

# ROMANIA: A CASE STUDY IN USING POLICY REFORM TO IMPROVE ACCESS TO OPIOID MEDICINES

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## I. INTRODUCTION

For over a decade international groups like the World Health Organization (WHO) and the United Nations General Assembly have recognized what national healthcare providers have long experienced: inadequate availability of therapeutic opioids for patients in need.<sup>1</sup> Opioids like codeine and morphine are essential in

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the treatment of moderate to severe pain.<sup>2</sup> Several opioids, most notably methadone, are also highly effective in the treatment of opioid addiction.<sup>3</sup> Yet, national drug control laws often present serious obstacles to the adequate provision of these therapeutic opioids.<sup>4</sup> These obstacles persist despite international law mandating balanced drug control policies that minimize diversion of controlled substances into illicit channels while ensuring the availability of opioids for medical purposes.<sup>5</sup> Breaking down these regulatory barriers can be a daunting challenge because it requires technical assistance individualized to unique national needs and resources.<sup>6</sup> Moreover, drug policy is known as one of the least fluid areas of policy development.<sup>7</sup> Still, as this paper highlights with the case of Romania, reform is possible.

Over the last few decades Romania has undergone a systematic process of legal reform to improve access to essential opioids. The work of internal advocacy champions from the health care sector spurred this reform, while funding and

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1. Cancer Prevention and Control, W.H.A. Res. WHA58.22, Doc. A58/16, at 103 (May 25, 2005) (recognizing that the provision of palliative care for all individuals in need is an urgent, humanitarian responsibility); Treatment of Pain Using Opioid Analgesics, E.S.C. Res. 2005/25, at 2 (July 22, 2005) (recognizing the importance of improving the treatment of pain through the use of opioid analgesics especially in developing countries); Economic and Social Council Commission on Narcotic Drugs, Rep. on its 48th Sess., Mar. 19, 2004, Mar. 7 – 11, 2005, Dec. 7 – 8, 2005, 4, 6, U.N. Doc. E/2005/28/Rev. 1 (2005) (recognizing that medical use of narcotic drugs is indispensable for pain relief and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes). For additional information about global disparities in access to therapeutic opioids and pain care, see generally Evan D. Anderson & Corey S. Davis, *Breaking the Cycle of Untreated Pain*, 24 Temple Int. & Comp. L.J. 329 (2010).

2. See *infra* Part II-A.

3. See *infra* notes 26-27 and accompanying text (describing Medication Assisted Treatment (MAT)).

4. WORLD HEALTH ORG., ACHIEVING BALANCE IN NATIONAL OPIOIDS CONTROL POLICY (2000), <http://apps.who.int/medicinedocs/pdf/whozip39e/whozip39e.pdf> [hereinafter ACHIEVING BALANCE]. The International Narcotics Control Board (INCB), the UN agency responsible for enforcing international drug control treaties, has recognized that in many countries “fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. *Id.* The problem may also arise as a result of the manner in which drug control laws and regulations are interpreted or implemented. *Id.* See also Allyn Taylor, Lawrence O. Gostin & Katrina Pagonis, *Ensuring Effective Pain Treatment: A National and Global Perspective*, 299 J. AM. MED. ASS'N 89, 89-91 (2008).

5. See e.g., Allyn L. Taylor, *Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs*, 35 J. LAW MED. & ETHICS 556, 564 (2007) (describing the “Central Principle of Balance”).

6. See Anderson & Davis, *supra* note 1, at 355-363 (describing the political, social, and logistical impediments to access to opioids).

<sup>7</sup> See e.g., Kevin F. Ryan, *Clinging to Failure: The Rise and Continued Life of U.S. Drug Policy*, 32 LAW & SOC'Y REV. 221, 221-222 (1998) (noting for the U.S. context that “perhaps the clearest example of the imperviousness of the policy process to research findings is contemporary drug policy, and the attempt to figure out why our failed policy has not long since been jettisoned . . .”).

technical support of external entities has sustained it.<sup>8</sup> While only one of several countries to undergo opioid policy reform, Romania's experience in improving access to opioids for pain treatment is especially notable for its speed, efficiency, and comprehensiveness.

This article tells the story of reform in Romania.<sup>9</sup> Like many examples of policy reform, Romania's experience in reforming its opioid policy is not yet complete. There is still much to be done in Romania, in both pain and drug dependency treatment. Access to MAT, for example, remains limited in Romania despite some incremental policy advances.<sup>10</sup> We use the Romanian experience not to establish that one particular approach to reform will achieve a specific set of health outcomes, but to show that systematic reforms efforts can catalyze positive changes in an area in which law has been a longstanding impediment to health.

The story begins in the early 1990s, when opioids for medical treatment were widely unavailable. At the time, these essential medicines were either illegal or so heavily regulated that they were inaccessible, even for the treatment of severe pain experienced in end-of-life care.<sup>11</sup> For in-patient care, only a limited group of specified diagnoses could be treated with powerful opioids. Dosing amounts and intervals in pain treatment were determined by rigid laws that had changed little since 1969, rather than by the clinical judgment of trained practitioners.<sup>12</sup> Outpatient pain treatment for injuries or chronic conditions was severely restricted by onerous regulations governing the prescription, distribution, and administration

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8. Daniela Mosoiu et al., *Reform of Drug Control Policy for Palliative Care in Romania*, 367 LANCET 2110, 2113-17 (2006) [hereinafter Mosoiu et al., *Reform*].

9. This article is based on a comprehensive review of available English-language literature. It is not intended as a forensic description of legal and socio-political change. Unlike a scientific case study or rigorous historical research, we did not conduct structured interviews nor did we use systematic methods in collecting and synthesizing evidence. Our reliance on secondary sources and translations of Romanian laws is a limitation reflected in the broad strokes of reform we describe. However, this technical limitation does not undermine our purpose of conveying the steps necessary to catalyze and sustain policy reform.

10. See Daniela Mosoiu, *Romania 2002: Cancer Pain and Palliative Care*, 24 J. PAIN & SYMPTOM MGMT. 225, 227 (2002) [hereinafter Mosoiu, *Romania*] (explaining that as of 2002, "dextropropoxyphene, oxycodone, morphine oral solution, fentanyl patches, buprenorphine, and nalbuphine" were illegal to prescribe).

11. See Daniela Mosoiu, *Romania 2002: Cancer Pain and Palliative Care*, 24 J. PAIN & SYMPTOM MGMT. 225, 227 (2002) [hereinafter Mosoiu, *Romania*] (explaining that as of 2002, "dextropropoxyphene, oxycodone, morphine oral solution, fentanyl patches, buprenorphine, and nalbuphine" were illegal to prescribe).

