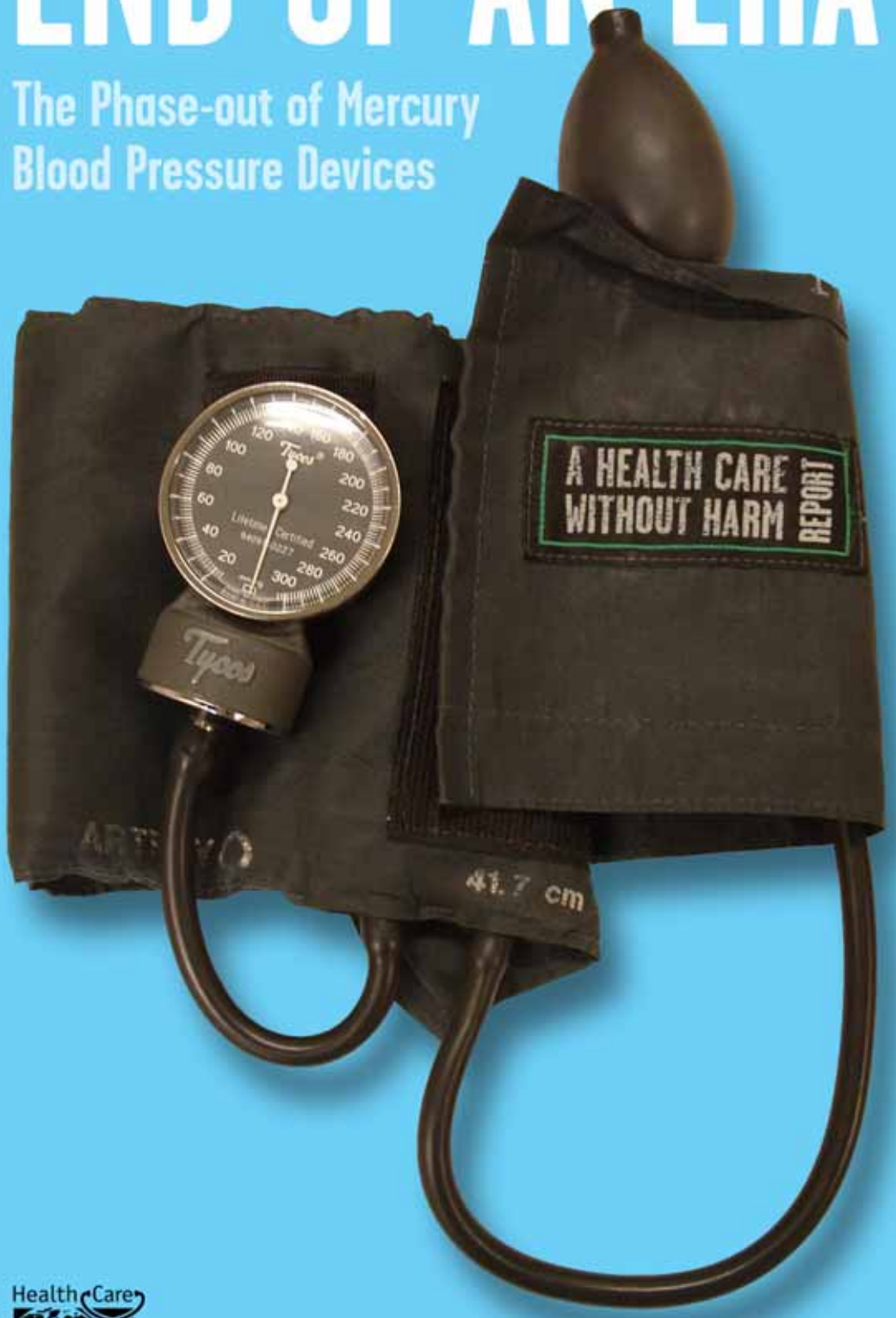
# END OF AN ERA

## The Phase-out of Mercury Blood Pressure Devices




Health Care Without Harm

# END OF AN ERA

## The Phase-out of Mercury-Based Blood Pressure Measurement Devices in the United States and its Implications for Europe and the Rest of the World

A Health Care Without Harm report

Health Care Without Harm

# END OF AN ERA

TABLE OF CONTENTS




This report was written by Jamie Harvie, PE and Joshua Karliner, Health Care Without Harm


Health Care Without Harm is an International Coalition for more than 400 organizations in 52 countries working for a health care sector that does no harm to people, communities and the environment.


September 22, 2008

www.noharm.org

# PART ONE
# INTRODUCTION

The European Parliament has mandated a review of the technical and economic feasability of alternatives to mercury column sphygmomanometers--medical devices used to measure blood pressure.

This brief report provides an overview of the tremendous success the US healthcare community has experienced in delivering safe, accurate, affordable mercury-free blood pressure measurement. We hope it will benefit the deliberations in the EU.

Mercury is a naturally occurring heavy metal that is linked to numerous health effects in wildlife and humans. At ambient temperature and pressure, mercury is a silvery-white liquid, though it can readily vaporize and may stay in the atmosphere for up to a year. When released to the air, mercury is moved by global transport processes and deposited globally. Mercury ultimately accumulates in lake bottom sediments, where it is transformed into a more toxic form, methyl mercury, which builds up in fish tissue.[1]

Mercury is a potent neurotoxin, a global priority pollutant and a PBT -a persistent bioaccumulative and toxic chemical. Mercury is a neurotoxin, meaning that it damages the central nervous system. Exposure to it can adversely affect the brain, spinal cord, kidneys and liver. Mercury easily crosses the placenta, passing from mother to unborn child, where it can impair neurological development of the fetus.[2]

A July 2000 US National Academy of Sciences (NAS) report indicates that more than 60,000 children may suffer from exposure to methylmercury while in-utero. According to the US Centers for Disease Control, 1 in 8 women in the United States have a blood mercury level high enough to impact fetal development.[3]

In 1997 a United States Environmental Protection Agency (EPA) study found that medical waste incinerators were the fourth largest source of anthropogenic mercury emissions to the US environment.[4] In 1998, the US EPA and the American Hospital Association (AHA) signed a Memorandum of Understanding (MOU) to address health care's contribution to mercury pollution and called on the nation's hospitals to virtually

eliminate mercury. Since 1998, Health Care Without Harm has been working with EPA, AHA, allied organizations and our health care partners to reduce and eliminate mercury use in healthcare in the US.

