

# UNITED STATES MISSION TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

January 2, 2013

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Mr. Anand Grover

Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health
Office of the United Nations High Commissioner for Human Rights

Dear Messrs. Mendez and Grover,

This letter is submitted in response to your letter dated June 11, 2012 concerning "the treatment suffered by children and young adults enrolled in the residential programme of the Judge Rotenberg Center (JRC)" located in Canton, Massachusetts. The Department of State has provided your letter to various federal and state entities in order to obtain information related to the allegations contained therein. The entities which we have communicated on this matter include the United States Department of Justice (DOJ), the United States Food and Drug Administration (FDA), the New York State Department of Health (DOH) and the governor's Special Advisor on Vulnerable Persons, and the Commonwealth of Massachusetts' Department of Developmental Services (DDS).

By way of background, the Individuals with Disabilities Education Act (IDEA) requires public schools to make available to all eligible children with disabilities a free appropriate public education in the least restrictive environment appropriate to their individual needs. IDEA requires public school systems to develop appropriate Individualized Education Programs (IEPs) for each child with a disability who requires special education and related services. The specific special education and related services outlined in each IEP reflect the individualized needs of each student. Each student's IEP must be developed by a team of knowledgeable persons and must be reviewed at least annually. The team includes the child's teacher; the parents, subject to certain very limited exceptions; the child, if determined appropriate; a qualified agency representative; and other individuals at the parents' or agency's discretion. If parents disagree with the proposed IEP, they can request a due process hearing and a review from the state educational agency if applicable in that state and can appeal the state agency's decision to state or federal court.

As noted in your letter, the JRC uses Graduated Electronic Decelerators (GED) to deliver contingent skin shocks as a form of aversive behavior control. Two of the three versions of the GED that the JRC currently uses, the GED3A and GED4, are modified beyond what was originally cleared by FDA,1 and the JRC's production of these devices is in violation of the Federal Food, Drug, and Cosmetic Act. The FDA recently sent a warning letter to JRC identifying the infringing conduct, demanding prompt corrective action, and requesting a meeting to discuss discontinuing the use of the modified devices. See, December 6, 2012 Letter from Muthar S. Shamsi, FDA District Director to JRC (attached and available at

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm331291.htm).

In addition to the inspections and communications initiated by the FDA, the use of aversive therapy by JRC has been challenged through a variety of state and federal legislative and judicial actions. In May of 2011, the founder and director of the JRC, Matthew Israel, was charged with misleading a grand jury and subsequently resigned from his position as part of a plea agreement that included a five-year term of probation. Meanwhile, the DOJ investigation into possible violations of civil rights laws at the JRC remains open and ongoing. As indicated in our June 28, 2010 response to a previous special mandate-holder letter on this subject, we will gladly provide additional information once that investigation is complete.

In the meantime, there have been some developments on the state level that are worth noting in so far as they respond, in part, to the questions raised in your letter. In Massachusetts, a variety of measures that would regulate or ban the use of aversive treatment have been introduced in recent years, none of which have been passed into law. Most recently, two budget amendments (#548 and #555), which addressed and restricted the use of aversive treatment within the Commonwealth, were introduced in 2011. Although both passed in the State Senate, both amendments failed to pass through the joint conference committee and therefore did not become law. See, October 2, 2012 Letter from Massachusetts State Senator Brian Joyce (attached). Separately, the DDS amended its behavior modification regulations in October of 2011 in order to ban all schools in Massachusetts, including JRC, from using certain aversive interventions, unless a child had a court-approved treatment plan that allowed for their use prior to September 1, 2011. See, 115 Mass. Code Regs. 5.14; Bryant v. N.Y. State Educ. Dep't, Docket No. 10-40290-cv, at \*13 (2d Cir, August 20, 2012) (available at http://caselaw.findlaw.com/us-2nd-circuit/1609202.html). Under the revised regulation, aversive interventions are defined to include "contingent application of physical contact aversive stimuli such as spanking, slapping, hitting or contingent skin shock." 115 Mass.