12. Evan D. Anderson et al., *Closing the Gap: Case Studies of Opioid Access Reform in China, India, Romania & Vietnam*, TEMPLE U. LEGAL STUD. RES. PAPER NO. 2009-25, 56 (2009), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1356769](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1356769) (stating Romania adopted comprehensive drug control legislation in 1969, which remained unchanged until reforms in 2005 and 2007). Romania did not become a signatory to the 1961 Single Convention on Narcotic Substances until January of 1974. Single Convention on Narcotic Drugs, 1961, as amended by the Protocol Amending the Single Convention on Narcotic Drugs, 1961, Aug. 8, 1975, 18 U.S.T. 1407, 976 U.N.T.S. 105 [hereinafter Single Convention]; see also Mosoiu, *Romania*, supra note 11, at 227 (stating old regulations are one of many barriers hindering access to opioids).

of these drugs.<sup>13</sup> Misconceptions and fears of opioids were widespread among patients and physicians alike.<sup>14</sup>

Around the turn of the century, advocacy surrounding palliative care started to galvanize. As that advocacy matured within Romania, important collaborations developed with groups outside of the country that had access to specialized technical resources.<sup>15</sup> Funding from a few key sources played a critical role in facilitating these collaborations and sustaining momentum for reform. Less than a decade later, this momentum culminated in a ceremony in Bucharest commemorating the drafting of new pain regulations that thoroughly changed the legal framework for drug control in Romania.<sup>16</sup>

Political changes that were underway during this period – including Romania's accession into the European Union (EU) – also helped to facilitate drug control reform.<sup>17</sup> But the dramatic changes to Romanian drug control policy were not dependent on the convergence of fortuitous events. Key stakeholders worked collaboratively to support reform through the deliberate application of resources at important leverage points. In this respect, the Romanian experience exemplifies the benefits of an intervention model set forth elsewhere in this issue.<sup>18</sup> We use the same model to structure our story of drug policy reform in Romania.

In Part II, we describe the gap that existed prior to legal reform between the need for opioids and access to them in the treatment of moderate to severe pain in Romania. We also review the need for opioids in the treatment of drug dependency. In Part III, we discuss the legal and regulatory barriers that prevented access to essential opioids in Romania prior to reform. Part IV describes how the process of legal reform unfolded in Romania with emphasis on the key inputs that catalyzed and sustained change. This section highlights the importance of sustainability, flexibility, collaboration, and balance in the reform process. We summarize and conclude in Part V with a discussion of how the lessons learned from the Romanian experience can be applied elsewhere.

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13. *See infra* Part II-B.

14. *See infra* Part II-B.

15. *See infra* note 96 and accompanying text.

16. Mosoiu et al, *Reform, supra* note 8, at 2113 (describing effects of Law no. 339/2005).

17. For example, a condition of accession to the EU was the creation of drug use monitoring surveillance. *See EU Beefs up Medicine Surveillance Rules*, EURACTIV.COM, (Sept. 23, 2010), <http://www.euractiv.com/en/health/eu-beefs-medicine-surveillance-rules-news-498049> (noting that surveillance enables patients to be more informed on medicines and subsequently allows them to report adverse effects directly to national authorities).

18. The model, which developed from funding by the United Kingdom Department for International Development (DfID) is predicated on the idea that reform is possible in any country when meaningful collaboration between international NGOs and national champions is nurtured and sustained. Scott C. Burris & Corey S. Davis, *A Blueprint for Reforming Access to Therapeutic Opioid Medications*, TEMP. UNIV. CTR. FOR HEALTH LAW POL'Y & PRACTICE 1, 4 (2008), available at [http://www.painpolicy.wisc.edu/internat/DCAM/Burris\\_Blueprint\\_for\\_Reform.pdf](http://www.painpolicy.wisc.edu/internat/DCAM/Burris_Blueprint_for_Reform.pdf).

## II. ROMANIA IN THE EARLY 2000S: AN UN-MET NEED FOR ESSENTIAL MEDICINES

### A. *Background: The Need for Opioids*

Opioids are essential for pain treatment.<sup>19</sup> The treatment of pain is among the most basic of human rights.<sup>20</sup> Opioids are therefore needed in every country because moderate to severe pain from childbirth, acute accidents, and post-operative care exists in every part of the globe. To adequately treat pain, opioids must be provided in sufficient amounts and through reasonably accessible channels. The need for opioids is particularly great in Romania because of the high incidence and late diagnosis of cancer and the significant number of people living in Romania with HIV/AIDS.<sup>21</sup> Both diseases are associated with significant pain in their later stages.<sup>22</sup> Cancer is the second leading cause of death in Romania; more than two-thirds of Romanian cancer patients are diagnosed when the disease

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19. Meredith Noble et al., *Long-term Opioid Management for Chronic Noncancer Pain*, 1 THE COCHRANE LIBRARY 1, 3 (2010), available at <http://www.asipp.org/documents/Nobeletal.pdf> (studying the use of opioids for those suffering chronic noncancer pain); see also *infra* note 20, at 2; WORLD HEALTH ORG., WHO MODEL LIST OF ESSENTIAL MEDICINES 2 (2010), available at [http://www.who.int/medicines/publications/essentialmedicines/Updated\\_sixteenth\\_adult\\_list\\_en.pdf](http://www.who.int/medicines/publications/essentialmedicines/Updated_sixteenth_adult_list_en.pdf) [hereinafter ESSENTIAL MEDICINES 2010] (including opioids on list of essential medicines).

20. N. I. Cherny et al., *Formulary Availability and Regulatory Barriers to Accessibility of Opioids for Cancer Pain in Europe: A Report from the ESMO/ EAPC Opioid Policy Initiative*, 21 ANNALS OF ONCOLOGY 615, 615 (2010) (implying that major international organizations acknowledge access to adequate pain medication is a basic human right); see also Laura Thomson, *Access to Pain Treatment and Palliative Care: A Human Rights Analysis*, 24 TEMPLE INT'L & COMP. L.J. 365 (2010) (discussing the right to health, including the treatment of pain).

21. See Luminita Dumitrescu, *Palliative Care in Romania* 71 (Nov. 27, 2006) (unpublished Ph.D. dissertation, Rijksuniversiteit Groningen), available at <http://dissertations.ub.rug.nl/faculties/medicine/2006/l.dumitrescu/> (stating that most Romanians contact their doctor "in later stages of the disease, when cure is almost impossible. . . . due to the lack of awareness of this type of care, the absence of such services in many areas . . . and to the belief that cancer is an incurable disease . . ."); Mosoiu et al., *Reform*, *supra* note 8, at 2110 (stating that in developing countries cancer is often diagnosed late). For incurable cancer, opioid therapy is an essential component of palliative care. WORLD HEALTH ORG., CANCER CONTROL 6 (2007), available at <http://www.who.int/cancer/media/FINAL-Palliative%20Care%20Module.pdf> (stating that in developing countries cancer is often diagnosed late); see Daniela Mosoiu, *Romania: Changing the Regulatory Environment*, 33 J. PAIN & SYMPTOM MGMT. 610, 611 (2007) [hereinafter Mosoiu et al., *Changing the Regulatory Environment*] (stating that the number of people living with HIV/AIDS in Romania is as many as 14,000); see also UNGASS COUNTRY PROGRESS REPORT, *infra* note 51, at 5 (stating that "Romania is one of the few countries in Central and South Eastern Europe with a significant number of people affected by HIV/AIDS").