As a result, over the last decade we have witnessed the progressive phase-out of the use of mercury-based medical devices from the US healthcare community both through voluntary initiatives and legislative mandates.

The major US health care institutions consulted for this report have had few, if any concerns about the accuracy or affordability of the alternatives. Or as Kathy Gerwig, Vice President for Kaiser Permanente, a multibillion dollar, 37 hospital group, puts it, “In the years since we made the change to mercury-free (aneroid) devices, we have not had any issues with accuracy or other complaints.”

We are similarly witnessing movement in the developing world. For instance, the Philippines has just set into motion a two-year plan to completely phase-out mercury-based medical devices. Health care systems in Argentina, Brazil and Mexico are replacing thermometers and sphygmomanometers with alternatives. The vast majority of blood pressure devices purchased by Cuba are aneroid (non-mercury). In South Africa, the province of Kwa Zulu Natal is also successfully replacing mercury-based blood pressure devices.[5]

These initiatives are all coming together under the umbrella of a global partnership, co-led by the World Health Organization and Health Care Without Harm to eliminate 70% of mercury based-medical devices globally by 2017.

What’s more, the United Nations Environment Programme, at the behest of the European Union and others, is debating whether to negotiate a global treaty to phase-out mercury across a diversity of economic sectors.

We have also witnessed the substitution of mercury-based medical devices in European countries such as Sweden, as well as in individual hospitals in countries ranging from France to Austria, to the United Kingdom. But Europe lags behind the United States in addressing the human and environmental health risks associated with the production, transport, use and disposal of mercury blood pressure devices.

The EU has the opportunity to help lead the world toward mercury-free health care by making the right decisions and mandating the phase-out of production and export of mercury-based blood pressure devices with accurate, safer and affordable alternatives.

The EU can help lead the world toward mercury-free health care.

# PART TWO
# SUMMARY OF FINDINGS

## 1. THE EUROPEAN PARLIAMENT HAS MANDATED A REVIEW ON THE FEASABILITY OF ALTERNATIVES TO MERCURY SPHYGMOMANOMETERS BY OCTOBER 2009.[6]

> Of all mercury instrumentation used in health care, the mass of mercury deployed in mercury column sphygmomanometers (80 to 100g/unit) make them collectively one of the largest mercury reservoirs in the health care setting.

> The sphygmomanometer is also one of the most challenging devices to eliminate because of perceived or real issues with regard to the cost and accuracy of the alternatives.

> Health Care Without Harm decided to document the experience of the US health care sector in addressing this question over the last decade to help inform the debate in the EU.

> We found that the US healthcare community has experienced tremendous success in delivering safe, accurate, cost-effective mercury-free blood pressure measurement.

## 2. THE US LEADS THE EUROPEAN UNION IN ADDRESSING THE PROBLEM OF MERCURY IN HEALTH CARE.

> In both the US and the EU, mercury thermometers are nearly completely phased out. In the US, this has been achieved largely through voluntary and state-level legislation. In Europe, this has been achieved through an EU-mandated ban.

> However, blood pressure devices (sphygmomanometers) are another story. While some countries, such as Sweden, have successfully eliminated mercury-based blood pressure devices, and a number of hospitals throughout the EU have done the same, the US health care system is, based on available information, well out in front of the EU in this area of environmental health.

> This situation could change if the EU mandates a phase-out of mercury sphygmomanometers sales and export.

## 3. HUNDREDS OF US HOSPITALS HAVE SUCCESSFULLY PHASED-OUT MERCURY SPHYGMOMANOMETERS WITH ALTERNATIVES. THEY REPORT LITTLE OR NO PROBLEM WITH THE TRANSITION.

> By 2001, over 600 hospitals had committed to end their use of mercury in healthcare through a pledge developed by HCWH.

> In 2002, Practice GreenHealth (formerly Hospitals for a Healthy Environment, h2E) began an award program, the *Making Medicine Mercury Free Award*, for those hospitals that had virtually eliminated their use of all mercury. To date, over 250 hospitals have received this award.

> According to a 2005 survey of 554 health care facilities conducted by the American Hospital Association, 73 percent of respondents had removed all mercury sphygmomanometers.[7]

> Hospitals and hospital systems representing over 80 medical centers and more than 200,000 employees have provided HCWH with letters that detail the success of their mercury elimination programs.

## 4. GROUP PURCHASING ORGANIZATIONS (GPOS) SERVING THOUSANDS OF US HOSPITALS NO LONGER PROCURE MERCURY-BASED MEDICAL DEVICES.

> GPOs represent over $52 billion or 96 percent of all contract health care purchases made in the U.S.[8]

> In a 2005 survey of GPOs, three of the five largest USGPOs had implemented mercury-free purchasing policies that ban items from contracts except where a non-mercury alternative is not available.[9]

> Overall, the sales of mercury-containing devices are decreasing, and those of non-mercury alternatives are increasing in the United States. During this market shift, GPOs have not experienced a decrease in total sales, which seems to indicate that consumers are not simply buying mercury-containing items from other vendors.

> This year, two of the largest GPOs in the United States sent letters to HCWH highlighting the market transformation away from mercury blood pressure devices.

## 5. TWELVE US STATES ARE PHASING OUT MERCURY SPHYGMOMANOMETERS VIA LEGISLATIVE MANDATES

> In addition to voluntary initiatives undertaken by hospitals, health care systems and purchasing organizations, several state governments have pursued a legislative approach.

> Eleven States -the members of the Interstate Mercury Education and Reduction Clearinghouse (IMERC)- have enacted legislation regulating the sale and distribution of mercury-added sphygmomanometers.

> Three States -Rhode Island, Louisiana and Connecticut- have effectively banned mercury-based blood pressure devices by restrictions on the sale of products by mercury content.

> The other eight -California, Illinois, Maine, Massachusetts, Minnesota, New Hampshire, Vermont, and Washington- have restricted sphygmomanometer sales by name.