<sup>&</sup>lt;sup>1</sup> The JRC originally obtained clearance for the original Graduated Electronic Decelerator (GED), a Class II Aversive Conditioning Device (21 CFR 882.5235), in 1994. Clearance was obtained via the United States Food and Drug Administration's (FDA) Premarket Notification process, also referred to as the 510(k) process. A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective as another legally marketed device (21 CFR 807.92(a)(3)). A 510(k) device is not considered by FDA to be approved.

Code Regs. 5.14(3)(d)(1). We understand that this will lead to the eventual prohibition of aversive therapy practices in Massachusetts.

In New York, the Board of Regents, which governs the State Education Department (SED), promulgated regulations in 2006 prohibiting all schools, including "approved outof-state day or residential schools" such as JRC, from using aversive interventions. See, N.Y. Comp. Codes R. & Regs. Tit. 8, § 19.5(b)(1) (2012); September 17, 2012 Letter from New York Deputy Secretary of Health James E. Introne (attached). This regulation defines "aversive intervention" as an intervention "intended to induce pain or discomfort to a student for the purposes of eliminating or reducing maladaptive behaviors." Id. § 19.5(b)(2). This prohibition includes a grandfather clause that allows for annuallyrenewable exemptions in the case of children whose "individualized education plan" (IEP) was approved before June 30, 2009. Id. That regulation was recently reviewed by the United States Court of Appeals for the Second Circuit, which upheld a lower-court's dismissal of a statutory and constitutional challenge brought on behalf of certain parents whose children are enrolled at the JRC. See, Bryant, Docket No. 10-40290-cv. In addition, in June of this year, New York State passed the "protection of people with special needs act," S. 7749/A.10721, which includes certain new reporting requirements that the Deputy Secretary of Health believes "will ensure that no facility, inside or outside of New York State, can use aversive interventions except upon a 'person-specific authorization'." See, Letter from New York Deputy Secretary of Health James E. Introne. New York has indicated further that they "expect that by June of 2014 all [New York] residents at JRC, including those few who remain subject to court-approved aversive interventions, will be offered placements in New York state where such interventions are not authorized." Id.

Sincerely,

Peter F. Mulrean

Deputy Permanent Representative

#### Attachments:

- (1) December 6, 2012 Letter from Muthar S. Shamsi, FDA District Director to JRC
- (2) October 2, 2012 Letter from Massachusetts State Senator Brian Joyce
- (3) September 17, 2012 Letter from New York Deputy Secretary of Health James E. Introne

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### The Judge Rotenberg Educational Center 12/6/12



Department of Health and Human Services

Public Health Service Food and Drug Administration One Montvale Avenue Stoneham, Massachusetts 02180 (781) 587-7500 FAX: (781) 587-7556

#### WARNING LETTER CMS # 367480

VIA UPS Next Day Air
December 6, 2012
Glenda Crookes
Executive Director
The Judge Rotenberg Educational Center
240 Turnpike Street
Canton, Massachusetts 02021-2359

Dear Ms. Crookes:

On October 3, 2012, through October 17, 2012, an investigator from the United States Food and Drug Administration (FDA) inspected your facility located at 250 Turnpike Street, Canton, Massachusetts. As a result of this inspection, we observed the Graduated Electronic Decelerators (GED) 3A and GED4 devices at your facility. Our inspection revealed that your firm has an inventory of (b)(4) GED3A devices and (b)(4) GED4 devices, for a total of (b)(4) GED devices. Furthermore, our inspection revealed that use of the GED devices has been authorized for (b) (4) students through the Massachusetts Probate Court.

In a letter dated May 23, 2011, FDA notified your facility that the changes and modifications to the originally-cleared GED device require a new premarket notification under 21 CFR 807.81(a)(3). As a result, the GED3A and GED4 devices violate the Federal Food, Drug, and Cosmetic Act (Act) because your facility has failed to obtain FDA clearance or approval. Specifically, the devices are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your facility does not have an approved application for premarket approval in effect, pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360i(q).

