



Maine: First US Legislation for Unused Patient Pharmaceutical Returns

END USER DRUG DISPOSAL CONFERENCE

APRIL 25-26, 2006, PORTLAND, OREGON

*Global perspective of the importance of pharmaceutical drug disposal programs*

Stevan Gressitt, MD

Medical Director, Northeast Occupational Exchange

Maine Benzodiazepine Study Group

314 Clark Road

Unity, Maine, 04988

207-441-0291

Gressitt@uninets.net



Disclaimer: It is the opinion of the author that no single piece of legislation, nor any one single program, will fit the geographic differences, population disparities in density and age, and infrastructure variances across the United States. Though Maine has passed the first piece of state legislation regarding unused pharmaceuticals, it may or may not serve as a model for other states. I am also grateful to all in this room without whose work we could not have passed the legislation in Maine. The legislation would not have occurred without the preceding and credible work of Christian Daughton of the U.S. Environmental Protection Agency, and others. <sup>1</sup> Opinions expressed are strictly mine, and not the position of any specific organization. I would like to acknowledge the support of Northeast Occupational Exchange for this presentation.

Legislation was the outcome of a proposal that originated at the 2002 Maine Benzodiazepine Study Group annual meeting. There had been discussion of how to reduce abuse or misuse of benzodiazepines, a widely prescribed DEA Schedule IV class of medication. Rates of use, misuse, and abuse were difficult to obtain. Schedule IV pharmaceuticals are poorly tracked and, as a class, the benzodiazepines are not always reported discretely but are usually included in another category, such as sedative/hypnotic. Appended is a comprehensive compilation of FDA approved benzodiazepines.<sup>2</sup>

Subsequent to the conference, the pharmaceutical relationship to crime was presented by the National Drug Intelligence Center that substantiated our concerns:

<sup>1</sup> [Environmental Stewardship and Drugs as Pollutants](#)—Christian G. Daughton, US EPA/ORD, the Lancet, October 5, 2002, Vol 360, 1035-1036. Found at: <http://www.epa.gov/nerlesd1/chemistry/pharma/images/lancet-final.pdf>

<sup>2</sup> Appendix A

States Pharmaceuticals Most to Property Crime	Where Contribute Crime	States Pharmaceuticals Contribute Most to Crime	Where Violent
<u>Maine</u>		<u>35.3</u>	<u>28.8</u>
West Virginia		32.4	17.3
Kentucky		28.0	15.1
Alaska		16.7	
Virginia		11.8	
Massachussetts			8.9
Michigan			7.0
<u>Nationwide</u>		<u>2.5</u>	<u>2.2</u>

Source: National Drug Threat Survey  
2004 ( in publication)

It is quite likely that the overall use of illegal drugs is higher in the US than currently conventionally reported, as shown by the conclusion of the paper titled "Cocaine in surface waters: a new evidence-based tool to monitor community drug abuse:"<sup>3</sup>

*Surveys of the general population are useful to describe patterns of drug abuse, but they are very expensive, and certainly too lengthy to detect changing trends promptly. Continuous monitoring of illicit drug consumption would be very important for assessing the actual extent of this phenomenon, and detecting changes in trends. A more realistic picture of local use patterns for the most common illicit drugs would also be needed to identify priority problems and plan selective countermeasures. The evidence-based approach first tested here, which is in principle adaptable to other illicit drugs, could be refined and further validated to become a general, rapid method to help estimate drug abuse at the local level. This approach, with its unique ability to monitor changing habits in real time, could be helpful to social scientists and authorities for continuously updated appraisal of drug abuse.*

The rationale for the legislation, consisting of the following four points, was given in public discussions:

1. Accidental ingestion, particularly among children and the elderly
2. "Pharming" or theft
3. Unnecessary accumulation and waste of health care dollars
4. Environmental impact

1. Accidental ingestion: One of the concerns that drove the legislation is the accidental ingestion of pharmaceuticals, both by children and by the elderly. Information on this can readily be found at the Centers for Disease Control.<sup>4</sup> In addition, the Poison Prevention Week Council has summarized some of the risks.<sup>5</sup> The following is from a press release of the Council:

*March 15, 2005 National Poison Prevention Week Warns: Most Child Poisonings Result from Common Household Products. Every 7 minutes, a child arrives at an emergency room due to a suspected poisoning. About 78,000 children under five years old visited U.S. hospital emergency rooms due to unintentional poisonings in 2003 – about one every seven minutes, the U.S. Consumer Product Safety Commission (CPSC) reported today. Most of these poisonings included products commonly found in the home.<sup>6</sup>*

<sup>3</sup> Cocaine in surface waters: a new evidence-based tool to monitor community drug abuse, *Environmental Health: A Global Access Science Source* 2005, 4:14 doi:10.1186/1476-069X-4-14, Ettore Zuccato, et al.