22. S. Ahmedzai, *New Approaches to Pain Control in Patients with Cancer*, 35 EUR. J. CANCER S8, S8 (1997); François Larue, Alain Fontaine & Sophie M. Colleau, *Underestimation and Undertreatment of Pain in HIV Disease: Multicentre Study*, 314 BRIT. MED. J. 23, 26 (1997) (suggesting that pain increases as HIV progresses); see also John Koeppel et al., *Ongoing Pain Despite Aggressive Opioid Pain Management Among Persons With HIV*, 26 CLINICAL J. OF PAIN 190 (2010) (stating that having a long history of AIDS correlates with more pain).

is in an advanced and largely untreatable stage.<sup>23</sup> For many years, Romania also had one of the highest rates of HIV infection in the Central European Region, due to an epidemic of pediatric HIV/AIDS caused, in part, by unscreened blood products.<sup>24</sup> The indispensable value of opioids, particularly morphine and codeine, in treating pain from cancer, HIV/AIDS, and other conditions is recognized by their designation as essential medicines by the World Health Organization (WHO).<sup>25</sup>

Opioids are also needed in Romania for the treatment of drug addiction. Illicit drug use, particularly injection drug use, has been a major public health problem in Romania for the last few decades.<sup>26</sup> In 2000, there were an estimated 16,000 injection drug users (IDUs) in Bucharest alone.<sup>27</sup> Injection drug use is associated with high rates of HIV/AIDS, Hepatitis B and Hepatitis C, and overdoses.<sup>28</sup> One intervention proven to reduce these associated harms is prescribing therapeutic opioids to injection drug users as replacement therapy, or

23. Mosoiu et al., *Reform*, *supra* note 8, at 2110.

24. Simona Rută & Costin Cernescu, *Influence of Social Changes on the Evolution of HIV Infection in Romania*, 65 INT'L J. ENVTL. STUDIES 501, 502 (2008) (detailing the pediatric epidemic that occurred in the early 1990s, which was partly attributed to the out-dated practice of giving blood transfusions to newborn infants). Also contributing to the high rate of infection was the fact that HIV/AIDS was not officially recognized by the Romanian government until after the overthrow of the Ceausecu regime. Celestine Bohlen, *Upheaval in the East: Romania's AIDS Babies: A Legacy of Neglect*, N.Y. TIMES, Feb. 8, 1990, at A1. Before this period, HIV spread widely through unscreened blood transfusions and re-use of syringes. *Id.*

25. ESSENTIAL MEDICINES 2010, *supra* note 19, at 1, 2.

26. *See, e.g., Drug Treatment Overview for Romania*, EUROPEAN MONITORING CENTER FOR DRUGS AND DRUG ADDICTION, <http://www.emcdda.europa.eu/data/treatment-overviews/Romania> (last visited Nov. 10, 2010). The Romanian government began tracking epidemiological data related to drug use and public health in the mid-1990s. In 1999, Romania began issuing yearly reports. These reports are the source for the statistics in this case study demonstrating the need for opiate substitution therapy in Romania.

27. *Id.*

28. *Id.* Drug overdose is also a significant problem: a 2003 study conducted by the Romanian Harm Reduction Network revealed that one-third of sampled IDUs had “witnessed or . . . [experienced] an overdose.” NAT'L ANTI-DRUG AGENCY, ROMANIA NATIONAL REPORT ON DRUGS SITUATION 2003 11 (2004), *available at* [http://www.emcdda.europa.eu/attachements.cfm/att\\_34499\\_EN\\_NR2004Romania.pdf](http://www.emcdda.europa.eu/attachements.cfm/att_34499_EN_NR2004Romania.pdf). [hereinafter NAT'L ANTI-DRUG AGENCY, 2003 REPORT]; EUROPEAN MONITORING CENTER FOR DRUGS AND DRUG ADDICTION, ANNUAL REPORT 2005 THE STATE OF THE DRUG PROBLEM IN EUROPE 69 (2005), *available at* [http://www.emcdda.europa.eu/attachements.cfm/att\\_37249\\_EN\\_TDAC05001EN1.pdf](http://www.emcdda.europa.eu/attachements.cfm/att_37249_EN_TDAC05001EN1.pdf) [hereinafter ANNUAL REPORT 2005]; REITOX NAT'L FOCAL POINT, “ROMANIA” NEW DEVELOPMENT, TRENDS AND IN-DEPTH INFORMATION ON SELECTED ISSUES 44-46 (2006), *available at* [http://www.ana.gov.ro/rom/drug\\_situation.pdf](http://www.ana.gov.ro/rom/drug_situation.pdf); *see generally* Tinka Markham Piper et al., *Overdose Prevention for Injection Drug Users: Lessons Learned from Naloxone Training and Distribution Programs in New York City*, 4 HARM REDUCTION J. 3 (2007) (stating that injection drug use can lead to overdose); *See* World Health Organization, UNAIDS, UNODC “Policy Brief: Antiretroviral Therapy and Injecting Drug Users,” WHO/HIV/2005..06 *available at* [www.who.int/hiv/pub/prev\\_care/arvidu.pdf](http://www.who.int/hiv/pub/prev_care/arvidu.pdf) (stating that in addition to HIV, injection drug use can result in infection of hepatitis B, C, and D, and result in other health problems like overdose and severe bacterial infections).

Medication Assisted Treatment (MAT).<sup>29</sup> Additionally, MAT provides opportunities for early diagnosis of other health problems and access to health services.<sup>30</sup> For these reasons, MAT is standard practice for treating opioid addiction in industrialized countries.<sup>31</sup> The two most commonly prescribed opioids for MAT – methadone and buprenorphine – are included in the WHO’s Model List of Essential Medicines.<sup>32</sup>

### ***B. Inadequate Access Before 2005: A Public Health Problem***

While measuring the amount of undertreated pain at the population level is difficult,<sup>33</sup> two types of data reflect the inadequate access to therapeutic opioids in Romania prior to legal reforms. The first is national opioid consumption data,<sup>34</sup>

