Informational and Supporting Documents
R.I. Senate Bill 0169 / House Bill 5290
April 2015

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CSC Advisory Board
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www.CytotoxicSafety.org
Presentation to the Committee:

Three Sources of Accidental Exposure to Hazardous Chemotherapy Drugs

Theresa L. O'Keefe, Ph.D.

Accidental exposure during hazardous drug preparation and administration:

- Restricted to highly trained medical personnel
  - Oncology Nurses and Pharmacists, Healthcare workers and Cleaning staff
- All drugs on the NIOSH Hazardous Drug list
- Contamination
  - Measured in employee's urine, changes in white blood cells and bladder cells
  - Increases in miscarriages, birth defects, cancer, negative skin and immune effects
    - Bone, breast and rectal cancers in Oncology Nurses
- Management - OSHA Hazardous Drug Policy
  - Drug administration and managing of excreted patients’ bodily fluids
  - Training and procedures
  - Protective equipment and medical devices
  - Profound reduction in contamination and damage to Oncology staff

Accidental exposure to patients’ bodily fluids during period of chemotherapy excretion:

- Only NIOSH hazardous drugs with high excretion rates
- Limited number of days after drug administration
- For oncology outpatients:
  - Spouses, children, grandchildren and friends provide CRITICAL support to patients
  - Trained home healthcare workers may use protective equipment
  - Family and associates don't know when to use any protective equipment
    - Great risk of cancer, miscarriages, birth defects, skin and immune effects
    - Extreme risk to pregnant women and young children
  - Lack of training and equipment means danger to family members and associates on par to oncology nurses prior to OSHA Hazardous Drug Policy

www.CytotoxicSafety.org
Case studies

- Level of cytotoxic drugs in urine of patients’ spouses higher than currently seen in oncology health care workers
- Extensive contamination in patients’ homes

_The need: easy to use system that quickly and safely captures and contains contaminated bodily fluids._

Environmental exposure:

- Areas of greatest risk
  - Septic system and well water or recreational water
  - Drinking water extraction from rivers downstream of municipal wastewater discharge
- Wastewater treatment poor at removing excreted chemotherapy drugs
  - Removes < 2% of excreted cyclophosphamide and ifosfamide
  - Covered by World Health Organization Safe Management of Wastes from Health-care Activities

_The need: simple system for the safe, responsible disposal of hazardous chemicals including contaminated septic wastes._
The Honorable Brian Patrick Kennedy  
Chairperson, House Corporations Committee  
Rhode Island General Assembly  
82 Smith Street  
Providence, RI 02903  
United States of America

Lyon, 10th March, 2015

Dear Mr Kennedy,

House Bill 5290

I regret that I am unable to be present at the hearing of this House Bill in person.

This hearing discusses an important topic in protecting cancer patients, carers and potentially the general public from exposure to cancer causing chemicals. Remarkable efforts continue to be made to identify human carcinogens which are causes of cancer in men and women. Once such causes have been identified, steps can be taken to avoid the exposure of populations wherever possible.

Chemotherapy drugs have been proven to cause second primary neoplasms in patients receiving them and once this had been identified, steps were initially introduced to avoid exposure to medical personnel in the preparation and delivery of these compounds. Many drugs are used to treat cancer and over 20 chemotherapy drugs, including widely used agents such as cyclophosphamide, doxorubicin, 5-FU and etoposide, cause patients receiving them to excrete identified human carcinogens in vomit, sweat, urine or faeces.

With the cancer burden increasing with the ageing of the population and the increasing tendency to give patients chemotherapy as out-patients, the potential for increasing numbers of individuals to be exposed to carcinogens in excreted material is increasing also. It is of considerable concern that systems for the collection of this carcinogenic waste outside the hospital environment are to the largest extent unavailable.

Guidelines have been prepared for hospitals, oncology doctors and nurses and cancer drug producers to avoid or minimise their exposure to these carcinogenic risks. When patients are sent home following treatment, advice is given to restrict use to one specified toilet to the patient or, if not possible, to 'flush' twice. This will reduce the exposure to patients and their carers but will not eliminate the potential exposure. In addition, it could be foreseen that there are circumstances in which failure to deal with this source of carcinogens could lead to wider exposure in communities.

