1-1-2008

Newsletter, Winter/Spring 2008, vol. 3, issue 1

The Dean Rusk International Law Center

Repository Citation

This Article is brought to you for free and open access by the Dean Rusk International Law Center at Digital Commons @ Georgia Law. It has been accepted for inclusion in Newsletters by an authorized administrator of Digital Commons @ Georgia Law. Please share how you have benefited from this access For more information, please contact tstriepe@uga.edu.
In 1990, Dean Rusk took part in the 8th Annual Report of the Secretaries of State held here in Athens, Ga. Eighteen years later, as part of the commemoration of the Rusk Center’s 30th Anniversary, a highly distinguished group of former secretaries of state will convene once again in Athens during late March for a round table discussion on U.S. foreign policy moderated by Terence Smith of the television program The Newshour with Jim Lehrer.

The Annual Report of the Secretaries of State began in 1983 and developed into a series of conferences produced by the Southern Center for International Studies (SCIS) located in Atlanta. Dean Rusk was instrumental to the success of these early conferences, both through his participation as a former secretary of state in the first nine Annual Reports and through his support of the work of SCIS. Honoring this tradition, the Dean Rusk Center and SCIS will host the former secretaries of state – a group that will include Henry Kissinger, James Baker III, Warren Christopher, Madeleine Albright and Colin Powell – for “The Report of the Secretaries of State: Bipartisan Advice for the Next Administration” on March 27 at the Classic Center in Athens.

“The Report of the Secretaries of State is precisely the type of conference that fits into the Rusk Center’s mission of providing a forum for debate on international legal and policy issues,” explains Center Director and former Ambassador C. Donald Johnson. “At the Center, we seek to gain insight from participants who have been directly involved in the shaping of law and policy. I can think of no better way to do that than by working with longtime friends of Dean Rusk at the Southern Center for International Studies to bring this group of distinguished former secretaries of state to Athens for an exciting roundtable discussion on foreign policy.”

For more information about the upcoming conference, please visit: www.uga.edu/uskcenter/announcements.html

Co-chair of Iraq Study Group delivers foreign policy talk

On March 27, 2007, before a packed house at the UGA Chapel, Lee H. Hamilton, president and director of the Woodrow Wilson Center, former Congressman, vice-chair of the 9/11 commission, and co-chair of the Iraq Study Group, delivered a timely lecture, titled “A Balanced View of American Power,” as the 2007 Sibley lecturer. In his talk, Hamilton addressed what he sees as the major foreign policy challenge facing the United States today, which is found in a seeming contradiction – the world’s most powerful nation is unable to bend the world to its will.

Hamilton described how we have gone from talks of transforming the world with American power in the years directly

continued on page 4
Announcements

Study Abroad & Global Internship Programs

• China program expands to add additional course – Based on feedback from student surveys and on the success of the first two years of the program, the Rusk Center has expanded the 2008 Georgia Law Summer Program in China by adding a fourth credit and five days to the existing three-week itinerary. The new course, International Intellectual Property Law, will be taught by Professor Paul Heald, Allen Post Professor of Law at the University of Georgia. For more information, please visit: www.uga.edu/ruskcenter/china/

• Brussels Seminar receives highly favorable report from ABA inspector – In its 35th consecutive year of operation the Brussels Seminar was expanded to offer students four hours of ABA-approved credit. The ABA inspector’s report to the Accreditation Committee and Council stated the following: “This is an outstanding foreign summer law program that the University of Georgia School of Law should be proud to have among its repertoire of offerings; it clearly enhances the reputation of the University of Georgia School of Law both in the U.S. and abroad.” For more information, please visit: www.uga.edu/ruskcenter/brussels.html

• Global Internship Program makes its mark at Georgia Law and beyond – Entering into its sixth year of operation, and in response to the growing enthusiasm of first and second year law students, the program now offers more than 45 venues in 25 countries around the world. Students have the opportunity to work in a broad range of settings – from the more traditional, such as France, Chile and Canada, to the more exotic, such as Papua New Guinea and Mongolia. For more information, please visit: www.uga.edu/ruskcenter/externships