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29. David S. Metzger et al., *Drug Abuse Treatment as AIDS Prevention*, 113 PUB. HEALTH REP. 97, 99 (1998) (noting that an IDU in a MAT program is given an opioid medication in a medically supervised, safe and controlled clinical environment); Robert Heimer & Harold Pollack, *The Impact and Cost-Effectiveness of Methadone Maintenance Treatment in Preventing HIV and Hepatitis C*, in *HEPATITIS C AND INJECTING DRUG USE: IMPACT, COSTS AND POLICY OPTIONS* (J. Jager et al. eds., 2004) (indicating that medication, in combination with psychosocial services, reduces and may completely eliminate both the craving for the illegal opioids and the further injection of illicit drugs). In addition, MAT patients must remain in treatment for an adequate period of time for it to be effective; the minimum threshold being three months, but in some cases effective treatment can take several years. WORLD HEALTH ORG., WHO/UNODC/UNAIDS POSITION PAPER 8, available at [http://www.who.int/substance\\_abuse/publications/en/PositionPaper\\_English.pdf](http://www.who.int/substance_abuse/publications/en/PositionPaper_English.pdf) [hereinafter POSITION PAPER]. However, when properly implemented, an opioid treatment policy contributes to public health at the individual as well as the community level. *Id.* at 32. For example, MAT benefits injection drug users by removing the harms associated with injection drug use including the risks of blood-borne infections, bacterial infections and drug overdose; it can also reduce the spread of HIV in the community because IDUs infected with HIV can transmit the disease through sexual contacts, as well as through “transmission to unborn children by infected mothers” and “commercial sex work.” Linda Gowing, et al., *Substitution Treatment of Injecting Opioid Users for Prevention of HIV Infection*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS 1, 2, 29 (2008). However, a MAT policy is impossible without greater access to opioids like Methadone, which has been used in MAT for over four decades and is the preferred medication for MAT in the US and most of Europe. ANNUAL REPORT 2005, *supra* note 28, at 13.

30. POSITION PAPER, *supra* note 29, at 23.

31. See Peter Lawrinson et al., *Key Findings from the WHO Collaborative Study on Substitution Therapy and HIV/AIDS*, 103 ADDICTION J. 1484, 1484 (2008) (discussing the effectiveness of opioid substitution therapy in low resource countries and industrialized countries).

32. ESSENTIAL MEDICINES 2010, *supra* note 19.

33. Even measuring pain at the individual level is difficult. Rory J. O’Connor & Alan Tennant, *Measuring Pain: Issues of Interpretation*, 372 LANCET 443, 443 (2008) (stating that there are challenges to measuring pain in individual patients because of the inherently subjective nature of pain and absence of validated measures of pain). For this reason, there are no validated biometric or population level measures of untreated pain.

34. PAIN & POLICY STUDIES GROUP, OPIOID AVAILABILITY IN THE WORLD 5 (Sept. 3, 2004), available at <http://www.painpolicy.wisc.edu/publicat/monograp/geneva04.pdf> [hereinafter OPIOID AVAILABILITY IN THE WORLD]. One source of evidence is the disparities in the per capita consumption of essential opioids between Romania and other countries. *Id.* It is difficult to make

which the International Narcotics Control Board (INCB) tracks on an annual basis for all signatories to the major international drug control treaties.<sup>35</sup> With one exception, per capita opioid consumption in Romania prior to 2000 had never exceeded one milligram for morphine, 0.1 milligrams for methadone and 0.025 milligrams for fentanyl.<sup>36</sup> In comparison, in 2001, per capita consumption of morphine in the United States was about 35 milligrams, 95 milligrams for methadone, and 114 milligrams for fentanyl.<sup>37</sup> Indeed, Romania's per capita consumption of morphine was among the lowest in Europe for many years, far below the global per capita mean.<sup>38</sup>

Prior to reforms in 2005, Romania's drug policy included several barriers to adequate access to essential opioids. Numerous opioids – including some listed as essential medicines by the WHO – were forbidden for all uses in Romania.<sup>39</sup> Additionally, the dosages and indications for which other opioids could be prescribed were significantly restricted.<sup>40</sup> Thus, even technically legal drugs were often subject to such burdensome regulations as to be effectively inaccessible for many patients.<sup>41</sup> The process of obtaining drugs was so slow and cumbersome that

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finely tuned conclusions from national consumption data because the accuracy of those statistics is unknown and each country's use varies. One country may prefer one opioid over another. Nevertheless, per capita data generally shows stark differences between countries. *Id.*

35. See generally INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2009, U.N. Doc. E/INCB/2009/1 (2010) (presenting consumption data in its annual report).

36. PAIN & POLICY STUDIES GROUP, 2007 CONSUMPTION IN ROMANIA 1, 3, 5 (2010), available at <http://www.painpolicy.wisc.edu/internat/EURO/Romania/opioids.pdf> (showing Romania's consumption levels from 1980-2008. The one exception was a once off spike in morphine consumption in 1996.) [hereinafter 2007 CONSUMPTION IN ROMANIA].

37. OPIOID AVAILABILITY IN THE WORLD, *supra* note 34, at 5.

38. PAIN & POLICY STUDIES GROUP, 2007 CONSUMPTION OF MORPHINE 2 (2009), available at <http://www.painpolicy.wisc.edu/internat/global/morphine07.pdf> (showing global mean figures). As recently as 2007, Romania's per capita consumption of morphine was approximately 12 times smaller than the global mean of 5.9823 mg. *Id.*; see also 2007 CONSUMPTION IN ROMANIA, *supra* note 36, at 4 (charting Romanian consumption levels from 1980-2008).

39. Mosoiu, *Romania*, *supra* note 11, at 227 (stating that, for example, prior to recent legal reforms, dextropropoxyphene, oxycodone, morphine oral solution, buprenorphine and nalbuphine were all illegal to prescribe); see also ESSENTIAL MEDICINES 2010, *supra* note 19 (showing that oral morphine is listed on the illegal list).

40. Luminita Dumitrescu et al., *Palliative Care Between Past and Future*, 3 MEDICAL ROMANA 153 (2003) in PALLIATIVE CARE IN ROMANIA 25, 37 (Luminita Dumitrescu, ed. 2006), available at [http://dissertations.ub.rug.nl/FILES/faculties/medicine/2006/l.dumitrescu/13\\_thesis.pdf](http://dissertations.ub.rug.nl/FILES/faculties/medicine/2006/l.dumitrescu/13_thesis.pdf)

("Treatment doses and intervals are set by law and not by the professionals, which limits prescription. For example, only one product may be prescribed at one time/consultation."); see also Daniela Mosiou et al., *Romania: Changing the Regulatory Environment*, *supra* note 21, at 611 (2007) ("According to the old law, doctors were allowed to prescribe opioids for outpatients only with advanced cancer or with obliterative arteritis with necrosis. Even for these patients, the process was extremely complicated: authorization was required with a dry stamp prescription in triplicate and there was just one dispensing pharmacy per district (usually serving a population of 400,000 inhabitants).").