In a letter dated June 29, 2012, FDA again notified your facility that the GED3A and GED4 devices are adulterated and require the submission of a premarket notification. In responses to the letters dated May 23, 2011, and June 29, 2012, your facility stated that it is planning to make a submission under section 510(k) of the Act, 21 U.S.C. § 360(k), for changes and modifications to the GED3A and GED4 devices by December 2012. We still have not received any submission from your facility.

Your facility should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your facility's response to this letter should be sent to: Karen Archdeacon, Compliance Officer, Food and Drug Administration, One Montvale Avenue, 4<sup>th</sup> Floor, Stoneham, Massachusetts 02180. If you have any questions about the content of this letter, please contact Ms. Archdeacon at (781) 587-7491.

In addition, we have scheduled a meeting at the FDA campus in Silver Spring, Maryland, Building 66 on Wednesday, January 9, 2013, to discuss the contents of this letter and to discuss your proposed 510(k) submission. The purpose of this meeting will be to discuss an appropriate transition period, as of the date of the meeting, to discontinue use of the violative GED3A and GED4 devices. Use of violative devices after this transition period may subject those devices and responsible persons at your facility to enforcement action, including product seizure, without further notice. Please contact Ms. Archdeacon, at the above number to confirm this date or to reschedule a mutually convenient time.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your facility's responsibility to ensure compliance with applicable laws and regulations administered by FDA.

Your facility should investigate and determine the causes of the violations noted in this letter, in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the close of the inspection, and in the letters dated May 23, 2011, and June 29, 2012.

Sincerely yours,

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Mutahar S. Shamsi District Director New England District

Page Last Updated: 12/10/2012

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 Ph. 1-888-INFO-FDA (1-888-463-6332) Email FDA



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#### MASSACHUSETTS SENATE

STATE HOUSE, BOSTON 02133-1053

#### SENATOR BRIAN A. JOYCE

ROOM 413A, STATE HOUSE
TEL (617) 722-1643
FAX (617) 722-1522
RES (617) 696-0200
E-Mail Brian.A.Joyce@state malus

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October 2, 2012

Jason Pielemeier
Special Advisor
United States Department of State
Bureau of Democracy, Human Rights and Labor
2201 C. Street, Room 7822
Washington, DC 20570

Dear Mr. Pielemeier.

#### CAUCUSES:

CHILDREN'S LEGISLATIVE CAUCUS
BIOTECHNOLOGY CAUCUS
LEGISLATIVE CAUCUS ON OLDER CITIZEN'S CONCERNS
M.W.R.A. LEGISLATIVE CAUCUS

Thank you for this opportunity to comment on the Judge Rotenberg Center (JRC) located in Canton, Massachusetts. I have followed the appalling events at the JRC not only as a legislator, but also as a father. When I watch the video of Andre McCollins' horrific ordeal, I cannot imagine my child experiencing the kind of pain the JRC inflicted upon him. I find it truly incomprehensible that in this day and age the government permits the JRC to administer so-called aversive therapy on innocent, disabled children.

So-called aversive therapy consists of the deliberate use of a physiological state of shock, in other words, a sensation of pain or discomfort, for the purpose of psychiatric treatment. Level III aversive interventions include electrical shock, pinching, food deprivation, sleep deprivation, and a host of other cruel practices. Clinicians first used aversives in the 1930s to "cure" people of homosexuality. Butchers also used aversives to deaden hogs prior to slaughter. The JRC still relies on this pseudo-science that the scientific community discredited 50-60 years ago.