> In addition, the state of Michigan, which is not a member of IMERC, has enacted a ban on the sale of mercury-added sphygmomanometers, effective January 1, 2009.

> Together, these states account for approximately 30 percent of the U.S. population.

> Overall, between 2001 and 2007, the total amount of mercury sold in sphygmomanometers, as reported to IMERC-member states, has decreased by approximately 60 percent.

## 6. MANUFACTURERS, RESPONDING TO SHIFTING DEMAND, ARE PRODUCING THE ALTERNATIVES

> Two of the former leading US based mercury blood pressure device manufacturers, Welch Allyn and Trimline Medical, have ended their production of mercury blood pressure devices.

## 7. PEER REVIEWED SCIENTIFIC STUDIES SHOW THAT THE ALTERNATIVES ARE ACCURATE

> Peer reviewed literature from the last decade shows that aneroid and digital sphygmomanometers are just as accurate as mercury-based devices.

> Mercury and non-mercury blood pressure devices provide accurate measurement as long as instruments are calibrated.

> It is imperative that the healthcare community and governments ensure that alternative devices are purchased from manufacturers that follow techniques and testing protocols that are independently certified.

> After considering the scientific evidence, a report produced by the World Health Organization (WHO) department addressing cardiovascular diseases concluded in 2005 that even in low resource settings, “in light of the toxicity of mercury, it is recommended that mercury blood pressure measuring devices be gradually phased out in favour of affordable, validated, professional electronic devices.”[10]

> WHO also points out that “international protocols for blood pressure measuring device validation have been released by the Association for the Advancement of Medical Instrumentation, the British Hypertension Society, and the European Society of Hypertension Working Group on Blood Pressure Measurement.”

# PART THREE
# IN THEIR OWN WORDS: QUOTES FROM US HEALTH CARE LEADERS ON MERCURY FREE BLOOD PRESSURE DEVICES

*"In the years since we made the change to mercury-free (aneroid) devices we have not had any issues with accuracy or other complaints."*

—Kathy Gerwig, Vice President, Workplace Safety and Environmental Stewardship Officer, Kaiser Permanente (A healthcare provider and HMO with 156,000 employees, 13,729 physicians, 37 medical centers, 400 medical offices, and $34.4 billion in annual operating revenues and $1.3 billion in net income)

*"In the more than three years that we have made the changes to aneroid units, and digital blood pressure units, we have not had any issues with accuracy ...I hope ... that you will be convinced as we were, that it is in the best interest of all concerned to eliminate mercury sphygmomanometers"*

—Nancy Mulvihill, Vice President, Covenant Health Systems (a not-for-profit, Catholic health and elder care system serving New England with over 6000 employees)

*“ I am writing to share our successful experience in the elimination of mercury blood pressure devices... As our experience has demonstrated, cost effective viable alternatives to mercury blood pressure measurement are available in the marketplace.”*

—Mary Ellen Leciejewski, OP, Catholic Healthcare West (a not-for-profit health care system composed of 41 hospitals, 68 clinics and 9 trauma centers)

*“Our Biomedical department does a random survey on 1% of our aneroid manometers each year. In the 7 years we have been doing this, none of the aneroid units surveyed has been outside of the manufacturers + - 2mm standard.”*

—Bruce E. Cunha RN, MS, COHN-S, Marshfield Clinic (a large, multi-clinic system with 7500 employees and 730 providers)

*“As our experience with our hospital members has demonstrated, cost effective viable alternatives to mercury blood pressure devices are available... We support the goal of mercury free healthcare and believe efforts by the European Union to phase-out the sale and export of mercury blood pressure devices will be an important step for human health and the environment.”*

—John W. Strong, President and CEO, Consorta (A Group Purchasing Organization serving more than 500 acute care 250 extended care facilities across the US).

*“Premier has demonstrated our support of the effort to eliminate mercury in healthcare settings for more than 7 years... Premier contracts no longer include mercury containing thermometers or sphygmomanometers.”*

—Gina Pugliese, Vice President, Premier Safety Institute (A Group Purchasing Organization serving more than 2,000 U.S. hospitals and 53,000-plus other healthcare sites)

# PART FOUR
# ACCURACY OF MERCURY, ANEROID AND DIGITAL BLOOD PRESSURE DEVICES

Mercury is the only common liquid metal. Its usefulness stems from its unique combination of weight, ability to flow, electrical conductivity, chemical stability, high boiling point and relatively low vapor pressure. For over one hundred years, mercury was the ideal choice for use in medical devices that measure temperature (thermometers) and pressure (sphygmomanometers), and in other applications where density and flexibility were needed (esophageal dilators).

Of all mercury instrumentation used in health care, the mass of mercury used in mercury sphygmomanometers (80 to 100g/unit), collectively make them one of the largest mercury reservoirs in the health care setting. By choosing a mercury free alternative, a health care institution can have a tremendous impact in reducing the potential for mercury exposure to patients, staff and the environment.

Some medical professionals still consider mercury to be the "gold standard," for measuring blood pressure. Yet, as peer reviewed studies from the last decade demonstrate, this is not, and probably never was true.

Mercury and non-mercury blood pressure devices provide accurate measurement as long as both instruments are calibrated. Examples of both inaccurate mercury and mercury-free sphygmomanometers can be found in the medical literature, though this inaccuracy is typically related to poor maintenance and calibration.[11] A large number of scientific studies have concluded that mercury-free measuring devices produce the same degree of accuracy as mercury devices, provided they are properly maintained and calibrated. For instance, a study at the Mayo Medical Centre concluded that aneroid sphygmomanometers provide accurate pressure measurements when a proper maintenance protocol is followed.[12]

A US study from 2003 concluded in summary that "research on sphygmomanometers suggests that there are numerous good alternatives to mercury sphygmomanometers. Aneroid sphygmomanometers are cost competitive, have a long history in the field, and have been found acceptable by many hospitals."[13]

In a UK study, an aneroid device achieved an A grade for both systolic and diastolic pressures and fulfilled the requirements of the Association for the Advancement of Medical Instrumentation. The conclusion was that the aneroid device could be recommended for use in an adult population.[14]