41. Mosoiu et al., *Reform*, *supra* note 8, at 2113 (discussing physicians' ability to prescribe

it was not unheard of for a patient to die before the paperwork authorizing the treatment of her pain was processed.<sup>42</sup>

Prior to reform, access to opioids in Romania was also impeded by a shortage of prescribers and a general dearth of knowledge about providing care to terminally ill patients.<sup>43</sup> Before the turn of the century, nurses were not permitted to prescribe opioids, while doctors were often afraid to do so because of popular misconceptions about the risks of addiction<sup>44</sup> or fear of harassment by law enforcement.<sup>45</sup> Consequently, reports suggest that few patients—as little as 15% of cancer patients, for example—received appropriate pain management.<sup>46</sup>

At the time, access to MAT in Romania was severely limited.<sup>47</sup> In 2000, it was illegal to prescribe buprenorphine for MAT and though methadone was introduced in 1998, prescribing was only allowed on a highly restricted basis.<sup>48</sup> By 2003, the few centers in the entire country providing MAT<sup>49</sup> were all located in Bucharest; covering only 400 patients<sup>50</sup> out of an estimated 24,006 IDUs living in

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a maximum of a three-day supply of opioid analgesics in Romania for short-term purposes, as well as varied and significant barriers to access in longer-term cases, including the need for special authorization to prescribe); *see also* Luminita Dumitrescu & Wim van den Heuvel, *Evaluation of Palliative Care at Home: The Families' Perspective*, 23 J. PALLIATIVE CARE 54, 57 (2007) (“Obtaining such medication, if at all affordable by patients, requires a lot of paper work and, consequently, much of the time that they could have benefited the patient was lost.”).

42. Anderson et al., *supra* note 12, at 62.

43. *See* Ana-Claudia Bara et al., *Reforms of Health Care System in Romania*, 43 CROAT. MED. J. 446, 448 (2002) (detailing the shortage of medical professionals in Romania compared to other EU countries prior to the turn of the century); Luminita Dumitrescu et al., *Experiences, Knowledge, and Opinions on Palliative Care among Romanian General Practitioners*, 47 CROAT. MED. J. 142, 142, 145, 147 (2006) (finding that 60% of 1283 general practitioners polled in Romania believed they had insufficient knowledge to provide palliative care to the terminally ill, while just 6% considered themselves well-informed about palliative care for cancer patients, and raising lack of Romanian-language texts as possible explanation).

44. Mosoiu et al., *Reform supra* note 8, at 2113 (finding that bias against opioids has been documented in both professional and general populations in Romania).

45. This fear may also be linked to the prevalence of under-the-table payments made to medical professionals in the country. Bara et al., *supra* note 43, at 451 (indicating that under-the-table payments hamper access to healthcare for those with low incomes).

46. Dumitrescu et al., *supra* note 40, at 37-38.

47. In 2005, there were only two centers offering methadone maintenance, and both were located in Bucharest. CENTRE FOR INTERDISCIPLINARY ADDICTION RESEARCH (ZIS) OF THE HAMBURG UNIVERSITY, QUALITY OF TREATMENT SERVICES IN EUROPE DRUG TREATMENT SITUATION AND EXCHANGE OF GOOD PRACTICE 366 (2008), *available at* [http://ec.europa.eu/health/ph\\_determinants/life\\_style/drug/documents/drug\\_treatment\\_frep\\_en.pdf](http://ec.europa.eu/health/ph_determinants/life_style/drug/documents/drug_treatment_frep_en.pdf)

48. NAT'L ANTI-DRUG AGENCY, ROMANIA NATIONAL REPORT ON DRUGS SITUATION 2010 114 (2010) [hereinafter NAT'L ANTI-DRUG AGENCY, 2010 REPORT], *available at* [http://www.politiaromana.ro/RO\\_National\\_Report\\_2010.pdf](http://www.politiaromana.ro/RO_National_Report_2010.pdf) (describing the very limited availability of methadone, available only at a pilot center within the George Marinescu Hospital, established in 1997); *see also Drug Treatment Overview for Romania, supra* note 26.

49. CENTRE FOR INTERDISCIPLINARY ADDICTION RESEARCH, *supra* note 47, at 366.

50. NAT'L ANTI-DRUG AGENCY, 2010 REPORT, *supra* note 48, at 115 (stating that maximum capacity for treatment centers at the time allowed for 400 patients total).

the city during that time.<sup>51</sup> One of the impediments then was the limited number of trained providers. In 1999, only four physicians in the entire country had been trained in the treatment of drug addiction.<sup>52</sup> As Romania candidly admitted to the European Monitoring Center for Drugs and Drug Addiction, “[d]ue to the lack of all the therapeutic links as well as of the specialized personnel, it can be said that during 1999, no complete and appropriate treatment was offered to addicted persons.”<sup>53</sup> This admission of inadequate programming and policy continued to characterize care in Romania for a number of years as recognized in subsequent reports.<sup>54</sup>

### III. REGULATORY BARRIERS TO ESSENTIAL OPIOID MEDICINES IN ROMANIA BEFORE 2007

The 1961 UN Single Convention on Narcotic Drugs (Single Convention) and subsequent treaties require countries to regulate the flow of opioids and other controlled substances.<sup>55</sup> These international treaties require, in general terms, that countries implement laws that reduce the diversion of opioids into illicit channels while at the same time ensuring access to opioids for medical and scientific purposes.<sup>56</sup> This requirement is known as the Principle of Balance; laws that unduly impede access to opioids for medical purposes violate this obligation.<sup>57</sup> In addition, countries are explicitly obligated to provide access to those opioids that are included on the WHO Essential Medicines list.<sup>58</sup>

At the end of the twentieth century, numerous barriers to adequate access existed in Romanian laws and policies. These regulatory choices reflected an imbalanced commitment to drug control and a failure to actively support access to therapeutic opioids as required by international commitments. One of the primary impediments to adequate access was the lack of infrastructure for assessing the

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51. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, UNGASS COUNTRY PROGRESS REPORT: ROMANIA 12 (2010), *available at* [http://data.unaids.org/pub/Report/2010/romania\\_2010\\_country\\_progress\\_report\\_en.pdf](http://data.unaids.org/pub/Report/2010/romania_2010_country_progress_report_en.pdf) [Hereinafter UNGASS COUNTRY PROGRESS REPORT].

52. Anderson et al., *supra* note 12, at 69.

53. PHARE PROJECT ON DRUG INFORMATION SYSTEMS BRIDGING PHASE, NATIONAL REPORT ON THE DRUGS SITUATION IN ROMANIA 59 (European Commission 2000).

54. *See* THE EUROPEAN INFORMATION NETWORK ON DRUGS AND DRUG ADDICTION ROMANIA DRUG SITUATION 2003 30 (2004) (“The treatment system available for drug addicted in 2003 was not very different from previous years. The therapeutic chain was incomplete.”).

55. *See generally* Single Convention, *supra* note 12; Convention on Psychotropic Substances, Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175 [hereinafter Convention on Psychotropic Substances]; Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, Dec. 20, 1988, 1582 U.N.T.S.164 (recommending the removal of barriers to facilitate increased access to opioid analgesics) [hereinafter Convention Against Illicit Traffic].