Graduate Legal Studies

Class of 2008 is welcomed for new LL.M. – This year’s LL.M. class, comprised of students from Belgium, Russia, France, Serbia, Kenya, Guyana, Uganda, Philippines, Venezuela and Korea, is the first to take part in the newly restructured LL.M. program, which offers students the option of following an All-Courses track or an LL.M. Essay track. For more information, please visit: www.uga.edu/ruskcenter/llm.html

Spring 2008 Colloquium Series Speakers

Since 2006, the International Law Colloquium has brought leading international law scholars to the Rusk Center and the University of Georgia to present substantial works-in-progress before UGA students and faculty. For further information on the colloquium, please contact Daniel Bodansky (bodansky@uga.edu).

This program is made possible through the Kirbo Trust Endowed Faculty Enhancement Fund.

February 1 - Gregory Shaffer (Wing-Tat Lee Chair of International Law, Loyola University): “A Structural Theory of WTO Dispute Settlement: Why Institutional Choice Lies at the Center of the GMO Case”

February 8 - Beth Simmons (Clarence Dillon Professor of International Affairs and Director of the Weatherhead Center for International Affairs, Harvard University): “Theories of Commitment”

February 15 - Nadia Bernaz (Lecturer, Irish Centre for Human Rights, National University of Ireland at Galway): “Caribbean Court of Justice: Reflections on a Truly Hybrid Court”

February 22 – Ingrid Wuert (Professor of Law, Vanderbilt University): “An Originalism for Foreign Affairs?”

February 29 – Tonya Putnam (Assistant Professor of Political Science, Columbia University): “Beyond Presumption?: Explaining Variation in U.S. Extraterritorial Jurisdiction over Civil Claims”

March 21 – Paul Schiff Berman (Jesse Root Professor of Law, University of Connecticut): “Global Legal Pluralism”


April 4 – David Caron (C. William Maxeimer Distinguished Professor of Law, University of California at Berkeley): “Why International Courts and Tribunals Look and Act as They Do”
Director’s Note

This year marks the 30th Anniversary of the Dean Rusk Center. In 1977, under the guidance of Dean Rusk himself, the Center began working to expand international law offerings and programs at Georgia Law. Today – 30 years later – we continue to offer students, faculty members and other participants unique international law opportunities through a variety of programs and public events.

In March of 2007, we had the distinct pleasure of presenting Lee Hamilton as the 102nd John A. Sibley Lecturer. Hamilton’s lecture, in commemoration of the Rusk Center’s 30th Anniversary and sponsored by the Charles Loridans Foundation of Atlanta, focused on the need for the United States to take a more modest and balanced view of American power (see cover). It was a special privilege for me, personally, to introduce Hamilton, who is not only a friend of mine but also someone who knew Dean Rusk well, since he was first elected to Congress in the 1960s. There really could have been no better way to commemorate the Rusk Center’s anniversary than by having someone of Hamilton’s stature and well-documented bipartisanship share his perspectives on the important topic of today’s U.S. foreign policy. I think Dean Rusk would have approved.

Soon after this event, and on a related note, we partnered with the Center for European Law, Vrije Universiteit Brussel, in organizing and hosting a two-day colloquium on the international fight against terrorism. EU and U.S. experts gathered in Athens to address a range of transcendent anti-terrorism and security issues equally affecting both sides of the Atlantic and beyond. Two keynote addresses, one by Jonathan Faull, Director General for Justice, Freedom and Security at the European Commission, and the other by Congressman Jim Marshall (D-GA), were also delivered during the two-day colloquium (see page 6). In November, another two-day event was held at the Rusk Center, this time featuring Diana Wallis – Vice President of the European Parliament – as the Willson Center-Dean Rusk Center Annual Lecturer, and as part of an EU-U.S. conference and a U.S. Secretaries of State roundtable presented in cooperation with the Southern Center for International Studies; featuring former secretaries of state: Henry Kissinger, James Baker, Warren Christopher, Madeleine Albright and Colin Powell – our aim is to continue to provide relevant programs and events that illuminate issues of international importance. Often, we seek to do this from an interdisciplinary point of view, as well as from a legal perspective, in order to stay on the cutting edge of world affairs and provide the most current and relevant understanding of issues in international law. We hope that you will join us in this effort, and continue to take an interest in the work of the Dean Rusk Center.