<sup>4</sup> Appendices B and C.

<sup>5</sup> Appendix D.

<sup>6</sup> <http://www.poisonprevention.org/News%20Release.pdf>

It is noteworthy that the EPA has already offered advice for purchasing potentially toxic chemicals. Not earth-shattering advice at that:

*Buy limited quantities. If you use products only occasionally or seasonally, such as paints, paint strippers, and kerosene for space heaters or gasoline for lawn mowers, buy only as much as you will use right away.*<sup>7</sup>

Perhaps we should bear this in mind as efforts to increase the duration between prescription refills results in larger quantities being mailed to patients. Many policies encourage this and promote longer prescriptions.

2. Pharming: In Maine, we are concerned about appropriation of pharmaceuticals by family members, as well as by burglars, for inappropriate private use or for sale. I have no data on pharming and the numbers for pharmaceutical related crime that are referenced above may be the best that I can provide today.

3. Accumulation: Concerns about accumulation relate to both pharming and environmental degradation, but also to prescription practice: patient compliance with prescriptions averages roughly 50%. There is a significant volume of literature addressing methods to improve that figure. I am unfamiliar with any general survey of the non-institutionalized public. Nursing home data are available through the American Society of Consulting Pharmacists but it is unlikely there is much to compare to the general public. A program that analyzes the accumulated drugs that are returned may also offer information that will be helpful to those who are trying to address the cost of prescription drugs, assuming that, with the exception of the death of a patient, an unused prescription is a waste of health care dollars.

4. Environmental impact: While we were aware of studies done in other states that showed the presence of pharmaceuticals in fish, rivers and water (post-treatment), we were unable to find any numbers in Maine for comparison, leaving a large research gap to be addressed. We became aware that water samples had been taken in Maine for pharmaceuticals, but which were being tested, and where, was unknown. The date for completion was extended repeatedly. This past week some results for endocrine disruptors arrived; there is word that the pharmaceutical numbers are "coming." Questions about volume were the most problematic. Currently the law enforcement community in Maine has been destroying approximately 9 tons of drugs per year, using incineration within the state. We knew from the Shipman report that 523 English tons were being collected for calendar year 2003 into pharmacies across the UK. We knew that 1,000 pounds had been collected in Prince Edward Island approximately six years ago, and that two years ago 3,000 pounds were collected. Both were in two-week, take-back-to-the-pharmacy programs. The method of return would not be acceptable in the US and, indeed, raised some security concerns there. The quantities collected in Alberta, British Columbia, and Australia are all through pharmacies and are publicly available. All point to a large volume, but this is not a comprehensive review of international collections.<sup>8</sup>

Starting from the proposal at the conference, and using the four major reasons for concern to look for support, we eventually obtained letters, calls of support or expressions of interest to the legislature from the following among others:

Maine Medical Association  
Maine Psychiatric Association  
Northeast Occupational Exchange  
Maine Benzodiazepine Study Group  
Maine Dental Association  
Maine Rivers  
Maine Children's Alliance  
Memorial University of Newfoundland, Faculty of  
Medicine, Psychiatry  
Theo Colborn, PhD

Maine Osteopathic Association  
Maine Association of Substance Abuse Programs  
Dave Galvin, Hazardous Waste Management, King  
County, Washington State  
Abdelkrim Smine, PhD, Senior Program Associate, Global  
Assistance Initiatives, USP  
Northern New England Poison Control Center  
Dominion Diagnostics  
Strong Environmental  
Chalotte Smith

At the outset, the major problem seemed to be who would be willing to return the medications. Would an incentive be required? There were also efforts to derail the whole proposal. At one point fear of "white powder" in

<sup>7</sup> <http://www.epa.gov/iaq/pubs/insidest.html#Look5>

<sup>8</sup> Shipman Report Volume 4. To be found at: <http://www.the-shipman-inquiry.org.uk/fourthreport.asp> see section 7.76

mailers was raised, and the cost of shutting down a postal center was brought up as well. Fear of diversion, fear of incineration and dioxins being generated were arguments raised against the proposal. The two most relevant controlling sets of regulations were found to be those of the Maine Department of Environmental Protection and the federal DEA. As is now better known publicly than a couple of years ago, DEA registrants (practitioners, clinics, hospitals) are not permitted to accept controlled drugs out of the closed distribution system that has so carefully been put into place. This system exists to ensure pharmaceutical safety, to permit recalls, and to limit diversion.