The UK Medicines and Healthcare Products Regulatory Agency (MHRA) states that aneroid

and mercury sphygmomanometers both need to be checked regularly in order to avoid errors in blood pressure measurement; the British Hypertension Society recommends testing every 6 to 12 months.[15]

Frequently lost in the discussion over device accuracy, and equally important is the issue of measurement technique. A 2002 Working Meeting on blood pressure measurement in the United States highlighted numerous studies which found that basic measurement technique and inappropriate cuff size were providing significant errors in measurement.[16]

Both mercury and aneroid sphygmomanometers use the ausculatory technique, and have been in use for about 100 years; when maintained and calibrated, either gives accurate results.[17] Both devices are required to meet voluntary standards for accuracy set by the Association for the Advancement of Medical Instrumentation (AAMI). Examples of both inaccurate mercury and mercury-free sphygmomanometers can be found in the medical literature, though this inaccuracy is typically related to poor maintenance and calibration. Both mercury and aneroid sphygmomanometers require maintenance and give accurate results when properly calibrated. Other alternatives include automated blood pressure measuring devices and hybrid sphygmomanometers.

A 2005 report by the WHO on blood pressure measuring devices for low resource settings concluded that both aneroid and mercury devices -which use the ausculatory technique- were prone to inaccuracies. Therefore, "given the inaccuracy of the auscultatory technique, validated and affordable electronic devices, that have the option to select manual readings, appear to be the preferred option for low resource settings.[18]

Switching to mercury free sphygmomanometers in clinical settings has not caused problems in clinical diagnosis and monitoring in Sweden. The Swedish government, in fact, has completely eliminated mercury column sphygmomanometers.[19]

Many non-mercury devices satisfy the criteria of professional organizations such as the British Hypertension Society, the European Hypertension Society and the Association for the Advancement of Medical Instrumentation. The British Hypertension Society (BHS) has created a list of vendors of sphygmomanometers that have met the BHS criteria and are suitable for clinical practice.[20]

According to WHO, regularly updated information on the state of the market and on devices that have passed a validation test according to international protocols is available by dabl® Educational Trust, an independent, not-for-profit educational organization (www.dableducational.com), as well as by the French agency of medical devices (AFFSSAPS) (http://afssaps.sante.fr)

Mercury and non-mercury devices provide accurate measurement when they are calibrated.

Many non-mercury devices satisfy the criteria of Europe's professional organizations.

# PART FIVE
# CONCLUSIONS AND RECOMMENDATIONS

While tremendous progress has been made, there is still work to be done to virtually eliminate mercury from healthcare. The European Union can help lead this global effort.

As the European Union addresses a potential mercury blood pressure device ban, it is imperative that the examples and call to action from healthcare professionals around the globe are heard. Moreover, the years of safe, effective mercury free blood pressure medicine practiced in the United States provide ample evidence for the viability and safety of mercury free alternatives.

The letters contained in the Annex of this report are consistent with the experience in Sweden's healthcare sector, outlined in the conclusions of a 2005 report o by the Swedish Chemical Inspectorate, KEMI.

*The conclusions that can be drawn from contacts with a broad array of people with a deep knowledge in the area of blood pressure measuring in conjunction with up to date peer reviewed scientific studies are:*

■ *There were only positive experiences reported from the phase out of mercury in the most wide spread equipment called sphygmomanometers, which today is complete.*

■ *No negative medical, practical or economic experiences were found from the phase out of mercury containing sphygmomanometers.*

■ *There are no problems in diagnosing any condition using non-mercury sphygmomanometers including in the presence of arrhythmias, preeclampsia and in accelerated (malign) hypertension….*[21]

No negative medical, practical or economic experiences were found from the phase out of mercury containing sphygmomanometers.