Over the JRC's 36-year history, six children have died while in their care. In addition to these horrific deaths, the JRC has committed countless barbaric acts against our most vulnerable children. Just four years ago, an individual called a group home in Stoughton as part of a prank, requesting that two children receive shocks. Prompted solely by the stranger's voice on the phone, staffers shocked the children, sometimes while restrained. One student received several dozen shocks. The other received 80 shocks. These children received so many shocks that they required hospital care. The Hotline Reports from the Disabled Persons Protections Commission has documented these and other appalling incidents. (enclosed)

Prompted by my outrage over these barbaric acts, I have led the legislative effort for an outright ban of so-called aversive therapy for over a decade. Each and every time the Senate passes a piece of legislation, the JRC persuades the House to back down.

In recent legislative sessions, I worked with Representative John Scibak, a licensed psychologist with extensive experience treating children with severe behavioral and emotional issues, to draft legislation that would require any persons applying this so-called treatment to be trained and licensed. The bill will simply ensure that persons administering aversives receive the proper training and licensing. The JRC has effectively thwarted our efforts to push this very minor measure through the legislature. During the 2011-2012 legislative session, the Behavioral Analysts Bill (S.2379) passed in the Senate, but died on the last day of session on the House floor.

In addition to the Behavioral Analysts bill, I filed three other measures during the 2011-2012 legislative session. The first measure, An Act to create and authorize level IV behavioral treatment (S.49), would create a new category of level IV interventions, require the use of level IV interventions to be supported by scientific evidence, and direct the Department of Developmental Services (DDS) to promulgate regulations regulating the use of level IV interventions. The second measure, An Act to create a special commission on behavior modification (S.50), would create a special commission to investigate the current status of aversive therapy in the Commonwealth and the policies and procedures in place governing their use. The third measure, An Act relative to the humane treatment of disabled persons (S.51), would ban the use of aversive interventions outright. As in past legislative sessions, the Joint Committee on Children, Families and Persons with Disabilities sent each of these measures to study.

We have seen some progress, however. Last year, the Department of Developmental Services (DDS) passed regulations limiting the use of level III aversive interventions. I credit Governor Patrick, Secretary Bigby, and Commissioner Howe for this positive development. The regulations allow continued use of level III interventions for individuals who, as of September 1, 2011, have an existing court-approved behavior plan that includes level III interventions. The regulations also allow their renewal each year, so long as level III interventions remain a part of a court-approved plan. Any person placed on a court-approved treatment plan after September 1, 2011 has been spared from this barbaric practice.

Seizing on this positive development, I filed two amendments to the Senate budget. The first amendment (555) sought to codify the DDS regulations. The second amendment (548) sought to ban the use of level II aversives entirely. Both amendments passed easily in the Senate, but neither survived the budget conference committee, composed of three members of the Senate and three members of the House, that negotiates the final state budget. When I spoke with my Senate colleagues on the conference committee, I learned that my aversives amendments had become a point of contention during negotiations. House members opposed their inclusion so strongly, that both amendments were left out of the final state budget.

Legislative efforts to ban the use of aversives have stalled in Massachusetts for a number of reasons. First and foremost, efforts have failed because of the exorbitant amount of money

that the JRC spends on legal services, lobbyists, and public relations personnel. Over the past ten years, the JRC has generated over \$400 million, most of it tax dollars. To protect its profitable revenue stream, the JRC has spent well over \$18 million on lawyers, lobbyists and public relations personnel. (see enclosed 990 filings)

The JRC also has an extraordinary history of litigiousness, which in turn has stalled legislative efforts. One striking example illustrates this point. After the commissioner and assistant commissioner of what was then called the Department of Mental Retardation tried to stop the use of level III aversives, the JRC successfully sued the state under the Weld Administration. The commissioner and assistant commissioner of the Department lost their jobs as a result, putting a chilling effect on subsequent administrations. Not only has the JRC sued the state, it has also threatened to sue its own former employees for speaking out. Former employees of the JRC remain reluctant to reveal the true extent of this barbaric practice, because of the threat of suit – successfully concealing the torture of innocent children in a shroud of secrecy.