As an aside here, it was only after the legislation passed that we noted a patent issued to Diebold, the self-service and security corporation, that was described as follows: "An apparatus for accepting return of unused medical items is part of a system (10) used for automated dispensing and tracking of medical items within a medical facility." (Patent application # 679203) <sup>9</sup> And it is noted that since then, the DEA has just recently issued regulations on automated pharmacy dispensers. These are anticipated to address unnecessary dispensing and waste health care dollars, as well as diversion.

Separating controlled from non-controlled drugs was felt to be an insurmountable problem; hence the decision tended to focus on including all pharmaceuticals under the most restrictive umbrella. A review of all legislation across the United States dealing with unused medicine returns from the public was performed by the Center for Substance Abuse Research (CESAR) at the University of Maryland. That study was placed on the CESAR web page and offered to the State of Maine's Joint Standing Committee on Health and Human Services in testimony.<sup>10</sup>

After the successful public hearing before the Committee, the partisan nature of the vote of the full Legislature proved to be disappointing. The two political parties split and held their partisan positions. Other and larger issues were at hand, including some serious problems at the Department of Health and Human Services and with the State budget. A help was having a web page that had specific links to provide information on unused medicine. <sup>11</sup> What did pass was a statute that established the Unused Pharmaceutical Disposal Program to be administered by the Maine Drug Enforcement Agency. It was enabling legislation. The Legislature also authorized an Implementation Committee to address the design of the program. A copy of the law as passed is attached.<sup>12</sup>

It has been subsequently updated, but formal text is not available as of yet, and will not be available until September. Essentially the start date is changed July 1, 2006 and removes the restriction on public funds except for Maine's General Fund as a source. This would permit County, Federal, municipal, foundation, or private funding. I was a member of the Implementation Committee that was designated and appointed by the Senate and House. That Committee's report is public on the State of Maine web page.<sup>13</sup> I will spend some time reviewing the Committee's recommendations now:

### **III. RECOMMENDATIONS**

#### **A. Voluntary turn-in events**

*The implementation group reviewed voluntary turn-in events for unneeded prescription drugs and recommends encouraging turn-in events on the local level. The implementation group anticipates an increasing number of these events and greater amounts of collected unneeded drugs. The implementation group recommends that the Legislature consider product stewardship for voluntary turn-in events in order to provide continuing responsibility from pharmaceutical manufacturers for their products, including funding for education, outreach, collection, disposal and reporting.*

#### **Coordination**

*The implementation group recommends that the Maine Department of Environmental Protection, the Maine Drug Enforcement Agency, the Department of Health and Human Services and the Department of the Attorney General work together with manufacturers to enable more turn-in events to be held successfully. Coordination is needed to ensure that turn-in events are safe and convenient for individual citizens who participate, provide safeguards for the collection and identification of turned-in drugs and comply with state and federal law and rule regarding the handling of controlled substances and hazardous waste. The implementation group suggests that a statistically valid sampling of collected unneeded drugs be done and recorded to provide information about drug prescribing and waste.*

#### **Educational materials and outreach**

*The implementation group suggests that the Office of the Attorney General, the Departments of Environmental Protection and Health and Human Service, the Maine Medical Association and the Maine Hospital Association work together to prepare*

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<sup>9</sup> Appendix E.

<sup>10</sup> Appendix F.

<sup>11</sup> Appendix G.

<sup>12</sup> Appendix H.

<sup>13</sup> <http://mainegov-images.informe.org/legis/opla/drugrpt.pdf>

informational materials for interested parties, participating municipalities, law enforcement, medical personnel and community service organizations. Good information on how to successfully hold a voluntary turn-in event will increase the number of events, public participation and success.

#### **Funding**

Funding for collection, transportation, storage and disposal would enable a greater number of turn-in events to be held successfully. Funds may be needed for law enforcement, statistical sampling, reporting and disposal. The implementation group suggests that individuals and entities interested in voluntary turn-in events pursue funding for their local events and that the Legislature consider product stewardship to provide funding.