As we look towards our upcoming 2008 events – a future aviation policy colloquium focusing on the 2007 EU regulation on the law applicable to non-contractual obligations (see page 6).

On the global front, we have continued to grow our International Outreach and Education programs in an effort to provide additional, valuable international law opportunities at Georgia Law. Our study abroad programs have expanded with the inclusion of an ABA-approved, credit-bearing option in the Brussels Seminar on the Law and Institutions of the European Union, which celebrated its 35th anniversary this year, and with the addition of a fourth course/credit to the Georgia Law Summer Program in China (see page 8). Our Global Internship Program continues to expose Georgia Law students to the practice of international and transnational law through summer internships in foreign governmental agencies, academic centers, law firms, corporations and NGOs. This past summer, 22 students worked in 12 different countries. They were often involved in key projects and gained unique, real-world experience (see page 9).

Our in-house International Judicial Training Program (IJTP) has also grown to include a group of Armenian judges, who took part in training earlier this fall, and a 34-member group of Brazilian judges, who arrived in November. The ITP, in conjunction with the European Consortium supporting the Institute of Law, Birzeit University, also provided support for a visiting Palestinian law librarian who trained with Georgia Law library staff over a two week period. And, as a collaborative effort with Kennesaw State University, the Rusk Center recently hosted a delegation from China as part of a Chinese-funded national, legal education program (see page 7).

As we look towards our upcoming 2008 events – a future aviation policy...
The Dean Rusk Center plays an active role in the international arena by hosting conferences and lectures that bring scholars, practitioners, government officials, business leaders, students and alumni together to discuss relevant international law and policy issues. These Rusk Center events seek to increase the understanding of international law and policy decisions, as well as explore solutions to challenges of global significance. Past meetings have been comprised of a wide array of national and international panelists and participants, including ambassadors, congressmen, senior-level government officials, United Nations representatives and military officers.

Selected events are published by the Rusk Center in the Occasional Papers Series or in the Georgia Journal of International and Comparative Law. To access select Occasional Papers online, please visit: www.uga.edu/ruskcenter/publications.html. To order hardcopies of Occasional Papers, please contact April Macáková at macakova@uga.edu or 706.542.7875.

---

Co-chair of Iraq Study Group delivers foreign policy talk in commemoration of the Dean Rusk Center’s 30th anniversary

---

following 9/11, to seeing the limitations of that very power today everywhere we turn. We face rising levels of violence in Iraq and Afghanistan, a hard-line President in Iran, a defiant Hezbollah in Lebanon, moves toward authoritarianism in Russia, the rising powers of China and India, and the lashing out of ultra-leftist governments in Latin America. In dealing with these issues, support for American action has diminished due, in large part, to the rejection of international obligations and treaties, the replacement of traditional alliances such as NATO and other international institutions in favor of the so-called “coalition of the willing,” and the refusal to engage diplomatically, and pragmatically, with our enemies.
“Our power is not dissipated,” Hamilton explained. “Far from it – but our power is diminished.” Yet, the world still looks to us for leadership; world leaders come to Washington every day. “They all come because they want the help of the United States,” Hamilton explained. And if America does not help, more often than not, progress is not made. “But,” Hamilton warned, “we cannot make a nation want what we want for them. They have to choose themselves.”

Our foreign policy should reflect that, Hamilton pointed out, and added that our foreign policy needs to do what every successful political figure does when a constituent asks for the impossible – say to the constituent, ‘I’m on your side, I feel you pain.’ “We have to say to those people, ‘Look, we can’t solve your problems – your countries are going to have to do that – but we want to try to help. We’re on your side.’”

Which still leaves the toughest question facing policy makers today, Hamilton explained: “When do you use American military power?” Hamilton reasoned that we must protect our national security by having an American military that is second to none, but that we must also have a sense of modesty about that power. He continued, “There may be a primacy of American power, but it is not omnipotent. The greatest 20th century triumphs of the American military took place within broad international coalitions, not when we acted by ourselves.”