Every step needs to be taken to reduce exposure to all known cancer causing agents. Accordingly, there is a need for action to eliminate exposure to known human carcinogens excreted in vomit, sweat, urine or faeces.

Yours sincerely,

Peter Boyle  
President
The Honorable Brian Patrick Kennedy, Chairperson  
House Corporations Committee  
Rhode Island General Assembly  
82 Smith Street  
Providence, RI 02903

Re: House Bill 5290

Dear Chairperson Kennedy:

I am writing to inform your committee of our support of House Bill 5290 which would provide for the disposal of human wastes contaminated by toxic chemicals due to the administration of cytotoxic chemotherapy drugs.

Our organization provides chemotherapy compounding services for major hospitals and treatment centers throughout the country. We take the threat of cytotoxic chemotherapy chemicals exposure very seriously; using OSHA and NIOSH safety protocol guidelines and regulations, we strive to ensure that the health risks to our employees are minimized as much as possible. **Patient’s families, caregivers, and our environment deserve these same protections.**

In the 2013 World Health Organization’s “Safe management of wastes from health-care activities,” the “Blue Book” of safe, sustainable and affordable management of healthcare waste, the responsibility of:

- Controlling cytotoxic waste falls on the Pharmacist
- Cost of containment of the waste to be paid for by those responsible for paying for healthcare activities

In 2012, the average cost of cancer treatment that includes chemotherapy is reported as $167,000. The cost of containing cytotoxic human waste will be minimal compared to the overall treatment costs. **However, the benefits of cancer prevention, through direct exposure in the home setting as well as through contamination of our drinking water supplies, are enormous.**

Cytotoxic chemotherapy drugs are already highly regulated in healthcare setting; a regulation gap exists for control in the home setting. Bill 5290 would provide the framework for crucial patient information and equipment to provide for the safe handling of these highly toxic chemicals.

Please contact me with any questions or concerns you may have.

Sincerely,

Burt Zweigenhaft
Vice Chairman
Onco360
410 Park Avenue, Suite 820
New York, NY 10022
Tel: 877.662.6633
Fax: 877.662.6355

www.CytotoxicSafety.org
March 3, 2015

The Honorable Brian Patrick Kennedy, Chairperson
House Corporations Committee
Rhode Island General Assembly
82 Smith Street
Providence, RI 02903

Re: House Bill 5290

Dear Chairperson Kennedy:

I am writing to inform your committee of our support of House Bill 5290 which would provide for the disposal of human wastes contaminated with toxic chemicals due to the administration of cytotoxic chemotherapy drugs.

I am one of the contributors on several chapters of the World Health Organization’s “Safe management of wastes from health-care activities,” the “Blue Book” as it is called on the safe, sustainable and affordable management of healthcare waste, published in August 2013.

This second edition clearly recommends the safe handling and disposal of waste urine, feces and vomit from patients, as they may contain potentially hazardous amounts of the administered cytostatic drugs or their metabolites, and which should be considered genotoxic for at least 48 hours and in some instances up to 1 week after drug administration.

Similar to needle and pharmaceutical disposal programs implemented in Rhode Island and many other states, the point of generation of these items has moved out of the acute care setting and into the community. This has been an area of concern for employees in healthcare facilities, and is now to caregivers in the homes of patients receiving chemotherapy as well as the family members of those patients.
The WHO publication noted above states:

“Any discharge of genotoxic waste into the environment could have disastrous ecological consequences.”

In 2013 and 2014, two studies were published that support the desperate need to control cytotoxic human waste from chemo patients:

- The patient’s chemotherapy drugs were found in the family member’s urine samples
- Significant surface contamination was also documented in the bathroom, with high levels on the floor
- Their conclusions were - “Exposure to the family members at home occurred from the contact with patient excreta containing the drugs.”

Because patients and family members are routinely misinformed of the dangers in their home environment, they are not able to protect themselves from exposure to cytotoxic chemicals, which are known to cause cancer, miscarriages, and birth defects, among other serious health issues. They must be provided a safe mechanism for disposing of the contaminated secretions and excretions to protect the family members as well as the environment.

The full reports can be accessed at www.CytotoxicSafety.org as well as various other important documents and studies that reinforce the need to close this regulation gap.