The JRC has also capitalized on the legislature's reliance on experts. Each legislative session, legislators have thousands and thousands of bills to consider. Because of the sheer number of bills and their complexity, we often turn to experts. The JRC's former director, Mathew Israel, would present himself as a subject matter expert, refer to himself as Dr. Israel, and bring the most self-injurious students to public hearings. He would consistently threaten legislators that if they passed a ban on aversives, the students he treats would present an imminent danger to themselves and others. Legislators understandably remained reluctant to decide on the availability of a course of treatment where they often lacked expertise.

I will continue to work to end the JRC's abuse of innocent, disabled children. I will continue to expose the darker truth concealed by cartoon characters and carousels, and I will continue those efforts until the smell of burning flesh no longer haunts the halls.

Please do not hesitate to contact me if I can provide any additional information or assistance.

BRIAN A. JOYCE

State Senator



## STATE OF NEW YORK EXECUTIVE CHAMBER

**ALBANY 12224** 

ANDREW M. CUOMO GOVERNOR JAMES E. INTRONE DEPUTY SECRETARY

September 17, 2012

Jason Piclemeier

Special Advisor.

Bureau of Democracy, Human Rights and Labor

U.S. Department of State

2201 C Street, NW

Washington, DC 20520

Thank you for your inquiry regarding the steps New York State has taken to address the use of aversive interventions in institutions like the Judge Rotenburg Educational Center, Inc. ("JRC") in Massachusetts, which take care of children and adults with significant behavioral problems.

First, the State's Education Department (or SED), which is governed by the Board of Regents, regulates educational services and programs for New York residents placed in in-state as well as out-of-state residential institutions. See N.Y. Educ. Law 18 § 4403(3). The Education Department is not an executive agency under the supervision of the Governor. In 2006, the Board of Regents promulgated a regulation prohibiting any and all schools, including "approved out-of-state day or residential schools" (such as JRC), from using aversive interventions. N.Y. Comp. Codes R. & Regs. tit. 8, 7 § 19.5(b)(1) (2012). The regulation defines an "aversive intervention" as an intervention "intended to induce pain or discomfort to a student for the purpose of eliminating or reducing maladaptive behaviors," such as the contingent application of painful, intrusive, or similar stimuli or activity. Id. § 19.5(b)(2). The Second Circuit Court of

that is intended to induce pain or discomfort to a student for the purpose of eliminating or reducing maladaptive behaviors, including such interventions as:

<sup>1</sup> In full, the regulation defines "aversive intervention" as an intervention

Appeals recently upheld the Education Department's ban on aversive interventions and rejected a challenge brought by parents of certain children at JRC who received such interventions.<sup>2</sup> The only exception to this complete ban in the Education Department's regulations applies to those specific children whose individualized education plan ("IEP") developed pursuant to the Individuals with Disabilities Education Act "include[d] the use of aversive interventions as of June 30, 2009" and who "may be granted a child-specific exception in each subsequent school year . . . ." N.Y. Comp. Codes R. & Regs. 10 tit. 8, § 200.22(e). Consistent with this limited child-specific exception process, currently there are only 12 students recommended for use of aversive interventions whose IEPs recommended such services prior to 2009. Use of aversive interventions is totally prohibited for all other New York students. As of this writing, no facility other than JRC is treating any New York children or adults with aversive interventions. Moreover, no new admissions to JRC or any other facility are being — or could be — treated with aversive interventions.

(i) contingent application of noxious, painful, intrusive stimuli or activities; strangling, shoving, deep muscle squeezes or other similar stimuli;

(ii) any form of noxious, painful or intrusive spray, inhalant or tastes;

(iii) contingent food programs that include the denial or delay of the provision of meals or intentionally altering staple food or drink in order to make it distasteful;

(iv) movement limitation used as a punishment, including but not limited to helmets and mechanical restraint devices; or

(v) other stimuli or actions similar to the interventions described in subparagraphs (i) through (iv) of this paragraph.