Furthermore, Hamilton went on to say, “I think it is becoming clear what the rules of intervention ought to be. We ought to intervene if there is an imminent threat to the United States.” On the issue of regime change, he added, “The critical question here is not: ‘Is it desirable?’ It is desirable in any number of cases. The question is: ‘How are you going to do it? How are you going to achieve it?’ That’s the tough question. We cannot slay every tyrant; regime change is better left to the people under the regime.”

In closing, Hamilton suggested that policy makers sometimes need to be reigned in by the views of the public, and that “American foreign policy must always be sensitive and respectfully tuned to the views of the American people.” To illustrate the wisdom of this point he offered the results of a recent foreign policy poll, which he said in his home state of Indiana would have been described as a “down-home” judgment; one that included the American public’s desire to disengage responsibly from Iraq, take out Osama Bin Laden, engage in diplomacy with our adversaries, reduce dependence on foreign oil and maintain strong alliances.

“I think what Americans really want is American leadership, on behalf of the world, where our interests are protected, where we work with likeminded nations, and where the values of liberty and justice and opportunity are the norm and not the exception,” concluded Hamilton. “We have to be idealists without illusions. We have to be pragmatists with a vision.”


EU and U.S. experts tackle international terrorism

Partnering with the Center for European Law, Vrije Universiteit Brussel, last semester, the Rusk Center presented a two-day colloquium titled: The International Fight Against Terrorism: A Colloquium on the Prospects for Further Cooperation Between the European Union and the United States. Speakers from around the globe convened in Athens to address a range of transcendent issues relating to terrorism and security affecting both the EU and the U.S., including common challenges and achievements, data mining, and the conflict between freedom of the individual and governmental measures taken to protect civil society.

The colloquium brought together members of the European Commission, the European Parliament and the Council of the European Union with their counterparts from the United States Congress, the Department of Justice and the Department of Homeland Security. Notable speakers and panelists included Jim Marshall, U.S. Congressman from Georgia; Jonathan Faull, Director General for Justice, Freedom and Security at the European Commission; Gijs de Vries, former Counter-Terrorism Coordinator for the EU; and Baroness Sarah Ludford, member of the European Parliament and life peer in the House of Lords.

The conference opened with a keynote address delivered by Faull, which was followed by two panel discussions and an evening dinner with Marshall as the keynote speaker. A third panel was held the following day to conclude the colloquium’s activities. For more information and a complete program of the colloquium, please visit: http://www.uga.edu/ruskcenter/security.html
Vice President of the European Parliament speaks at Rusk

On November 5, Diana Wallis, vice president of the European Parliament, joined other American and European experts in private international law to explore new European Union legislation on the law applicable to torts and to compare it to approaches in U.S. law during a two-day event sponsored by the University of Georgia Dean Rusk Center – International, Comparative and Graduate Legal Studies and the Georgia Society of International and Comparative Law.

The first day of the event featured discussions titled “Colloquium on Rome II: The 2007 EU Regulation on the Law Applicable to Non-contractual Obligations – European and American Perspectives.” Presenters included: Diana Wallis, Kirbo Chair in International Law Gabriel M. Wilner of the University of Georgia School of Law, Professor Russell J. Weintraub of The University of Texas School of Law, Dean Symeon C. Symeonides of Willamette University College of Law and Dean Johan Meeusen of the University of Antwerp Law School. The proceedings of the colloquium will be published by the Rusk Center in its Occasional Papers Series.

On the second day of the event, Wallis delivered a speech titled “Who Runs Who: Does Europe Follow the U.S., or the U.S. Europe, on Major Policy Issues?,” which was co-sponsored by the Willson Center for Humanities and Arts as part of the Willson Center – Dean Rusk Center Annual Lecture. In her presentation, Wallis focused on the need for European politicians, such as herself, to draw from the experiences of the U.S., while also making sure to think critically about which specific approaches to global issues – such as Iraq, terrorism, the death penalty or environmental policy – might or might not be adopted by the EU.

“One of the things that has always been important to me, both as an elected parliamentarian and indeed even before as a lawyer, is the importance of global exchange and interchange between various peoples and various countries.” Wallis said. “I believe that when we look at one another’s achievements and use this sort of comparative approach we can learn from that, and we can learn much.”