56. *See generally* Single Convention, *supra* note 12; Convention on Psychotropic Substances, *supra* note 55; Convention Against Illicit Traffic, *supra* note 55.

57. *Drug Treatment Overview for Romania*, *supra* note 26.

58. Single Convention, *supra* note 12.

need for opioid medications. Without this capacity, Romania was unable to ensure either adequate importation or domestic production of opioids.<sup>59</sup>

Furthermore, even when opioids were in the country, access to them was subject to overly restrictive legal requirements. Strikingly – and perhaps surprisingly for readers from countries that provide wide latitude to doctors in clinical decision-making – Romanian drug control laws severely restricted the medical use of opioids in *inpatient* care.<sup>60</sup> For example, only brief post-surgical management of acute pain and the treatment of terminal cancer, advanced arthritis at the gangrene stage, and heart failure were recognized as appropriate uses for opioid medications.<sup>61</sup> Even for these conditions, physicians could only prescribe morphine for three days of inpatient care without receiving official exemptions.<sup>62</sup>

The laws governing outpatient care also created significant obstacles for many patients in need. To understand just how problematic these laws and policies were requires some understanding of outpatient care in Romania.<sup>63</sup> In Romania, most cancer patients and terminal patients are cared for at home by hospice physicians or general practitioners.<sup>64</sup> Under the pre-reform regulations, in order for a patient to be treated at home for severe pain, a complex chain of events had to occur.<sup>65</sup> First, a family doctor or hospice physician had to create a certificate confirming the patient's pain.<sup>66</sup> That certificate was then taken to the outpatient department of a state hospital where it had to be signed by an oncologist.<sup>67</sup> The oncologist at the hospital would then decide the type and dose of the opioid and would select a

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59. See Mosoiu et al., *Reform supra* note 8, at 2113 (Romania was one of the first Eastern European countries to address the lack of infrastructure beginning in the late 1980s). The 1961 Convention on Narcotic Drugs created a closed system of drug control requiring countries to submit to the International Narcotics Control Board annual estimates of the amounts of opioids required to satisfy all domestic medical and scientific needs. Single Convention, *supra* note 12, art. 19. Governments may not import, manufacture or distribute more than the estimated requirement of any individual drug, although the estimate is easily amended to accommodate unforeseen needs. *Id.* So, if a country does not properly report the amount of opioid needed, that country's supply will be inadequate. Inadequate reporting remains a problem in Romania. INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS BOARD FOR 2008, 107, U.N. Doc. E/INC/2008/1 (2009) (“[I]n Romania the existing mechanism for the monitoring and control of internationally controlled substances is neither sufficient nor functioning adequately” and “the availability of opioids for the treatment of pain does not appear to meet the requirements of the population in Romania.” As a result, the Board urged Romania “to accurately determine the national medical and/or scientific requirements for narcotic drugs and psychotropic substances and to take all steps necessary . . . to ensure that those substances are available for medical purposes.”).

60. Mosoiu et al., *Reform, supra* note 8, at 2113.

61. Mosoiu et al., *Changing the Regulatory Environment, supra* note 21, at 610-14.

62. *Id.*

63. Mosoiu et al., *Reform, supra* note 8, at 2114.

64. Dumitrescu, *supra* note 21, at 78.

65. Mosoiu et al., *Reform, supra* note 8, at 2114.

66. *Id.*

67. *Id.*

pharmacy to dispense it.<sup>68</sup> The authorized certificate then had to be taken back to the family physician or hospice physician who could, at that point, issue a prescription for ten to fifteen days of pain medicine.<sup>69</sup> However, the family doctor could not make any changes to the type or amount of opioid, even if the patient's status had changed.<sup>70</sup> The patient's family was responsible for bringing the certificate to the hospital oncologist, bringing that authorization back to the treating physician and taking the physician's prescription to the pharmacy to receive the drug.<sup>71</sup> If the specified type and dosage of the opioid was not in stock in the pharmacy, the process had to be repeated from the beginning.<sup>72</sup> A patient could only be prescribed one opioid via one route at a time, so a second drug could not be prescribed for break-through pain<sup>73</sup> to patients who received slow-release opioids.<sup>74</sup>

The pre-reform legal barriers to access to opioids used for MAT were even more significant. From 1997-2000, MAT services were restricted to three inpatient facilities. Service at these facilities was frequently interrupted by funding shortages and difficulties complying with regulatory requirements.<sup>75</sup> High fee-for-service costs were also a known obstacle.<sup>76</sup> The first national law governing illicit drug use in Romania, enacted in 2000, did not authorize or support medical, psychological, and social assistance services for drug dependency such as MAT.<sup>77</sup> However, that year, the Ministry of Health did expand pilot treatment units to additional centers including establishing the first methadone maintenance center.<sup>78</sup> During this time,

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68. *See id.* at 2113 (noting that these pharmacies must have special authorization from the MOH to store and dispense strong opioids); *see also* Taylor et al., *supra* note 5, at 90 (discussing how problems of physical access to narcotic analgesics contribute to the under-treatment of pain, especially among minority populations, and noting that Kerala, India recently facilitated a major increase in community-based palliative care by loosening onerous licensing requirements for pharmacies); WORLD HEALTH ORG, CANCER PAIN RELIEF CANCER PAIN 14-17 (2d ed. 1996) (noting that the WHO considers evaluation – including discussions with the patient about pain and a period where dosage is monitored and changed according the patient's needs – a vital first step in proper cancer pain management).

69. Mosoiu et al., *Reform, supra* note 8, at 2113.

70. *Id.*

71. *Id.*

72. *Id.*

73. *See* Russel K. Portenoy & Neil A. Hagan, *Breakthrough Pain*, 41 PAIN 273, 273-81 (1990) (defining break-through pain as a sudden flare of pain that “breaks through” the long-acting medication prescribed to treat persistent pain. Most people treated for persistent pain experience breakthrough pain and the ideal treatment is a strong, short-acting opioid medication that works quickly and lasts about as long as a breakthrough pain episode).

74. Mosoiu et al., *Reform, supra* note 8, at 2115.

75. European Monitoring Centre for Drugs and Drug Addiction National Anti-Drugs Agency, National Report on Drugs Situation 2010: Romania New Developments, Trends and In-depth Information on selected Issues, 114 (2010).

76. *Id.*

77. Csaba L. Degi, *A review of drug prevention system development in Romania and its impact on youth drug consumption trends, 1995-2005*, 28 DRUG & ALCOHOL REV. 419, 421 (2009).

