryonic and adult stem-cell research. Aaronson supports this initiative, calling it "good government" to address stem cells in legislation rather than through a constitutional amendment, though he continues to view his previously-announced efforts as a viable approach should the legislation not be enacted. The proposed act would place ultimate financial and oversight decisions in the hands of the Secretary of the state Department of Health. The Act would also focus on ethical issues by prohibiting the sale of

embryos for research, requiring that the embryos used in research would instead be donated from "left overs" from in vitro fertilization efforts. Finally, the Act would outlaw reproductive cloning and make it a second-degree felony.

Whether through legislation or through a constitutional amendment, Florida's aging population could be the key to unlocking funding for embryonic stem cell research, which promises treatment and cures for ailments like Alzheimer's disease and Parkinson's disease, and Floridians for Stem Cell Research and Cures believes that public support in South Florida is strong, leaving the more conservative, Northern part of the state to be persuaded.

But South Florida is also home to the group Citizens for Science and Ethics, which "seeks to protect Floridians from the additional tax burden of state imposed funding for embryonic stem cell research, while allowing fruitful stem cell research to continue unencumbered. . . . [and to promote] ethical guidelines that ensure that no revenues of the state shall be spent on experimentation that involves the destruction of a live human embryo through a constitutional amendment ballot initiative." Offering research based on adult stem cells, umbilical cord blood stem cells, and placental-derived stem cells as an alternative to embryonic stem cell research, the Citizens for Science and Ethics are sponsoring a drive to get the requisite number of signatures to support a ballot initiative for a constitutional amendment prohibiting state-funded research "that involves the destruction of a live human embryo."

Bernard Siegel, President of the Genetics Policy Institute, supports the Floridians for Stem Cell Research and Cures and contacted Aaronson to offer his scientific knowledge on the topic. Siegel, an attorney, is perhaps best known in the field for his 2002 petition to the Broward County Circuit Court, seeking protective custody of "Eve," the human being allegedly cloned by the Raelian group Clonaid. Through that effort, which Siegel has described as an opportunity to "make a footnote in some law journal," Seigel met a number of scientists who urged him to speak on behalf of legitimate science. He formed the Genetics Policy Institute in 2003, with the support of scientists like Gerald Schatten, a University of Pittsburgh School of Medicine professor who collaborated on human cell cloning research with Korean scientist Hwang Woo-Suk. (Interestingly, both Schatten and

Hwang have come under fire following a claim that Hwang falsified his landmark success in cloning embryonic cells for stem cell research. Hwang denies those charges, though he has admitted that two women in his lab had donated eggs for the research and that other donors had been paid. Schatten terminated his work with Hwang, stating his concern over those ethical lapses, but Schatten has also been accused as an accomplice in Hwang's falsified research reports. A full discussion of this controversy is outside the scope of this discussion, but the outcome of the investigations that will follow the accusations will be interesting, as will the impact on the public's enthusiasm for stem cell research if Hwang's much-publicized success is pierced.) The Institute has sponsored numerous stem cell conferences, including one at the United Nations designed to educate members about the distinctions between reproductive and therapeutic cloning.

The Florida struggle between proponents and opponents of stem cell research is interesting not only on its own merit, but also in the context of the nationwide debate. Following Senator Bill Frist's announcement that he would support legislation to reverse the restrictions imposed by President Bush on federal funding for embryonic stem cell research, and particularly through involvement by celebrities such as Nancy Reagan, Christopher Reeve, and Michael J. Fox, those in favor of stem cell research and those opposed to it have become more vocal and more determined to sway the law in their favor. It remains to be seen what the outcome will be in Florida, but it is certain that the national backers for the two opposing camps will be watching closely to learn lessons on the public's acceptance of embryonic stem cell research and advocates' ability to influence that acceptance through legal, ethical, moral, and scientific arguments.