*Swedish Chemicals Inspectorate*

# ANNEX
# LETTERS FROM US HEALTH CARE PROVIDERS DOCUMENTING THEIR EXPERIENCE WITH MERCURY-FREE HEALTH CARE

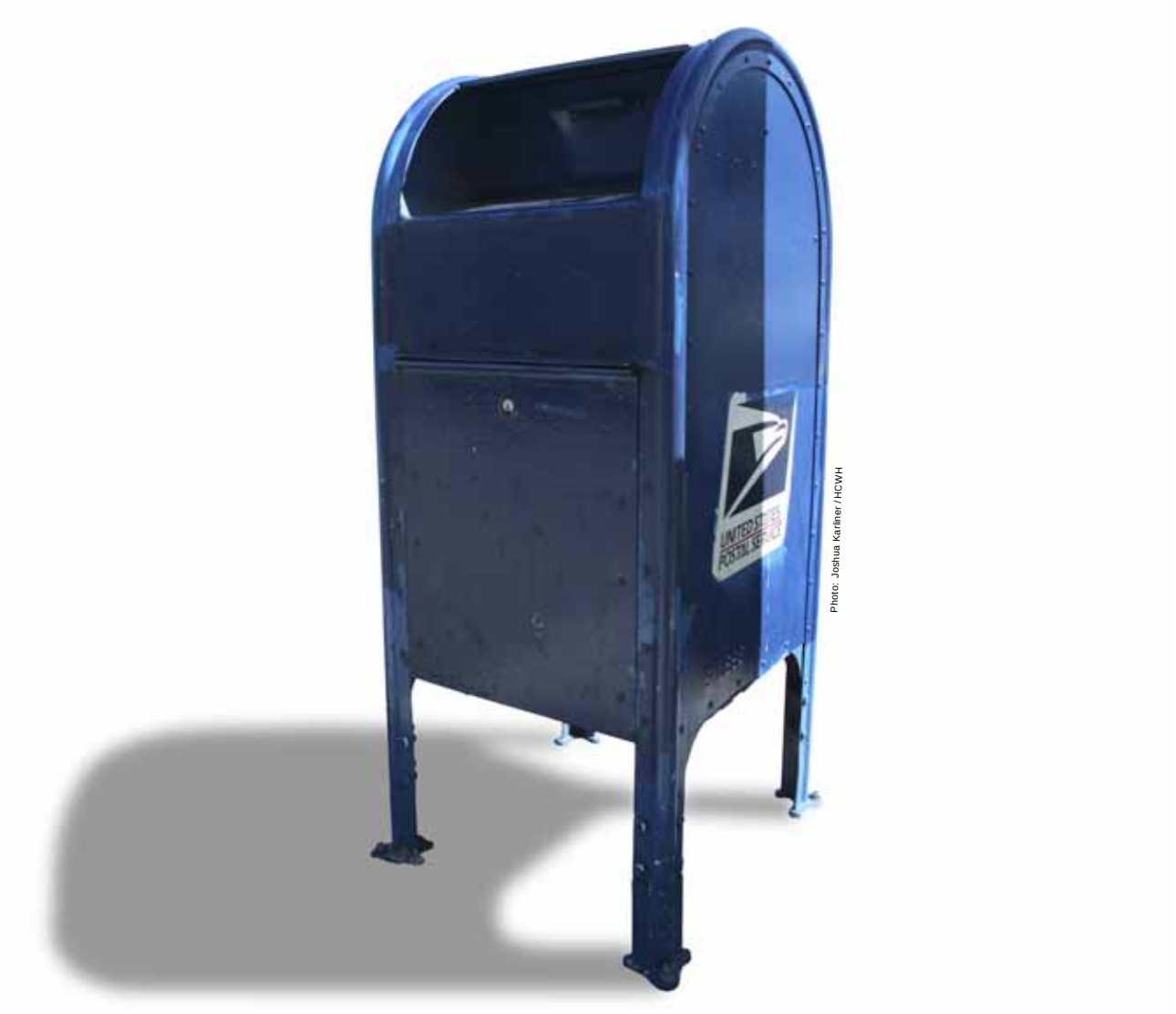


Photo: Joshua Karliner / HCWH

KAISER PERMANENTE®

Kaiser Foundation Health Plan, Inc.

Lisette van Vliet, Ph.D.
Toxics Policy Advisor
Health Care Without Harm Europe
28 Boulevard Charlemagne, B-1000 Brussels

August 1, 2008

Dear Dr. van Vilet:

As you explore phasing out the use of mercury-containing blood pressure devices in Europe, I am writing to share our successful experience in the elimination of mercury sphygmomanometers in our organization.

Kaiser Permanente is a not-for-profit group practice prepayment program headquartered in Oakland, California serving 8.7 million members in nine states and the District of Columbia. We operate 32 hospitals and 420 outpatient medical centers. In 2007, operating revenues were $37.8 million.

We are proud to have been one of the first signatories to the "Making Medicine Mercury Free" Campaign in 2001. We are now virtually mercury-free as a result of a five-year process to replace all mercury devices and products throughout our facilities nationwide.

Of all mercury instrumentation used in health care, the mass of mercury used in mercury sphygmomanometers (80 to 100g/unit), and their widespread use, collectively make them one of the largest mercury reservoirs in the health care setting. Choosing a mercury free alternative has a significant impact in reducing the potential for mercury exposure to patients, staff and the environment.

In a study done by Kaiser Permanente it was determined that when associated lifecycle costs are included (compliance, liability, training, etc.) the total cost per unit of an aneroid sphygmomanometer is about 1/3 that of a mercury-containing device.

In the years since we made the change to mercury-free (aneroid) devices we have not had any issues with accuracy or other complaints.

Sincerely,

K Gerwig

Kathy Gerwig
Vice President, Workplace Safety and
Environmental Stewardship Officer

Cc: Raymond Baxter, PhD, Kaiser Permanente
Jamie Harvie, Health Care Without Harm

Program Offices
One Kaiser Plaza
Oakland, California 94612
(510) 271-5910

COVENANT
HEALTH
SYSTEMS
*Our name is our promise*

420 Bedford St.
Lexington, MA
02420-1527

tel 781 862 1634
fax 781 862 5477

http://www.
covenanths.org

July 29, 2008

Lisette van Vliet, Ph.D.
Toxics Policy Advisor
Health Care Without Harm Europe
28 Boulevard Charlemagne, B-1000 Brussels

Dear Dr. van Vliet,

Covenant Health Systems has been asked to document for you our medical facilities' mercury sphygmomanometer elimination program.

Covenant Health Systems is a not-for-profit, Catholic health and elder care system serving New England with over 6000 employees. We joined with H2E in 2004 and committed to the removal of mercury from our system, including mercury sphygmomanometers. As Catholic healthcare providers committed to the health of our community, we knew this was the right thing to do.

When the facility managers from our 14 facilities were presented with the facts, they immediately went to work and implemented Covenant's commitment to the H2E pledge. If cost was ever presented as an issue, we knew that explaining the cost, both in terms of dollars and health, would allay the financial fears. (Spills can cost between $1,000 and $4,000 to clean up; while human health cannot be measured in dollars.)

We also knew from various studies, and our colleagues, that for the majority of blood pressure readings, an aneroid unit was well within accepted limits for variation of blood pressure. In the 3+ years that we have made the change to aneroid units, and an increasing number of digital blood pressure units, we have not had any issues with accuracy or other complaints.

I hope this information will help in answering some of the issues you may also be experiencing and that you will be convinced, as we were, that it is in the best interest of all concerned to eliminate mercury sphygmomanometers.

Yours truly,

Nancy Mulvihill

Nancy Mulvihill, Chair
Environmental Stewardship Committee

Catholic Healthcare West

August 12, 2008

Lisette van Vilet, Ph.D.
Toxics Policy Advisor
Health Care Without Harm Europe
28 Boulevard Charlemagne, B-1000 Brussels

Dr. van Vilet

I am writing to share our successful experience in the elimination of mercury blood pressure devices at Catholic Healthcare West (CHW). CHW is comprised of 41 hospitals, including 68 clinics and 9 trauma centers. It is located in various communities throughout California, Arizona, and Nevada. We are the largest not-for-profit healthcare system in California. CHW employs over 44,000 people, and in collaboration with nearly 7,500 active physicians, serves a growing population of approximately 22 million in the tri-state area.

Aware that elemental mercury and some mercury compounds are known to cause certain health problems in humans and animals, CHW issued a Mercury Elimination Policy in January of 2001. Our purpose in implementing this policy was to align CHW operations in a manner which demonstrated accountability for human and ecological resources and to protect human health and its environment. In addition, we wanted to enable CHW hospitals to meet mercury level standards established by the U. S. Environmental Protection Agency and the American Hospital Association.