78. *Id.*

it was illegal to use buprenorphine for any medical practice.<sup>79</sup> Fear about potential prosecution under penal provisions criminalizing “unnecessary” prescription of narcotics and the facilitation of drug use chilled the spread of MAT services by potential providers.<sup>80</sup> Despite efforts by the Ministry of Health to improve MAT access in 2000, policy barriers to MAT access remained, such as high threshold admission criteria at providing clinics.<sup>81</sup> It was not until 2005 that regulatory reforms standardized MAT services at the organizational level to better facilitate treatment for drug dependency.<sup>82</sup>

#### IV. THE ROMANIAN REFORM EXPERIENCE

The story of reform in Romania has been held out as one of the best examples for how to make incremental and measurable progress in promoting access to opioids for the treatment of pain. Elsewhere in this issue the lessons learned in Romania and other countries are refined into an intervention model.<sup>83</sup> We use the structure of that model to frame the story of legal change in Romania. Because the Romanian experience with pain policy informed the development of the model, the model fits our narrative for pain reform quite well. The structure fits the story of reform in MAT decidedly less so. Reform around MAT has happened much more slowly and much less systematically. Nevertheless, we use the same structure to tell that story too. While it isn't our main intention, some of the contrasts underscore why the process for pain worked and, more broadly, why the model makes sense as a good way to think about collaborative reform.

##### A. Palliative Reform

###### 1. Catalyzing Change

During the mid 1980s and 1990s, Romanian medical professionals became increasingly concerned with the inadequacy of palliative care; and advocates began to agitate for a change in professional perceptions of therapeutic opioid use. This advocacy coalesced in the late 1990s with the founding of the Romanian Association for Palliative Care by physicians Maria Lungu and Constantin

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79. Mosoiu, *Romania*, *supra* note 11, at 227.

80. Telephone Interview with Mihai Tanasecu, Delegate for the Romanian Harm Reduction Network (May 20, 2010) (threat of criminal sanction, in particular, chills widespread adoption of opioid medicines for MAT) [hereinafter Tanasecu]; *see also* Criminal Code of Rom., Art. 387(2) (2005) (Rom.) (outlining the consequences of non-compliance with provisions regarding illicit drug administration).

81. *See* EUROPEAN MONITORING CENTER FOR DRUGS AND DRUG ADDICTION, THE STATE OF THE DRUGS PROBLEM IN EUROPE 31 (2006) (“Romania . . . [is] characterized by low geographical coverage of methadone substitution, and in some places there is a waiting list for treatment.”).

82. NAT'L ANTI-DRUG AGENCY, ROMANIA NATIONAL REPORT ON DRUGS SITUATION 2007 38 (2007) [hereinafter NAT'L ANTI-DRUG AGENCY, 2007 REPORT] (describing the effects of Law no. 339/2005).

83. *See* Chiu et al., *supra* note 15.

Bogdan.<sup>84</sup> The early 1990s also saw the establishment of two centers dedicated to pain treatment, Hospice Casa Sperantei,<sup>85</sup> and St. Lawrence's Hospice, funded by foreign charities.<sup>86</sup> In 1999, Dr. Lungu and Dr. Bogdan founded the Romanian Society for Palliatology and Thanatology and hosted the first national conference for palliative care, with international participation.<sup>87</sup> The group was involved in a number of activities to educate medical professionals about palliative care, including the publication of a quarterly bulletin and an annual review.<sup>88</sup> Hospice Casa Sperantei also turned its attention toward educating medical professionals in palliative care by opening a palliative care resource-training centre in 1997.<sup>89</sup> The center provided palliative care-related resources<sup>90</sup> and offered postgraduate palliative care courses for doctors, nurses, and pharmacists.<sup>91</sup>

The work of these groups started to translate into early signs of reform around the turn of the century. In 2000, palliative care was "recognized by the Romanian Ministry of Health as a medical subspecialty."<sup>92</sup> This marked the first official recognition of palliative care as medical, rather than social, care.<sup>93</sup> At the same time, large philanthropic groups were starting dedicated efforts to increase access to palliative care in several countries in the region. The Open Society Institute (OSI)<sup>94</sup> was especially active in Eastern Europe at this time, funding and

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84. NAT'L ANTI-DRUG AGENCY, 2003 REPORT, *supra* note 28, at 9.

85. MICHAEL WRIGHT, THOMAS LYNCH & DAVID CLARK, INT'L OBSERVATORY ON END OF LIFE CARE, A REVIEW OF DONOR ORGANIZATIONS THAT SUPPORT PALLIATIVE CARE DEVELOPMENT IN FIVE WORLD REGIONS 19 (2008).

86. *Id.*

87. *Id.*

88. *Id.*

89. Alison Landon & Daniela Mosoiu, *Hospice 'Casa Sperantei' – Pioneering Palliative Home Care Services in Romania*, 18 PROGRESS IN PALLIATIVE CARE 23, 24 (2010).. The Center was named the Princess Diana Hospice Education Centre. NAT'L ANTI-DRUG AGENCY, 2003 REPORT, *supra* note 28, at 7. In the first ten years of hospice service, over 2,500 patients and their families were cared for at Casa Sperantei and 700 doctors, nurses and other professionals attended courses. *Id.* When the center opened, a program entitled Poland and Hungary: Assistance for Restructuring their Economies (PHARE), a European Union initiative to prepare countries of Central and Eastern Europe for accession into the Union, agreed to fund 75% of its courses for two years. *Id.* at 10. The education center has since achieved international recognition, addressing the training needs of health professionals within Romania and southeastern Europe. *Id.*

90. *Study Center Services*, HOSPICE "CASA SPERANTEI" BRASOV, ROMANIA, <http://hospice.org.ro/sc.htm> (last visited Oct. 25, 2010).

91. *Id.*

92. Mosoiu et al., *Reform*, *supra* note 8, at 2113.

93. EUROPEAN ASSOCIATION FOR PALLIATIVE CARE, ROMANIA (2006), *available at* <http://www.eapcnet.org/download/forPolicy/CountriesRep/Romania.pdf> ("Since 2000, palliative care has been recognized as a medical subspecialty by an order of the Ministry of Health.").

94. OPEN SOCIETY INSTITUTE, CENTRAL EURASIA PROJECT CALL FOR GRANT PROPOSALS 1 (2010), *available at* <http://www.soros.org/initiatives/cep/grants/2010call-for-proposals-20100427.pdf> (describing the OSI as a "private operating and grant making foundation that aims to shape public policy to promote democratic governance, human rights, and economic, legal and social reforms").

organizing a range of activities through its International Palliative Care Initiative.<sup>95</sup> The Pain and Policy Studies Group (PPSG), an academic center based in the United States, started working with the WHO in 2000 to provide technical assistance to countries interested in opioid policy reform.<sup>96</sup>

In 2002, national standards for palliative care were adopted and became part of a Ministry of Health strategy for the development of health services at the national level.<sup>97</sup> The standards were developed through a partnership project between the Romanian Association for Palliative Care and the National Hospice and Palliative Care Organization.<sup>98</sup> These changes signaled a growing consensus among national stakeholders of the importance of palliative care. But efforts in supplying sufficient pain relief were uncoordinated among national advocates.<sup>99</sup> In addition, restrictive regulations and widespread misconceptions about therapeutic opioid use were prevalent.<sup>100</sup>

Based on reports about this growing momentum and continued obstacles, in 2002, OSI, WHO, and PPSG sponsored a regional initiative in Budapest aimed at improving palliative care.<sup>101</sup> Stakeholders representing patients with cancer and AIDS, as well as palliative care advocates and government drug regulators from Romania, Bulgaria, Croatia, Hungary, Lithuania, and Poland were invited.<sup>102</sup> The objective of the conference was to provide participants with the knowledge necessary to evaluate their national opioid control policies.<sup>103</sup> One of the main

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95. *Public Health Care Program Palliative Care*, OPEN SOCIETY FOUNDATIONS, <http://www.soros.org/initiatives/health/focus/ipci/about> (last visited Dec. 19, 2010) (indicating that the goal of the International Palliative Care Initiative is to provide end of life care for patients and their families, with a special focus on vulnerable populations including the elderly, children, and patients living with cancer and HIV/AIDS).