Please contact me with any questions or concerns you may have.

Sincerely,

Ed Krisiunas, MT(ASCP), MPH
President

2 Evaluation of surface contamination with cyclophosphamide in the home setting of outpatients on cancer chemotherapy Journal of Nursing Education and Practice, 2014, Vol. 4, No. 10
The Honorable Brian Patrick Kennedy, Chairperson
House Corporations Committee
Rhode Island General Assembly
82 Smith Street
Providence, RI 02903
USA

Re: House Bill 5290

Bohus-Björkó, March 4, 2015

Dear Mr. Kennedy,

I am writing to inform your committee of my support of House Bill 5290 which would provide for the disposal of human wastes contaminated by toxic chemicals due to the administration of chemotherapy drugs.

Let's first introduce myself.

I have studied chemistry (main subjects organic chemistry and toxicology) at the University of Nijmegen in The Netherlands. In November 1996 I received my PhD degree in Medical Sciences at the University of Nijmegen by defending my thesis ‘Monitoring of occupational exposure to antineoplastic agents’, a study financed by the Dutch Ministry of Social Affairs and Employment.

In 1995, I have founded Exposure Control B.V., a consulting company that offers methods for environmental and biological monitoring of occupational exposure to chemotherapy drugs and other pharmaceuticals in hospitals and in the pharmaceutical industry (sampling – analysis – advise). Exposure Control B.V. is continued in 2011 as Exposure Control Sweden AB as our family has moved permanently to Sweden. Exposure Control Sweden AB is involved in several projects worldwide. About 300 hospitals including 100 US hospitals have been monitored over the last 20 years. I am (co-)author of about 40 scientific publications regarding environmental and biological monitoring of occupational exposure to chemotherapy drugs.
In 2012, we have published a paper about exposure of family members to chemotherapy drugs via excreta of treated cancer patients. Although we have expected some exposure, the results were really astonishing and concerns me a lot. We have discovered that exposure of family members during a rather short period is higher than found in health care workers handling chemotherapy drugs for more than 10 years. Hence, I write this letter to support the House Bill to prevent family members, friends and healthcare workers from being exposed to chemotherapy drugs in home care situations. Sensitive groups such as babies, small children and pregnant women need special attention and need to be protected. The potential adverse health effects of exposure to chemotherapy such as cancer, miscarriages, and birth defects are well known.

I consider the House Bill as a first step but much more is needed such as a guideline with practical advices and suggestions. I would recommend to monitor the situation on Rhode Island to get an impression about the actual situation and make recommendations based on these field studies. If any support is needed, I am very willing to help as I really see the need to improve the situation. I think the situation in the US will not be different from Japan, where we did the study.

Please contact me with any questions or concerns you may have.

Sincerely,

Dr. Paul J.M. Sessink PhD

EXPOSURE CONTROL SWEDEN AB
Backsippevägen 2
SE-47537 Bohus-Björkö
SWEDEN

Tel: +46 (0) 702692260
Email: info@exposurecontrol.nl
Website: www.exposurecontrol.nl
Outline of Economic Impact of Requirement for Proper Cytotoxic Waste Disposal in the State of Rhode Island

The Cytotoxic Safety Council, a non-profit research corporation focused on the safe handling and disposal of dangerous chemotherapy drugs and cytotoxic waste, provides the following data and information which is intended to aid in a fiscal analysis of the impact of legislation requiring safe disposal of those wastes in Rhode Island, which has been introduced in both chambers of the General Assembly for consideration in the 2015 session (See House Bill 5290 and Senate Bill 0169).

The impact analysis should have three key components:

1. The cost to State of a requirement that insurers provided for proper disposal of cytotoxic wastes;
2. The savings realized by avoidance of statistically preventable cases of cancer and birth defects in Rhode Island;
3. The impact of job creation and growth on tax revenues and economic activity.