Wallis’ lecture will be published by the Rusk Center as part of a 30th Anniversary series. For more information on the Center’s publications, please visit: www.uga.edu/ ruskcenter/publications.html
Outreach & Education

The Dean Rusk Center develops projects that serve to expand the international dimensions of teaching, scholarship and outreach at the School of Law. These projects originate primarily through staff initiatives, but also from external requests and personal initiatives of Georgia Law faculty and students. The Center works with interested national and international agencies and institutions on projects of mutual interest, providing support through project identification, creation and development, background research, funding and administration.

Armenian and Brazilian judges take part in judicial training program

During the 2007 fall semester, two different groups of foreign judges received judicial training coordinated by the Rusk Center and the Institute of Continuing Judicial Education. In late August, 15 members of the Judiciary of Armenia arrived in Athens for a two-week long training program, followed in November by 34 members of the Judiciary of the State of Pernambuco in Brazil. Both groups received training in topics such as court administration, judicial budgeting, caseload management, alternative dispute resolution, court technology, and judicial ethics and professionalism. Support for the Armenian group was provided by the World Bank.

Delegation of Chinese officials and academics visit Rusk Center

For the second time this year, the Dean Rusk Center welcomed a group of Chinese government officials and academics – made up mostly of senior level bureaucrats and law school deans – who were being hosted by Kennesaw State University as part of a legal education training program funded by the Chinese government. The group spent a half-day at the Rusk Center for overviews of Georgia Law’s admissions requirements and curriculum (presented by Professor Paul Kurtz, Associate Dean, School of Law); career services programs (presented by Beth Kirch, Director, Legal Career Services); and international offerings (presented by C. Donald Johnson, Director, Dean Rusk Center). Also included in the program were tours of the law school and the Rusk Center, as well as lunch at the Tate Student Center.

West Bank librarian trains at Georgia Law

Liana Quaider, a Russian trained librarian working in Palestine since 1981, recently spent two weeks training with Georgia Law’s Alexander Campbell King Law Library staff. Ms. Quaider, who is Head Librarian at Birzeit University Institute of Law – which houses the first and largest law library in Palestine – worked closely with Associate Director María Giménez and Georgia Law’s library staff to fashion a training program focused on budget issues, library organization and planning, donation requests, faculty and staff relations, and electronic resources. Support for the training program was provided by the Dean Rusk Center and the European Consortium supporting the Institute of Law, Birzeit University.
Study abroad & global internships

Two of the most important offerings of the Rusk Center are our study abroad and global internship programs, which allow students the opportunity to follow legal coursework and apply legal skills in diverse, international settings. The recent growth of this aspect of the Rusk Center’s work has provided a substantial boost to Georgia Law’s international profile. The following two articles feature the experiences of Georgia Law students who spent last summer working and studying abroad.

2 continents, 6 weeks, 7 credits... and the experience of a lifetime

Globetrotting around the world to study Chinese and EU law may not be the first thing that most rising second-year law students expect to be doing in the summer after their first year of law school. But that is exactly what students get when they attend both the Georgia Law Summer Program in China and the Brussels Seminar on the Law and Institutions of the European Union, the two Rusk Center summer, study abroad programs. This past summer, three Georgia Law students took advantage of this unique opportunity to travel the world and learn about two distinct and increasingly important foreign legal systems.

The Georgia Law Summer Program in China, held at two of China’s premiere institutions of higher learning (Tsinghua University in Beijing and Fudan University in Shanghai), provides students with a comprehensive introduction to the Chinese Legal System, with an emphasis on commercial and trade law.

“We intentionally set the China program early in the summer in order to allow students the time to do internships or have other experiences in the second half of the summer,” explained Rusk Center Assistant Director André Barbic. “We are extremely pleased that several China participants chose to spend the second half of the summer in Brussels, taking part in the longest running Georgia Law study-abroad program.”

The Brussels Seminar, now in its 35th consecutive year of operation, recently received a highly favorable report from the ABA as part of that organization’s formal accreditation process of the Seminar’s new four-hour, credit-bearing option. 21 students, including the three that had attended the China program, spent three weeks in the “capital” of Europe where they followed intensive coursework on the law and institutions of the European Community within the European Union.