We were among the initial signers of Healthcare Without Harm's "Making Medicine Mercury Free" Campaign.

Of all mercury instrumentation used in health care, the mass of mercury used in mercury sphygmomanometers (80 to 100g/unit), and their widespread use, collectively make them one of the largest mercury reservoirs in the health care setting. By choosing a mercury free alternative, a health care institution can have a tremendous impact in reducing the potential for mercury exposure to patients, staff and the environment.

As our experience has demonstrated, cost effective viable alternatives to mercury blood pressure devices are available in the marketplace. We support the goal of mercury free healthcare and believe efforts by the European Union to phase-out the sale and export of mercury blood pressure devices will be an important step for human health and the environment.

Sincerely,

Mary Ellen Leciejewski, OP

Mary Ellen Leciejewski, OP
Catholic Healthcare West
Ecology Program Coordinator

185 Berry Street, Suite 300
San Francisco, CA 94107-1739
415.438.5500 *telephone*
415.438.5724 *fax*

chwHEALTH.org

1000 North Oak Avenue
Marshfield, WI 54449-5777
715-387-5430
Fax 715-389-5505

MARSHFIELD CLINIC.

EMPLOYEE HEALTH AND SAFETY

**Lisette van Vliet, Ph.D.**
**Toxics Policy Advisor**
**Health Care Without Harm Europe**
**28 Boulevard Charlemagne, B-1000 Brussels**

**July 24, 2008**

**Dr. van Vilet**

I have been asked to document for you my medical facilities mercury sphygmomanometer elimination program.

Marshfield Clinic is a large, multi-clinic system with 7500 employees and 730 providers. In 1999, we started discussions relating to removal of mercury from our system, including mercury sphygmomanometers. It was found that our system has over 1600 mercury sphygmomanometers in use.

Issues that were brought up relating to changing to aneroid or digital sphygmomanometers included

Accuracy of non-mercury systems,
Cost of replacement
Cost of disposal

We addressed each of the above and came to the conclusion that removing mercury from our Clinical System was the appropriate thing to do.

To the issue of accuracy:

A thorough review of scientific papers of the time was done. Studies from the USA and Europe were found that indicated the accuracy of non-mercury manometers was accurate enough for most clinical use. Manufactures such as Tycos/Welch Allyn give a lifetime guarantee on the accuracy of their aneroid gauges, with a free replacement if the gauge is outside of the calibration area.

To also address issues our providers had in getting past their belief that a mercury manometer was the "Gold Standard", we did a survey of our manometers. In a survey I performed on 100 mercury manometers in various parts of our clinic, the following results were found. 22 % (22/100) of the units had the meniscus of the mercury column exactly at zero. 48% (48/100) of the units surveyed were between one and two

millimeters above zero. 19% (19/100) were three millimeters above zero. 9% (9/100) mercury manometer units were three to five millimeters above zero; and 2% (2/100) of these were more than 5 millimeters above the zero mark.

The primary reason for the mercury column not being at zero is that the manometer is open to the air and over time, the column attracts dust and dirt. In days past, manometers were drained, cleaned and refilled. This practice is no longer done due to the risk and hazards of working with mercury.

We also found that the accuracy of a blood pressure reading is affected by the height of the mercury column. In our system, most manometers were wall mounted. The readings may be affected if the patient were standing, sitting or lying down which changed the actual height of the mercury column in relation to the patient.

In addition, we found that in reading a mercury manometer, the angle of the eye of the person taking the reading is important. For best accuracy, the eye of the reader should be at 90 degrees to the meniscus. With wall mounted, or even manometers that are on a table, the reading of the meniscus would vary depending on the height of the person taking the reading as the eye angle changed.

The standard for a mercury manometer, according to the manufacturer is a + or – 2mm of mercury. This level of accuracy is also what is listed for the Tycos/Welch Allyn aneroid unit.

Given the other error factors that we acknowledged with the mercury manometers, we felt that for the majority of blood pressure readings, an aneroid unit was well within accepted limits for variation of blood pressure.

To follow up on the accuracy issue, our Biomedical department does a random survey on 1% of our aneroid manometers each year. In the 7 years we have been doing this, none of the aneroid units surveyed has been outside of the manufacturers + - 2mm standard.

As to the issue of cost: Cost of replacing mercury manometers should also be compared to the cost of a mercury cleanup. Our system experienced 3 mercury manometer spills (2 due to patients playing with the unit while waiting in the exam room, and one from a failure of the rubber seal in the unit). These spills cost us anywhere from $1000 to over $4500 to have cleaned up. Given that a large majority of our units were 10+ years old and the manufacturers could not give us any assurance that the rubber seals in these units would not also fail due to age, it was determined that replacing all mercury manometers was in our best financial interest.

We were also able to take advantage of a program that was offered by Tycos/Welch Allyn. The company agreed to accept back all of our mercury manometers and dispose of them at no cost to the Clinic. I cannot say if this program is still available, but it could be a large factor in a replacement program.

In the 7+ years that we have made the change to aneroid, and an increasing number of digital, blood pressure units, we have not had any issues with accuracy or other complaints.

I hope this information will help in answering some of the issues you may also be experiencing.

I have added a list of some of the papers we used when we looked at accuracy of blood pressure units and techniques.

1. COMMON PROBLEMS IN MEASURING BLOOD PRESSURE AND RECOMMENDATIONS FOR AVOIDING THEM, Reprinted from the American Heart Association, "Human Blood PRESSURE DETERMINATION. www.trimlinmed.com/html/common_misttakes.html
2. RECOMMENDED TECHNIQUES FOR BLOOD PRESURE MEASUREMENT, British hypertension Society, www.hyp.ac.uk/bhsinfo/techniques.html
3. March 10, 1998 letter replying to questions of aneroid accuracy by Welch Allyn VALIDATION OF THE WELCH ALLYN MAXI-STABIL ANEROID, King's College, University of London, London England, Dec. 1998

Yours truly,

Bruce E Cunha

Bruce E. Cunha RN, MS, COHN-S
Marshfield Clinic
1000 N. Oak Ave.
Marshfield WI, USA 54449
Cunha.bruce@marshfieldclinic.org.