#### **Starting date**

A starting date for voluntary turn-in events is not required because of their voluntary nature. If product stewardship were applied to voluntary turn-in events, a start date would be needed for manufacturer responsibility to begin.

#### **B. Mail-in program**

Public Law 2003, Chapter 679, which created the Unused Pharmaceutical Disposal Program, recognized that the enabling legislation was incomplete and established the implementation group to provide guidance to the Legislature. Specifically the legislation mentions the need for recommendations regarding postal regulations, methods and requirements for mailing packaging, minimizing drug diversion and theft and public education. The implementation group reached consensus on recommendations to move the disposal program forward. The implementation group recommends that the Legislature consider adding a product stewardship model to the mail-in program.

#### **Packaging for mailing**

The implementation group suggests that pharmaceutical manufacturers or the State or both provide the mailing packaging for the mail-in program that meets the requirements of the United States Postal Service and the Maine Drug Enforcement Agency. The implementation group recommends that the mailing packaging be made available at pharmacies, hospitals, physicians' offices and health clinics.

#### **Mail receipt, storage and disposal**

The implementation group recommends that the Maine Drug Enforcement Agency determine whether drugs would be mailed directly to MDEA or to a consolidator under contract with MDEA. MDEA rulemaking is necessary to establish the protocols for mailers and mailing, statistical sampling and reporting and disposal of drugs. Transportation to a disposal site, which is required to be done by a licensed handler of hazardous waste, would be accomplished by the consolidator. Hazardous waste disposal sites would accept the shipments of unneeded drugs shipped from Maine and would dispose of them by incineration.

#### **Educational materials and outreach**

The implementation group suggests that educational materials for pharmaceutical manufacturers, pharmacies, hospitals, physicians' offices, health clinics, law enforcement and individual citizens be provided by the Office of the Attorney General, the Departments of Environmental Protection and Health and Human Service, the Maine Medical Association, the Maine Hospital Association and the drug manufacturers, all within the limits of their existing resources.

#### **Funding**

Public Law 2003, Chapter 679 requires non-public funding in order to begin the mail-in program. Funding will be required for the prepaid mailers, distribution, postage, storage and disposal and public education materials. The implementation group recommends that Public Law 2003, Chapter 679 be amended in 22 MRSA section 2700, subsection 5, to allow receipt of non-General Fund public funding, including federal funds. Suggested legislation is included as Appendix E.

#### **Starting date**

The implementation group recommends that the starting date for the Unused Pharmaceutical Disposal Program be changed to allow for additional preparation time for the adoption of rules and the acquisition of funding. The implementation group recommends that Public Law 2003, Chapter 679, section 4 should be amended to provide for an effective date of July 1, 2006. Suggested legislation is included as Appendix E.

#### **C. Product stewardship**

Product stewardship is a concept that recognizes the responsibility of the manufacturer of a product from the manufacturing process through final disposal in an environmentally sound manner. The implementation group recommends that the Legislature consider a product stewardship model for voluntary turn-in programs and the mail-in program for prescription drugs, recognizing the cooperative efforts of individual citizens, prescription drug manufacturers and State government to provide safe collection and disposal for those drugs. If product stewardship were to be adopted by the Legislature, the implementation group recommends a starting date of July 1, 2007.

#### **D. General recommendations**

- The implementation group recommends that the Maine Legislature consider legislation to establish a redistribution program for unneeded pharmaceuticals. Under this program Maine residents of low and medium income who hold a valid prescription would be eligible to obtain for a very low fee prescription drugs that had been donated to the program from health facilities, drug manufacturers, drug wholesale and terminal distributors and hospitals. The drugs would all be unopened and packaged

*in tamper-evident unit dose packages or they would be unopened injectable, aerosol or topical medications. The program would not distribute controlled substances, drugs that had been tampered with or drugs within 6 months of their expiration date. See Appendix F for suggested legislation.*

*• The implementation group recommends that a letter be sent by the Maine Drug Enforcement Agency to the United States Drug Enforcement Administration supporting amendment to federal regulations to provide individual citizens and law enforcement safe and effective methods of disposal for controlled substances.*

Two national public health groups have taken positions on this issue. The first came from the United States Pharmacopoeia. Their resolution follows:

*2005–2010 Resolutions*

*Adopted at the 2005 USP Convention*

*March 13, 2005*

*9. Promoting Safe Medication Use and Disposal USP resolves to work with appropriate constituencies to continue developing programs to promote safe medication use and disposal*

Subsequently, The American Psychiatric Association passed resolution 12e this past June as follows:

*Reference Committee 1 Assembly May 20-22, 2005 ACTION PAPER*

*SUBJECT: Unused Pharmaceutical Return Program*

*INTENT: To provide a safe means for patients to dispose of unused prescription medication.*

*PROBLEM: In the United States, there has not been a safe way for patients to dispose of unused prescription medication; and the accumulation of unused prescription medication has been dangerous. Some people are dying from accidental poisoning, while others are dying by purposeful ingestion. Drug abusers are diverting unused controlled substances for illicit purposes. Americans are flushing unused or expired pharmaceuticals down the toilet and polluting our environment.*

*While most state governments and the federal government have not yet developed a response to this problem, the Maine Psychiatric Association in collaboration with the Maine Medical Association and other interested parties supported a bill that passed in the Maine Legislature entitled: "An Act to Encourage the Proper Disposal of Unused Pharmaceuticals." This bill allows individuals to safely dispose of their unused medications by mailing unused pharmaceuticals in a prepaid envelope to the Maine Drug Enforcement Agency for destruction.*

*ALTERNATIVES: 1. To improve public health and safety, the APA should encourage state legislatures and the federal government to adopt programs for the proper disposal of unused pharmaceuticals.*

*RECOMMENDATION: Alternative 1.*

*IMPLEMENTATION: The Council on Advocacy and Public Policy should be charged with the task of developing a strategy to encourage state legislatures and the federal government to adopt programs for the proper disposal of unused pharmaceuticals.*

*SUBMITTED BY:*

*Stevan Gressitt, M.D., Councilor, Maine Psychiatric Association*

*W. Bogan Brooks, M.D., Rep., Maine Psychiatric Association*

*ENDORSED BY: Maine Psychiatric Association and Area 1*

In addition, the American Society of Consultant Pharmacists and the American Society of Health System Pharmacists have both issued positions or formally undertaken a review for their coming annual meetings. We recognized the need for data collection, and a standard for that collection. We could not find a standard in existence; the need to address the four problems that led to the legislation drove a need for a data repository. This has progressed to development of the following web page: <http://www.communityofcompetence.com/sections/Registry.htm>. I have attached a copy of the screenshot.<sup>14</sup>

A number of data sets have been submitted or forwarded to the Registry. To date, only two sets have been felt to be obtained under adequately controlled settings: those of Northeast Occupational Exchange and those of New England Recycling Council. What remains problematic is the final reporting from the registry. Which form should be used, or which content should be extracted, remains unclear given the number of different purposes for which the data could be evaluated. The first set of numbers was from a collection in Bangor that covered all clinics. I simply collected all the medication that existed in the facilities that no one knew what to do with. Those medications were counted by an RN and then later by a pharmacist. The counts matched and they were provided at last year's Maine

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<sup>14</sup> Appendix I.

Benzodiazepine Study Group Conference. The two data sets from Maine are attached, as well as the standard collection form agreed on by consensus at the Bangor Conference.<sup>15</sup> The second data set provided information on the reason for non-use, which was not collected the first time, as the consensus form had as yet not been developed.

What is relevant is that the amount of controlled drug return dropped significantly between the first -unannounced clean up and the second that followed much discussion, press coverage, and internal conversation.

For comparison, the best survey of returned medication and pharmacoeconomic projection I have found is at the National Association of Board of Pharmacy in Canada. It is based on a take back in the Sudbury, Ontario region in 1995. It contains an interesting summary of what was returned, one table from which I am attaching:<sup>16</sup> In summary, their projections were:

*By multiplying by the appropriate factor, the \$67,000 collected actually represents over \$510,649 for the 29 participating pharmacies. If we assume the pattern of waste is consistent across the province of Ontario and we extrapolate to the 2,380 pharmacies in the province, the cost of the waste is approximately \$41,908,435. If extrapolated across Canada, the cost of this waste reaches approximately \$113,381,687.*

There is no formal taxonomy of return programs or types, but from the medical literature this appears to be what has been tried, written about or discussed:

1. Pharmacy take-backs
2. Visiting or Regional nurses or Public Health home visits (as in South Africa.)
3. Return to physician offices or emergency rooms.
4. Mail-back
5. Household hazardous waste events

For the "e-drug list" I am currently trying to compile an international listing of return programs. I have redacted personal information but have attached the current summary, which leaves much to be desired.<sup>17</sup> What seems clear is that in different countries, different specialties, disciplines or agencies are the lead; likewise, contacts are not uniformly one agency or one specialty or group.