“Dean Rusk played a key role in the establishment of the Brussels Seminar,” explained Rusk Center Executive Director Gabriel Wilner, “and the program’s success over the past 35 years is a testament to the value of having a program that offers an intensive overview of EU law, which is something that Dean Rusk always supported.”

Three Georgia Law students, all rising 2Ls, were the first ever to participate in both the China and Brussels programs in the same summer. Back in Athens, one of the students, Alex White, explained why he enjoyed this unique summer experience: “After getting a good base in the traditional first year law school subjects, it was great to dive right into a full summer of international law.” Avani Patel, another of the three students, added, “The summer after your first year is the best time to take part in these programs because after your second year there is more pressure to find a job. It’s also not bad to be starting your second year of law school with seven additional hours of credit, which helps lighten your class load for the next two years.”

In addition to the challenging coursework, the advantages of studying in the unique environments offered by these study-abroad programs were not lost on the students. Avani said that what she enjoyed most was being able to interact with Chinese and EU nationals outside of the classroom. “You really get a better idea of how things don’t always measure up to your own preconceived notions,” she explained. And according to Alex, “These summer programs are terrific because you feel like you really have time to soak stuff in, especially after the heavy workload of the first year of law school.”

Cultural experiences are also a highpoint of study abroad programs for many students. “I’m a big history and culture buff, so going to places like the Forbidden City and Tiananmen Square in Beijing was amazing. And in Brussels, I must have gone to La Grand-Place a dozen times. There was always something interesting going on,” explained Alex. Avani found that visiting Beijing and Shanghai, two vastly different cities, during the same program was a real advantage. “And in Brussels the food was amazing!” she added. All in all, it was a full and rewarding summer for students just wrapping up the first year of their law school careers.

For more information on these two study-abroad programs, please visit: http://www.uga.edu/uskcenter/exchange.html

“...it was great to dive right into a full summer of international law.”
Gaining a global perspective of the law
By Terresa Davis, 2L at Georgia Law

The small, South Pacific island-nation of Papua New Guinea is facing many of the challenges typically found in post-colonial nations, including civil conflict, a struggling economy and one of the highest crime rates in the world. Improving the legal system – and, therefore, the overall administration of justice – will significantly advance the government’s ability to guarantee peace, stability and social justice. An important, indeed essential, first step to achieving this goal involves solidifying the country’s common law and making information regarding that law publicly accessible.

The Global Internship Program at the University of Georgia School of Law is helping Papua New Guinea achieve this important goal. This past summer, I was lucky enough to be involved. Due to a lack of funding and personnel, the Papua New Guinea Law Reports (PNGLR) – the only official codification of the country’s Supreme Court judgments – has not been published since 2000, leaving the country without a standardized common law for the last six years. The people, and even the courts, are, therefore, unable to know the very law that governs them. This deficiency is hindering the already strained court system and severely jeopardizing the national administration of justice.

Through the Global Internship Program, the opportunity to help revive the PNGLR was offered as one of the 2007 summer internships. Building on previous work experience in Southeast Asia – as a project coordinator for Heritage Watch, a non-profit organization fighting to save Cambodia’s rich cultural heritage – I felt well prepared for this exciting and challenging task. In addition, the opportunity meant a great deal to me personally. I would be the third generation of my family traveling to Papua New Guinea; my grandfather had fought there during World War II, and my uncle had later spent years there as a civil engineer.

In May of 2007, I traveled to the capital of Papua New Guinea – Port Moresby, a beautiful but poverty-stricken city on the shores of the South Pacific. I was given an office at the University of Papua New Guinea School of Law, where I worked under Dr. R.W. James, an internationally renowned legal scholar now leading the university’s Law Publication Unit. The unit’s main responsibility is the publication of the PNGLR.

My first task was to develop and submit project proposals for the PNGLR which would be used to request funding from major international foundations. While confident of the project’s strengths, I was also aware of some of its limitations – namely, that printed editions of the PNGLR would only be available to a small percentage of the population due to the great difficulty, expense and danger of domestic travel, and, therefore, postal delivery. For judges, lawyers and citizens outside of the country’s capital to have access to the governing law the PNGLR would also need to be published in a free, easily accessible and searchable online database. Such a resource would be invaluable to the legal and academic community in Papua New Guinea, as well as to lawyers and scholars throughout the region and the world.