CONSORTA

August 4, 2008

Lisette van Vliet, Ph.D.
Toxics Policy Advisor
Health Care Without Harm Europe
28 Boulevard Charlemagne, B-1000 Brussels

Dr. van Vliet:

I am writing to share our successful experience in the elimination of mercury blood pressure devices within our organization. Consorta is a leading healthcare resource management and group purchasing organization based in Schaumburg, Illinois whose 11 shareholders are faith-based or non-profit health systems. Consorta's membership now encompasses more than 500 acute care sites and over 250 extended care facilities throughout the country.

As a group purchasing organization, Consorta pulls purchasing volume from our membership and works with various vendors to write contracts for the products and services our members purchase to provide high quality care to their patients and the community they serve across the country.

Consorta's members have expressed concern regarding mercury based products for many years. With mercury having an evidence base effect as a neurotoxin, our hospitals were compelled to be proactive in eliminating mercury based blood pressure devices in their facilities.

Of all mercury instrumentation used in health care, the mass of mercury used is in mercury sphygmomanometers (80 to 100g/unit). This collectively makes mercury sphygmomanometers one of the largest mercury reservoirs in the health care setting. By choosing a mercury free alternative, a health care facility can have a tremendous impact in reducing the potential for mercury exposure to patients, staff and the environment.

In early 2003, the nursing committee at Consorta was in the process of reviewing research, content, and the breath of product lines available for sphygmomanometers for a new contract. A clear direction was given by our membership to eliminate mercury containing products from the contract. At this time, only aneroid and electronic devices were placed on contract. Even looking at the cost of replacement and disposal, most health systems felt this was the right thing to do for their patients and staff. The trend was set for most facilities to move towards digital electronic blood pressure devices.

As our experience with our hospital members has demonstrated, cost effective viable alternatives to mercury blood pressure devices are available in the marketplace. We support the goal of mercury free healthcare and believe efforts by the European Union to phase-out the sale and export of mercury blood pressure devices will be an important step for human health and the environment.

Sincerely,

John W. Strong
President and CEO

Schaumburg Corporate Center • 1475 E. Woodfield Road, Suite 400 • Schaumburg, IL 60173 • 847/592-7800 phone • 847/592-7801 fax

imerc

INTERSTATE MERCURY EDUCATION
& REDUCTION CLEARINGHOUSE

August 11, 2008

IMERC
c/o NEWMOA
129 Portland Street, 6th floor
Boston, MA 02114

Lisette van Vliet, Ph.D.
Toxics Policy Advisor
Health Care Without Harm Europe
28 Boulevard Charlemagne, B-1000 Brussels

Dr. van Vliet:

I am writing to share the experience of the member states of the Interstate Mercury Education and Reduction Clearinghouse (IMERC) that have enacted legislation to prohibit the sale and distribution of mercury-added sphygmomanometers.

In 2001, IMERC was established by the member states of the Northeast Waste Management Officials' Association (NEWMOA), which includes Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont. The Clearinghouse was launched to help state environmental officials implement laws and programs aimed at reducing mercury in consumer products, the waste stream, and the environment. Since 2003, the states of California, Illinois, Louisiana, Minnesota, North Carolina, and Washington have joined IMERC.

In 2004, state legislation phasing-out or banning the sale and distribution of certain mercury-added products began to take effect. Currently, 11 IMERC-member states restrict the sale and distribution of mercury-added sphygmomanometers. Three of these states have enacted legislation that phases-out mercury-added products based on their mercury content. The amount of mercury contained in sphygmomanometers, between 54 and 136 grams according to the manufacturers, falls above the 1,000 milligram limit listed in the legislation of the following states, triggering their sales restrictions:

- Connecticut – effective **July 1, 2004**
- Rhode Island – effective **January 1, 2006**
- Louisiana – effective **July 1, 2008**

The other eight IMERC-member states that have enacted legislation restricting the sale of sphygmomanometers specifically mention these products in their legislation. These states include:

c/o NEWMOA · 129 Portland Street · Boston, MA 02114-2014 · Tel (617) 367-8558 · Fax (617) 367-0449 · www.newmoa.org

- Washington – effective **January 1, 2006**
- California – effective **July 1, 2006**
- Maine – effective **July 1, 2006**
- Vermont – effective **January 1, 2007**
- Minnesota – effective **August 1, 2007**
- New Hampshire – effective **January 1, 2008**
- Massachusetts – effective **May 1, 2008**
- Illinois – effective **July 1, 2008**

In addition, the state of Michigan, which is not a member of IMERC, has enacted a ban on the sale of mercury-added sphygmomanometers, effective January 1, 2009. The 12 states that have enacted legislation regulating the sale and distribution of mercury-added sphygmomanometers comprise approximately 30 percent of the U.S. population. Additional information about the phase-out and product ban legislation of the IMERC-member states may be found on the following Web pages: http://www.newmoa.org/prevention/mercury/imerc/phaseoutinfo.cfm and http://www.newmoa.org/prevention/mercury/imerc/productban.cfm

Under IMERC-member state notification requirements, manufacturers of mercury-added products are required to provide information about their products before offering them for sale (http://www.newmoa.org/prevention/mercury/imerc.cfm). Under these requirements, manufacturers have reported the total amount of mercury contained in sphygmomanometers sold in the U.S. during the calendar years 2001, 2004, and 2007 as follows:

- 2001 – **4,305 pounds**
- 2004 – **2,218 pounds**
- 2007 – **1,667 pounds**

Between 2001 and 2007, the total amount of mercury sold in sphygmomanometers, as reported to IMERC-member states, has decreased by approximately 60 percent.

Two manufacturers of mercury-added sphygmomanometers have applied for an exemption to the phase-out and product ban legislation in the IMERC-member states. One manufacturer applied in 2005 and again in 2006. The other manufacturer applied early 2007. The IMERC-member states that reviewed the applications denied them because research indicated that non-mercury sphygmomanometers are available at a reasonable cost and serve as a technically feasible alternative. Some states, including Maine, have yet to rule on the exemption applications.