1. Expense to State:
   a. Rhode Island diagnosed 6370 cancer patients in 2013.1 The United States has 13.7 million cancer patients in any given year.2 Approximately 22% percent of these patients undergo a chemotherapy regimen in a given year.3 Of these, roughly 650,000 are receiving outpatient chemotherapy treatment.4 If Rhode Island has roughly 1/300th of the national caseload (which may be low given our older population) that represents 2,166 chemotherapy patients. If 90% of these patients are prescribed cytotoxic treatments as some component of their drug regimen that represents roughly 1950 patients per year in Rhode Island.
   b. The base cost of the protective protocols such as those offered by providers such as Rhode Island based Pharma-Cycle, Inc. is approximately $1200 per kit, although some patients will need a supplemental kit if the drug treatment has a longer secretion period. Therefore, we roughly estimate the average cost per patient regimen is $1,500.
   c. We then assume, based on experience in the field and discussions with prescribing doctors, that the average patient will receive three infusions over a typical course of treatment;
   d. Therefore those 1950 patients who should be following these protocols will add cost of approximately $8,775,000 to the system.
   e. Of those costs, we estimate (based on CMS reporting) that in excess of 60% are paid by Federal Medicare and Medicaid and 10% from Veterans Administration/DOD funds. If these assumptions are correct as applied to Rhode Island, we would estimate new costs to the Rhode Island health care system, private and public, of approximately 30% or $2,632,500 per year shared by Blue Cross, United Healthcare and Tufts and the State of Rhode Island.
2. Cost Savings: The long term cost over ten years of not acting will be $414,000,000 in avoidable healthcare expenses for treating increased incidences of cancer, reproductive and developmental problems, allergic reactions and other adverse effects, some of which are irreversible even after low-level exposures.  

   a. Even if we only consider increased incidences of cancer, and even if we only assume that current lax protocols lead to 1 case in every 50 instances of exposure, the avoidable costs are overwhelming.

   b. Using the same number of Rhode Island patients – 1950 - estimated above to be undergoing cytotoxic treatments each year, and further estimating that these patients interact with an average of four caregivers or relations outside the currently protected hospital environment in a manner that would cause exposure to these chemicals, that means 7,800 Rhode Islanders are unknowingly put at risk each year.  If only 1 in 50 of these exposures were to lead to a future cancer diagnosis, that still represents 156 avoidable cancer cases in our state.

   c. At an average treatment cost of $167,856 per patient that reflects a recurring burden on our healthcare system in the range of over $26,000,000 each year, of which roughly $7,850,000 will fall on Rhode Island premium and tax payers.  With expected health care cost escalations of 10% per year, this yields a total impact of over $414,000,000 in the next decade.  Again, this is for cancer cases alone, and ignores the costs of birth defects, developmental problems, allergies and other attributable harms.

3. New Tax Revenues: Job Growth will yield additional revenue to the state as follows:

   a. At full build out, 400 jobs, of which 200 are full-time equivalent jobs (as the state defines them) paying over $42,000 per year.

   b. This should initially net the state roughly $1,300,000 in income tax revenue per year, with additional organic growth over the next ten years resulting in $20,000,000 in new state revenues.

   c. In addition, significant tax revenue would be generated from construction costs and labor related to build out of facilities to service new disposal needs.  We would expect that despite the new costs to the health care system, the state would see an initial revenue bump in years one and two from these sources.

Summary:

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<tr>
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<th>Annually</th>
<th>10 Year Term</th>
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<tr>
<td>Cost to Health Care System:</td>
<td>$8,775,000</td>
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<tr>
<td>Savings to Health Care System</td>
<td>$26,000,000</td>
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<tr>
<td>New Job Based Tax Revenue:</td>
<td>$1,300,000</td>
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<td><strong>Net Positive Fiscal Impact :</strong></td>
<td><strong>$18,525,000</strong></td>
<td><strong>$295,000,000</strong></td>
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1 American Cancer Society Facts and Figures 2014.
6 2012 National Institutes of Health figures.
7 All figures are estimated.
Theresa O’Keefe, Ph.D.
CSC Board of Advisors, Middletown, R.I.

Dr. O’Keefe has over 25 years in Immunology and Molecular Biology, Drug Discovery and Development as well as innovative water cleaning solutions. Following a Ph.D. at Tufts, and academic work at the MRC Lab Molecular Biology, Cambridge, UK, Dr. O’Keefe was recruited to biotech to drive the creation of Therapeutic Antibodies (LeukoSite, Millennium, Critical Therapeutics, Pfizer).