Having designed not-for-profit databases in the past, I readily agreed to head up this particular aspect of the project, and by the end of my two months in the country – in addition to submitting numerous funding proposals – I had completed the database framework. However, much work remains unfinished, and once completed, the judiciary, legal community and faculty of the school of law must be trained in the use of the database. Accordingly, I decided to finish the database – both the necessary technical work and the editing – over the course of the next year, and return to Papua New Guinea in the summer of 2008 to conduct training in its use.

I am very excited about having been, as well as continuing to be, a part of this project. I never thought that I would have an opportunity to make such a positive impact on an entire country while still a student in law school. The fact that I have, to me, is one of the greatest strengths of the Global Internship Program at the University of Georgia School of Law.
Promoting ethical standards in globalized drug trials through market exclusion

By Fazal Khan, Assistant Professor of Law, UGA

She was only ten years old and suffering from a serious infectious disease that was sweeping through West Africa, bacterial meningitis. But for this little girl and her family there was seemingly good news; there exists an effective treatment for bacterial meningitis, intravenous antibiotics. Further, once they arrived at the clinic in Kano, Nigeria, they saw Western doctors in white coats offering to provide medical treatment for free. And yet, three days later the girl died – not having received any proven antibiotic therapy, but only an experimental drug called Trovan.1

The family of the girl later claimed, along with many others, that instead of receiving proper medical care, they were unwitting participants in a multinational drug company’s experimental trial that led to the death or serious impairment of numerous children.2 But why would a drug company ever do something like this? Well, if data from the experiment helped the drug obtain market approval, and it became a market blockbuster, a company would have over a billion reasons.

The potential for tremendous financial reward generated by a newly approved drug provides a strong incentive for drug companies to move human subject testing to “developing countries,” where minimal ethical guidelines and little transparency are the norm. The drug industry is acutely aware that there is minimal threat of costly civil and criminal legal sanctions for any of their ethical violations in impoverished countries. One study looking at drug trials in sub-Saharan Africa found that only 16 percent of these clinical drug trials met international ethical standards, despite 81 percent of them reporting oversight by an ethics review board.3

The globalization of clinical trials really became enabled after a 1980 Food and Drug Administration (FDA) ruling that allowed data from foreign trials to be used in new drug applications (NDA). Certain foreign studies used to support an NDA may opt to avoid direct FDA regulation, but must still satisfy FDA-imposed ethical standards – either the Declaration of Helsinki guidelines or regulations of the country where the research was conducted, “whichever represents the greater protection of the individual.”4

The Declaration of Helsinki, an ethical code put out by the World Medical Association that governs research involving human subjects, has thus become the de facto international ethical standard. Therefore, in theory, under these FDA guidelines there should not be a “race to the bottom” problem, as an underdeveloped country’s lax standards would automatically be upgraded to Declaration of Helsinki standards. And yet, we are still seeing consistent violations of ethical standards.

Globalization of the pharmaceutical industry and clinical drug testing is not necessarily a bad thing. Indeed, without this process, cures for seemingly intractable diseases like cancer or AIDS might not be possible in the near future. Further, many patients in the developing world might not have access to any medical attention at all, were it not for clinical drug testing. However, the real and potential benefits offered by globalization in the drug industry do not require us to silently accept violations of ethical standards or the absence of accountability and justice. As Nobel-laureate economist Amartya Sen has stated:

Even though I’m pro-globalization, I have to say thank God for the anti-globalization movement. They’re putting important issues on the agenda… My attitude to globalization is that one has to recognize first of all its inevitability, secondly its importance as an intellectual, social, political force, even as an economic force, but recognize that it can be very unjust and unfair and unequal, but these are matters under our control.5

In other words, even though the process may be inevitable, we are not powerless to control the actions of drug companies who conduct testing on human subjects in developing nations.

What can be done to address this problem? Multinational companies are notoriously difficult to regulate. By using multiple facilities around the globe, corporations can strategically evade state power and certain national regulatory schemes. From an international law perspective, the challenges are both “horizontal” and “vertical” in nature, and the legal responses can be “hard” or “soft.”