Sincerely,

Becky Jayne

Rebecca Jayne
IMERC Chairperson

cc: Ron Ohta, California Department of Toxic Substances Control
Thomas Metzner, Connecticut Department of Environmental Protection
Chris Piehler, Louisiana Department of Environmental Quality
Enid Mitnik, Maine Department of Environmental Protection
Lori Segall, Massachusetts Department of Environment Protection
John Gilkeson, Minnesota Pollution Control Agency
Stephanie D'Agostino, New Hampshire Department of Environmental Services
Beverly Migliore, Rhode Island Department of Environmental Management
Karen Knaebel, Vermont Department of Environmental Conservation
Maria Victoria Peeler, Washington Department of Ecology

## NOTES


1. See, UNEP, Global Mercury Assessment, UNEP Chemicals, Geneva, December 2002. And Health Canada: http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/mercur/q47-q56_e.html

2. United States Environmental Protection Agency, http://www.epa.gov/mercury/effects.htm

3. CDC Morbidity and Mortality Weekly Report. "Blood and Hair Mercury Levels in Young Children and Women of Child Bearing Age-United States." 1999 Vol 50, No 08;140. 03/02/2001

4. U.S. Environmental Protection Agency - 452/R-97-004. "Mercury Study Report to Congress, Volume II:

5. For more detail see, Joshua Karliner and Jamie Harvie, The Global Movement for Mercury Free Health Care, Health Care Without Harm, November 2007, http://www.noharm.org/globalsoutheng/mercury-report-download

6. (http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007 :257:0013:01:EN:HTML) "By 3 October 2009 the Commission shall carry out a review of the availability of reliable safer alternatives that are technically and economically feasible for mercury-containing sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses.."

7. Cited in "Making Medicine Mercury Free: A 2005 Report on the Staus of Virtual Mercury Elimination in the Health Care Sector," Hospitals for a Healthy Environment, Arlington, 2005. http://www.h2e-online.org/docs/h2e2005MercuryReport.pdf

8. Werner, Curt. "HPN Survey: GPO contract purchases top $54 billion in 2002" Health Purchasing News. June 2003

9. Cited in "Making Medicine Mercury Free: A 2005 Report on the Staus of Virtual Mercury Elimination in the Health Care Sector," Hospitals for a Healthy Environment, Arlington, 2005. http://www.h2e-online.org/docs/h2e2005MercuryReport.pdf

10. "Affordable Technology: Blood Pressure Measuring Devices for Low Resource Settings," Cardiovascular Diseases, World Health Organization, Geneva, 2005.

11. Mion D, Pierrin AMG. How accurate are sphygmomanometers? Journal of Hypertension, 12: 245-248 (1998); 9. Markandu NK, Whitcher F, Arnold A,Carney C. The mercury sphygmomanometer should be abandoned before it is proscribed. Journal of Human Hypertension 14(1): 31-6 (2000).

12. Canzanello VJ, Jensen PL, Schwartz GL, "Are aneroid sphygmomanometers accurate in hospital and clinic settings?" Archives of Internal Medicine, 2001 Mar 12; 161(5): 729-31. See also, N.D. Markandu et al., "The Mercury Sphygmomanometers Should Be Abandoned Before it is Proscribed," Journal of Human Hypertension (2000) 14, 31-36.

13. "An Investigation of Alternatives to Mercury Containing Products" Prepared for Maine Department of Environmental Protection by the Lowell Center for Sustainable Production, University of Massachusetts, Lowell

14. The mean and standard deviation for systolic and diastolic pressures respectively were -0.6(4.6) mmHg and 1.3( 3.5) mmHg in sequential analysis, and -1.3(2.2) mmHg and -1.9(2.7) mHg in simultaneous analysis. Reinders, Annemarie; Jones, Clare R; Cuckson, Alexandra C; Shennan, Andrew H. "The Maxi Stabil 3: validation of an aneroid device according to a modified British Hypertension Society protocol." Blood Pressure Monitoring. 8(2):83-89, April 2003.

15. Medicines and Healthcare products Regulatory Agency (MHRA).MEDICAL DEVICE ALERT. Issued: 13 July 2006 at 11:00 Ref: MDA/2006/037

16. Summary Report: National High Blood Pressure Education Program (NHBPEP)/National Heart, lung, and Blood Institute (NHLBI) and American Heart Association (AHA) Working Meeting on Blood Pressure Measurement. National Institutes of Health, April 19, 2002

17. Wright EW. Sphygomanometers: Internal analysis of different techniques, Welch Allyn Inc. Jan. 11, 2000; WHO report

18. "Affordable Technology: Blood Pressure Measuring Devices for Low Resource Settings," Cardiovascular Diseases, World Health Organization, Geneva, 2005.

19. KEMI, "Mercury Free Blood Pressure Measurement Equipment: Experiences in the Swedish Health Care Sector," Swedish Chemicals Inspectorate, Stockholm, 2005

20. British Hypertension Society, "Validated Blood Pressure Monitors List" http://www.bhsoc.org/blood_pressure_list.stm

21. KEMI, "Mercury Free Blood Pressure Measurement Equipment: Experiences in the Swedish Health Care Sector," Swedish Chemicals Inspectorate, Stockholm, 2005

www.noharm.org

Health Care Without Harm Offices

HCWH - Europe
35 Isca Road
Exeter
EX2 8BQ
United Kingdom
ph: +44 1392 431 304
europe@hcwh.org

HCWH - US & Canada
1901 N. Moore Street
Suite 509
Arlington, VA 22209
ph: 703-243-0056
fax: 866-438-5769
cfunkhouser@hcwh.org

HCWH - Latin America
Tamborini 2838
CP 1429 - Ciudad de Buenos Aires
Argentina
phl/fax: +54 11 4545 7204
info@saludsindanio.org

HCWH - Southeast Asia
Unit 330, Eagle Court Condominium
26 Matalino Street, Brgy. Central Diliman,
Quezon City
1100 Philippines
ph: +63 2 9287572
fax: +63 2 9262649
merci@hcwh.org

For all other countries and global issues,
please contact: Catalina Farias Rodriguez
HCWH International Coordination
Tamborini 2838
1429 Capital Federal
Argentina
phl/fax: +54 11 4545 7204
catalina@hcwh.org


www.noharm.org