Her work included safe therapeutics for acute and chronic diseases, such as RA, sepsis, Crohn’s and psoriasis, as well as multiple types of cancer. Successes include many therapeutic drugs including Millennium’s Campath for chronic lymphoid leukemia and Vedolizumab for Crohn’s Disease.

In addition, Dr. O’Keefe co-founded Waltham Technologies to develop water cleaning to energy production processes. She is co-inventor of more than 25 patents and patent applications.

Peter Boyle, Ph.D.
President of the International Prevention Research Institute, Lyon, France

Mr. Boyle is internationally known for his research in epidemiology and disease prevention. He led the EUROCAN+PLUS project for the European Parliament which developed priorities for coordination of cancer research in Europe and was Editor of the World Cancer Report 2008 and the State of Oncology 2013 which highlighted the growing global cancer crisis.

Previous appointments include Director of the International Agency for Research on Cancer (IARC/WHO), President of the International Prevention Research Institute in Lyon and epidemiology posts in Milan and Boston.

He was a Member of the European Cancer Advisory Board and worked as scientific advisor to the European Commission on the European Tobacco Contents Directive which became law in 2012. He was also responsible for the revisions of the European Code Against Cancer.

Burt Zweigenhaft
Vice Chairman, Onco360, New York, N.Y.

Since joining Onco360 in 2007, Mr. Zweigenhaft has helped the company grow from being a single oncology pharmacy serving several hundred oncologists in the New York City region, to the fastest-growing, privately-held comprehensive oncology pharmacy solutions provider in the nation, serving more than oncologists, payers, pharmaceutical manufacturers, hospitals, and health systems nationwide.

Mr. Zweigenhaft has extensive experience across a broad spectrum of pharmaceutical and healthcare service markets including wholesale, retail, chain, mail service, PBM, specialty, infusion, oncology, disease management, managed care, Medicare, Medicaid, genetic diagnostics and health informatics.

He is regularly invited to speak at national conferences on the shifting and transitional cancer care services channel and is frequently quoted in the trade press. He currently co-chairs the Value-Based Managed Care Pharmaceutical Care Organization, serves on the editorial advisory boards of several oncology publications.
Ed Krisiunas, MT (ASCP), MPH
President WNWN Int., Inc., Burlington, C.T.

Mr. Krisiunas has been an expert in the health care waste management industry for 32+ years of experience in the sector. He is one of the contributors to the second edition of the World Health Organization’s “Safe Management of Wastes from Healthcare Activities,” often referred to as “The Blue Book.”

He has worked with many international health and environmental agencies, including the U.S. Agency for International Development (USAID), United Nations Development Programme Global Environment Facility (UNDP GEF), World Bank, German Development Bank, International Finance Corporation (IFC).

His consulting firm, WNWN International, specializes in the areas of health care waste management, infection prevention, and occupational safety for health care. He has traveled to over 50 countries on various projects and presentations/conferences related to:

- Evaluation of medical waste treatment technologies
- Microbiological efficacy testing of health care waste treatment technologies
- Development of guidance documents on the selection of treatment technologies
- Management of pharmaceutical/chemotherapeutic waste
- Management of electronic waste
- Development and implementation of national medical waste plans
- Safe Injection Practices

Paul JM Sessink, Ph.D.
Founder, Exposure Control, Bohus-Bjorko, Sweden

Dr. Sessink founded Exposure Control in 1995. He has published dozens of peer-reviewed studies and is considered an international expert in biological monitoring of occupational exposure to antineoplastic agents.

He studies organic chemistry and toxicology at the University of Nijmegen in The Netherlands. He received his Ph.D. in Medical Sciences at the University of Nijmegen by defending his thesis “Monitoring of occupational exposure to antineoplastic agents.”

Exposure Control is a consultancy firm that monitors occupational exposure to antineoplastic agents and advises hospitals and the pharmaceutical industry in the United States and the European Union. Dr. Sessink has recently been an author on a shocking new study documenting the contamination of chemotherapy patient’s family members and surfaces in the home setting.
### Problem Chemotherapy Drugs

These drugs are excreted at high concentrations* and can cause serious and often irreversible illness, including cancer, birth defects, and miscarriages. Details regarding excretion rates can be found at: [www.CytotoxicSafety.org/problem-chemo-drugs](http://www.CytotoxicSafety.org/problem-chemo-drugs)

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<tr>
<th>Drug Name</th>
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<td>Actinomycin D</td>
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<td>Bleomycin</td>
<td>Epirubicin</td>
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<td>Idarubicin</td>
<td>Temozolomide</td>
<td>Valrubicin</td>
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* Drug information is gathered from the Drug Package inserts; this information is required by the FDA from pharmaceutical companies before each drug is approved for use in humans.