For clinical drug trials, “horizontal” challenges constitute problems that arise between nations trying to regulate multinational drug companies that operate across international borders. “Vertical” challenges are problems with unethical trials that nations, more likely developing nations with limited resources, face inside their borders. “Hard-law” is represented by rule-based systems with binding authority on member states,

3 See David M. Kent et al., Clinical Trials in Sub-Saharan Africa and Established Standards of Care: Systematic Review of HIV, Tuberculosis, and Malaria Trials, 292 JAMA 237, 239 (2004).
4 See 21 C.F.R. Sec. 312.120(i)(c)(1)(2005).
...The potential for tremendous financial reward generated by a newly approved drug provides a strong incentive for drug companies to move human subject testing to “developing countries,” where minimal ethical guidelines and little transparency are the norm.

such as the system in place under the World Trade Organization (WTO). “Soft-law” represents guidelines, practices, and policies generated by non-governmental organizations for voluntary self-regulation by industry or future adoption by states.

Addressing the ethical problems associated with globalized trials, some scholars have advocated a “hard, horizontal” approach, investing an international organization such as the World Health Organization (WHO) with binding authority to enforce ethical standards in clinical trials on a global basis. The problem with this approach is one of sovereignty and enforcement. Namely, how would an international organization enforce its decisions upon an unwilling sovereign nation?

Other commentators have argued for a “hard, vertical” approach with horizontal effects; that is, an expansive reading of the Alien Tort Statute (ATS) to allow U.S. courts to enforce foreign violations of ethical standards. However, after the U.S. Supreme Court’s 2004 decision in Sosa v. Alvarez-Machain, it became more difficult for foreign plaintiffs to assert ATS claims. Indeed, the class of Nigerian plaintiffs who sued Pfizer in the U.S. over their Trovan drug trials (see supra) had their case dismissed for failure to state a cognizable ATS claim (the court indicated that their suit would be dismissed on forum non conveniens grounds as well). Thus, while the proposals discussed above advocate for more accountability and justice in globalized drug trials, it is unlikely that in practice they would offer more protection for vulnerable research populations.

A more feasible and effective strategy would be to use “horizontal, soft-law” measures such as increased monitoring and reporting on globalized drug trials that in turn could be used to enforce existing “hard-law” drug approval regulations vertically in lucrative markets such as the United States, Japan, and the European Union. The significance of these provisions is that drugs developed unethically could technically be excluded from the marketplace because of the impermissibility of the underlying clinical trials. Thus, if the fruits of unethical research were denied access to U.S., Japanese, or EU markets, it would have the same effect as a global prohibition, as no drug company would develop a drug in such a manner if they knew they would lose out on even one of these lucrative markets.

With the increasing accessibility of cheap internet communication, human research subjects and concerned citizens in developing nations can be empowered to effectuate much of the surveillance and monitoring activities of clinical drug trials. For instance, WHO could maintain a multi-lingual website for the reporting of alleged ethical abuses. A credible report could then prompt WHO officials to obtain a sworn statement from the reporter, which would then trigger an investigation into the alleged ethical abuses. Verified reports of ethical abuses can then be taken into account by drug regulatory agencies when determining whether a drug should obtain market approval.

Rusk Center Staff

C. Donald Johnson
Director

Gabriel M. Wilner
Executive Director

María E. Giménez
Associate Director

André B. Barbic
Assistant Director

Apríl Macáková
Office Manager

Rebecca Fameree
Administrative Associate

Newsletter design and illustrations: mPrint Design Studio, mprintdesign.com
Edited by André B. Barbic

© 2008 by the University of Georgia School of Law. The University of Georgia is a unit of the University System of Georgia. The University of Georgia is an Equal Opportunity/Affirmative Action Institution and does not discriminate on the basis of race, color, sex, religion, national origin, age, disability, or veteran status in its programs or activities. The director of the UGA Equal Opportunity Office at 3 Peabody Hall, Athens, Georgia 30602 (telephone (706) 542-7912) has been designated to handle inquiries regarding these nondiscrimination policies.