*Julie Fleming Brown is a patent litigator who has practiced most recently in Orlando, Florida.*

---

## **Committee Leadership**

### **Chair**

Erika Lietzan  
Covington & Burling  
1201 Pennsylvania Ave, NW  
Washington, DC 20004  
Phone: (202) 662 5165  
Fax: (202) 778 5165  
elietzan@cov.com

### **Vice Chair**

Steve Hall  
Stoll Keenon Ogden, PLLC  
1700 PNC Plaza  
Louisville, Kentucky 40202  
United States of America  
Phone: (502) 560 4250  
Fax: (502) 627 8750  
steve.hall@skofirm.com

### **Vice Chair**

Dan Pancamo  
Phelps Dunbar, L.L.P.  
365 Canal Street, Suite 2000  
New Orleans, LA 70130-6534  
Phone: (713) 626 1386  
Fax: (713) 626 1388  
pancamod@phelps.com

## **Section of Science & Technology Law Officers:**

### **Chair**

Richard L. Field  
Law Office of Richard Field  
755 Anderson Ave., 4A  
Cliffside Park, NJ 07010-2139  
Phone: (201) 941 8015  
Fax: (201) 941 8015  
field@pipeline.com

### **Chair-Elect**

William Sloan Coats  
White & Case LP  
3000 El Camino Real  
5 Palo Alto Square  
10<sup>th</sup> Floor  
Palo Alto, CA 94306  
Phone: (650) 213 0300 ext. 320  
Fax: (650) 213 8158  
wcoats@whitecase.com

### **Vice-Chair**

Gilbert F. Whittemore, Jr.  
Rath, Young & Piganatelli  
54 Canal St, Suite 300  
Boston, MA 02114-2011  
Phone: (617) 523 8080  
Fax: (617) 523 8855  
gilwhittem@aol.com

### **Secretary**

Ruth Hill Bro  
Baker & McKenzie LLP  
One Prudential Plaza  
130 E. Randolph St.  
Chicago, IL 60601-6342  
Phone: (312) 861 7985  
Fax: (312) 698 2078  
bro@bakernet.com

### **Budget Officer**

Kimberly Kiefer Peretti  
Department of Justice  
Computer Crime & Intellectual Property Section  
John C. Kenney Bldg.  
10th and Constitution, NW  
Suite 600  
Washington, DC 20530  
Phone: (202) 353 4249  
Fax: (202) 514 6113  
kimberly.peretti@usdoj.gov

## **Section Delegates to the House of Delegates**

Ellen J. Flannery  
Covington & Burling  
1201 Pennsylvania Ave, NW  
Washington, DC 20004  
Phone: (202) 662 5484  
Fax: (202) 778 5484  
eflannery@cov.com

Scott F. Partridge  
Baker & Botts, LLP  
910 Louisiana St, 35<sup>th</sup> fl.  
Houston, TX 77002-4995  
Phone: (713) 229 1569  
Fax: (713) 229 7769  
scott.partridge@bakerbotts.com

**Immediate Past Chair**

Ivan K. Fong  
Cardinal Health  
7000 Cardinal Place  
Dublin, OH 43017  
Phone: (614) 757 7768  
Fax: (614) 652 7325  
ivan.fong@cardinal.com

**Past Chair Liaison to Officers**

Thomas J. Smedinghoff  
Baker & McKenzie LLP  
One Prudential Plaza  
130 E. Randolph St  
Chicago, IL 60601-6342  
Phone: (312) 861 8670  
Fax: (312) 861 2899  
smedinghoff@bakernet.com

©2006 American Bar Association. All rights reserved. Editorial policy: *Biotech Briefing* endeavors to provide information about current developments in law, science, medicine, and technology that is of professional interest to the members of the Biotechnology Committee of the ABA Section of Science & Technology Law. Material published in *Biotech Briefing* reflect the views of the authors and does not necessarily reflect the position of the ABA, the Section of Science & Technology Law, or the Editor(s).

Membership questions or address changes? 1-800-285-2221 or abasvcctr@abanet.org