### Creating Awareness

There is a shocking lack of awareness about the risk of exposure to cytotoxic chemotherapy drugs in the home setting and the serious and often irreversible consequences to humans and the environment. Our website provides information, studies, and reports from health and environmental experts from around the world, including:

- The World Health Organization (WHO)
- Occupational Safety & Health Administration (OSHA)
- National Institute for Occupational Safety and Health (NIOSH)
- Centers for Disease Control and Prevention (CDC)
- U.S. Geological Survey (USGS)
- R.I. Department of Environmental Management (RI DEM)
- Barnstable County Department of Health, Massachusetts
- European Commission (EC)
- American Chemical Society (ACS)
- Society of Environmental Toxicology and Chemistry (SETAC)
Exposure of family members to antineoplastic drugs via excreta of treated cancer patients

Methods: Two patients were administered cyclophosphamide by i.v. bolus injection. One patient was administered 5-fluorouracil by i.v. bolus injection and thereafter immediately administered the same drug by continuous infusion for 46 h. Urine samples from the patients administered cyclophosphamide and their family members, and wipe samples from their home environment, were analysed for the unchanged form of cyclophosphamide. For 5-fluorouracil, the urine samples from the patient and the family member were analysed for the 5-fluorouracil metabolite a-fluoro-b-alanine. Wipe samples were analysed for 5-fluorouracil. Drugs were detected and quantified with gas chromatography in tandem with mass spectroscopy-mass spectroscopy or by high-performance liquid chromatography with ultraviolet-light detection.

Results: A total of 35 and 16 urine samples were collected from the three patients and their family members, respectively. The drugs were detected in all samples. Cyclophosphamide was detected at levels of 0.03–7.34 ng/cm² in 8 of the 12 wipe samples obtained from the homes of the patients administered cyclophosphamide. For the patient administered 5-fluorouracil, drug levels in his home environment were below the limit of detection.

Conclusion: We demonstrated contamination of the home setting and exposure of family members to cyclophosphamide via the excreta of outpatient receiving chemotherapy. Exposure of the family member of the patient administered 5-fluorouracil was also demonstrated. These findings indicate the importance of strict precautions by the members of treated cancer patients as well as healthcare workers, to reduce the risk of exposure to antineoplastic drugs.

Evaluation of surface contamination with cyclophosphamide in the home setting of outpatients on cancer chemotherapy

Abstract

Purpose: To monitor the urinary excretion of cyclophosphamide by five patients during the first 48 hours after cyclophosphamide administration and to evaluate surface contamination with cyclophosphamide in the patients’ homes via their excreta 48 hours after the completion of chemotherapy.

Methods: Urine samples were taken from five female patients with breast cancer at their homes during the 48 hours after administration of cyclophosphamide. Wipe samples were also collected from their home settings. All samples were analyzed for cyclophosphamide using gas chromatography with mass spectroscopy-mass spectrometry.

Results: Fifty-three urine samples were collected from the five patients during two days after cyclophosphamide treatment. Cyclophosphamide was positive in all urine samples. The quantity of cyclophosphamide excreted in each urine sample ranged from 0.09 to 65.99 mg. The urinary excretion of cyclophosphamide accounted for 9%–34% of the dose for four of the patients. Cyclophosphamide was measured at levels of 0.01–8.35 in 17 of the 28 wipe samples from all five patients. The areas contaminated with cyclophosphamide, common to all patients, were the toilet seat (0.04–8.35 ng/cm²) and the toilet floor (0.08–1.53 ng/cm²).

Conclusions: Surface contamination of the home settings of outpatients treated with cyclophosphamide was demonstrated 48 hours after cyclophosphamide administration. Contamination of the home setting with antineoplastic drugs administered to outpatients risks exposure to family members.