Finally, product surety aspects must be noted. Maine has experienced counterfeit Lipitor. Unused medicine return quantification and assay or sampling could serve to provide one form of pharmacosurveillance to identify what may be unidentified counterfeit drugs in a community. The Pharmaceutical Security Institute has published a public report on the impact of importation, and a cursory review of counterfeit medications. Global Options has released a far more extensive report. One identified sample, that was not as labeled, returned that had not been previously identified as a problem would prove the value of this both to the public, the manufacturer, and the health care industry.

Recommendations for clinical care are already published, in the Boivin paper on Waste Medicine and also in the [\*Pharmaceutical Journal\*](#):

- *Prescribe smaller quantities*
- *Optimize time intervals for repeat medication and prescribe in phase*
- *Regularly review repeat medication*
- *Improve information for patients*
- *Introduce policy guidelines within acute computer-generated prescribing*
- *Reduce unnecessary or inappropriate prescribing (this is a form of drug wastage)*<sup>18</sup>

These are not just reasonable, but will contribute to better patient care, reduction in adverse events, and waste prevention. Smarter prescribing may not be more economical in one analysis but will be when the totality of costs is calculated. For instance there is the argument that chiral pharmaceuticals, with some exceptions, are ecologically far superior to racemic preparations but are initially more expensive. Two examples are Lexapro and citalopram. One assumption is that with a reduction in the "home medicine-cabinet shelf life exposure time," each of the four points I

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<sup>15</sup> Appendix J for the first data set and Appendix K for the second collection, Appendix L for the Bangor Consensus Data Collection Form.

<sup>16</sup> Appendix M.

<sup>17</sup> Appendix N.

<sup>18</sup> [\*Pharmaceutical Journal\*](#) Vol 267 No 7167 p424 [29 September 2001](#) Comment, Drug wastage — what is acceptable? By [Evelyn Cromarty and George Downie](#)

mentioned at the outset will be addressed. Underlying the entire process, underlying the negotiations of what date or who will pick up or be responsible for which element of the return and destruction of the unused pharmaceuticals, is the need for more data. Both a broad group of different interests are necessary to move this process forward, and a range of groups are in need of different pieces or cuts through the data.

Finally, the issues of re-use and donations must be faced. Lack of standardized storage across the millions of homes in the U.S. means degradation rates due to temperature or humidity variations are unpredictable at present. DOD evaluations of properly stored medications have resulted in millions of dollars of savings due to clearly researched extended shelf life dates. Blind contributions sent to a recycler, however, are likely to include useless items. One Reverse Distribution facility I toured had a wheelchair that had been returned. In Bandah Aceh there is no clear reason why, after the Tsunami, boxes of silicone breast implants were received. The World Health Organization (WHO) has clear guidance on donations of medication; in the United States, the Partnership for Quality Medicine Donations has a lengthy history of trying to provide information on proper donations as it carries out humanitarian supply programs around the world. That they must now take on the cost of destruction. I claim no expertise in determining how to destroy unused medicine, but have found myself favoring plasma disintegration. There is always the WHO guidance on how to use a cement mixer to dispose of medication and there is The Drug Terminator.<sup>19</sup>

So Maine has legislation, and I am here to say that although I do not have a returned mail envelope to show you, I have been told that the cost of the next step will be in the neighborhood of \$15,000 to complete the regulations and testing for the program. All donations are to go to the MDEA/State Treasury. And I am here to offer-- to any who would care to help-- the mechanism, the template for other jurisdictions, and the invitation to assist with forming and finalizing a Registry that may be one of the largest data sources to advance patient care efficiencies, quality and safety.

I would like to pass this tin can to move this process forward for the benefit of all of us.<sup>20</sup> I would be happy to answer any questions, that I can answer. Thank you for the opportunity to speak to you.

Stevan Gressitt, M.D.

April 9, 2006

314 Clark Road, Unity, Maine, 04988

207-441-0291

gressitt@uninets.net

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<sup>19</sup> Appendix O.

<sup>20</sup> Appendix P.