N.Y. Comp. Codes R. & Regs. tit. 8, § 19.5(b)(2) (2012).

<sup>2</sup> See Bryant v. New York State Education Department, available at

http://www.ca2.uscourts.gov/decisions/isysquery/491ee982-3ae4-4f99-8ed4-1c82773852f3/3/doc/10-4029comp\_opn.pdf#xml=http://www.ca2.uscourts.gov/decisions/isysquery/491ee982-3ae4-4f99-8ed4-1c82773852f3/3/hilite/. In response to these changes in regulation severely restricting the use of aversives, the parents of students attending JRC initiated two federal lawsuits against SED (Alleyne, et al. v. SED and Mills, 516 F.3d 96 [2008] and 691 F.Supp2d 322 [N.D.N.Y. 2010] and Bryant, et al. v. SED, et al. \_\_\_F3d \_\_\_, [2012 WL 3553361, C.A.2 (N.Y.), petition for rehearing filed September 4, 2012], both of which are still pending.

The Alleyne plaintiffs are parents of severely disabled students attending JRC whose children were receiving aversive interventions under their IEPs prior to the adoption of the SED regulations. The Bryant plaintiffs are parents of children attending JRC who would be prevented from having aversive interventions recommended on their IEP under the 2009 regulations banning aversives. In both instances, the parents assert that aversive interventions are effective for their children and necessary to provide their children with a free, appropriate public education. The Education Department has successfully defended the amended regulations regarding aversives in both the Alleyne and Bryant litigations, where the courts upheld the Department's regulations restricting the use of aversives. In Alleyne, however, the District Court ordered continuation of the use of aversives for the plaintiffs' children who had already been subject to aversives in accordance with their IEPs as of the effective date of the amended regulations. Therefore, for the cleven (11) Alleyne students attending JRC, JRC may use aversive interventions for behaviors that are not limited to severe self-injurious and/or aggressive behaviors and may use the combined use of movement limitation and another aversive (e.g., mechanical restraints and use of shock). One other similarly situated student with aversives on a pre-existing IEP is not an Alleyne plaintiff. For this student, use of aversive interventions must be consistent with State requirements.

In addition to these regulations, in June of this year Governor Cuomo and the New York State Legislature passed the "protection of people with special needs act" (S.7749/A.10721), which included dramatic reforms to protect vulnerable persons in schools and other institutions. Among such reforms, that law required for the first time that all mandated reporters must report to a centralized hotline any incidents involving the "use of aversive conditioning." This new law will ensure that no facility, inside or outside of New York State, can use aversive interventions except upon a "person-specific authorization".

Further, in 2011 the Massachusetts Department of Developmental Services promulgated a regulation that bars JRC and all other schools in that state from using certain aversive interventions unless the child had a court-approved treatment plan permitting their use before September 1, 2011. See 115 Mass. Code Regs. 5.14 (2012).

The State's Office for People With Developmental Disabilities (OPWDD), which provides services to eligible New York residents with developmental disabilities, is currently in the process of identifying in-State placements for all of the New York residents at JRC who have aged out of educational funding and are being funded by OPWDD. Accordingly, we expect that by June of 2014 all of these residents at JRC, including those few who remain subject to court-approved aversive interventions, will be offered placements in New York State where such interventions are not authorized.

Finally, both the Governor's Office and the State Education Department continue to work constructively with the U.S. Department of Justice to address concerns raised by that Office regarding JRC's use of aversive interventions. We expect that those discussions may lead to additional actions to be taken with respect to JRC. We would be happy to provide additional information regarding that matter once it has been resolved.

Please let us know if you have any questions or require further information.

Sincerely,

James Introne

Deputy Secretary for Health & Director of Healthcare Redesign

See <a href="http://www.assembly.state.ny.us/leg/?sh=printbill&bn=A10721&term=2011">http://www.assembly.state.ny.us/leg/?sh=printbill&bn=A10721&term=2011</a>.