96. *About*, PAIN & POLICY STUDIES GROUP, <http://www.painpolicy.wisc.edu/about.htm> (last visited Dec. 19, 2010); see Anderson et al., *supra* note 12, at 61 (indicating that the international program of the PPSG develops and applies methods that can be used by health care professionals and governments to evaluate and improve national policies that govern availability and access to the controlled medicines); OPEN SOCIETY FOUNDATIONS, *EASING THE PAIN SUCCESSES & CHALLENGES IN INTERNATIONAL PALLIATIVE CARE 32 (2010)*, available at [http://www.soros.org/initiatives/health/focus/ipci/articles\\_publications/publications/easing-pain-201015/easing-pain-201015.pdf](http://www.soros.org/initiatives/health/focus/ipci/articles_publications/publications/easing-pain-201015/easing-pain-201015.pdf) (relating that IPCI has supported the PPSG by funding a pain policy fellowship that equips fellows with the knowledge and skills to evaluate national policy and improve the availability of pain medications in their respective countries).

97. Mosoiu et al., *Reform*, *supra* note 8, at 2113.

98. *Id.*

99. *Id.*

100. *Id.*

101. WHO REGIONAL OFFICE FOR EUROPE, *ASSURING AVAILABILITY OF OPIOID ANALGESICS FOR PALLIATIVE CARE 1 (2002)*, available at <http://test.cp.euro.who.int/document/e76503.pdf> [hereinafter OPIOID ANALGESICS].

102. Anderson et al., *supra* note 12, at 61-62.

103. OPIOID ANALGESICS, *supra* note 101, at 1.

goals of the conference was to establish collaboration between representatives of national, governmental, and palliative care organizations.<sup>104</sup> To this end, the six participating countries were encouraged to formulate an action plan aimed at improving the availability of opioid medications for relief of pain and suffering.<sup>105</sup>

At the conference, each country used the WHO Achieving Balance<sup>106</sup> guidelines to perform a preliminary assessment of their national opioid medication control policies.<sup>107</sup> After completing the assessment, each country developed an action plan to address regulatory barriers and patient access to drugs for pain in their countries.<sup>108</sup>

“Romania was the first country to take concrete action after the meeting.”<sup>109</sup> The Romanian Ministry of Health (MOH), whose members attended the conference, set up a task force in 2003 to address the problem of inadequate access to pain medication, with a focus on policy barriers in then-current drug control legislation.<sup>110</sup> “After one year of work, the MOH task force became the permanent Palliative Care and Pain Treatment Commission (Commission) within the MOH.”<sup>111</sup> The formation of the Commission was an official recognition of pain and palliative care as a distinct and legitimate specialty, which required carefully formulated regulation and support.

## 2. Assessment

By late 2002, government officials had demonstrated clear interest in reforming drug policy. But the steps needed to realize that reform remained unclear. The type of assessments required to guide such policy development are a crucial step in reform efforts and are resource intensive.<sup>112</sup> Significant financial and technical support was needed, therefore, at this point.<sup>113</sup> Based on the interest that Romania had demonstrated to improve palliative care, the country was selected by the WHO and the PPSG for technical assistance to assess and develop an action plan for policy reform.<sup>114</sup> These efforts were funded by the OSI.<sup>115</sup> This

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104. *Id.*

105. *Id.* at 4.

106. ACHIEVING BALANCE, *supra* note 4, at 120-24.

107. Anderson et al., *supra* note 12, at 62. The WHO guidelines, published in 2000, provide sixteen criteria for national governments to use when assessing whether national drug control laws conform to the twin aims of international law. David E. Joranson & Karen M. Ryan, *Ensuring Opioid Availability: Methods and Resources*, 33 J. PAIN SYMPTOM MGMT. 527, 529 (2007).

108. Anderson et al., *supra* note 12, at 62.

109. *Id.*

110. *Id.*

111. *Id.*

112. See Burris & Davis, *supra* note 18, at 39-40 (assessment used to document need for unmet care, identify barriers to quality care, define reforms and outcomes that will be successful, and mobilize interested parties to participate in the reform effort).

113. *Id.* at 42-43.

114. Mosoiu et al., *Reform*, *supra* note 8, at 2113-14.

115. Anderson et al., *supra* note 12, at 62.

combination of technical assistance and financial support was an essential bridge to move the reform process along.

In 2003, the Commission and the PPSG worked together to prepare recommendations for changing the regulatory policy governing opioids in Romania.<sup>116</sup> The first step was to study Romanian narcotics control policies and assess their effect on medical practices and patient care.<sup>117</sup> This assessment, which included focus group discussions among stakeholders, identified key regulatory impediments to opioid medicine use.<sup>118</sup> In addition, the PPSG conducted small group discussions with Commission representatives as well as health care professionals at a hospice in Brasov, Romania.<sup>119</sup> The discussions revealed that patients were unable to obtain opioid medications despite medical need.<sup>120</sup> The clinicians related stories about the difficulties that patients and doctors experienced navigating the prescription process. Clinicians described the practical impediments to provision including overly burdensome authorization requirements.<sup>121</sup>

The Commission and the PPSG then obtained translated copies of all relevant laws from staff members at Hospice Casa Sperantei.<sup>122</sup> PPSG used the WHO Achieving Balance Guidelines to perform a detailed technical review of Romanian laws and regulations.<sup>123</sup> The conclusion reached by PPSG was striking: a clinician “could not practice modern cancer pain management according to existing WHO guidelines” in the current “policy and practice environment.”<sup>124</sup>

### 3. Reforming Drug Control Laws and Regulations

The Commission and the PPSG submitted their report to the MOH in 2003.<sup>125</sup> The report recommended that existing law and associated regulations be modified to address the need for therapeutic opioids.<sup>126</sup> In particular, it asked the government to codify key language from the Single Convention that affirmed the need for opioid analgesics to treat pain and suffering.<sup>127</sup> The report suggested that the government remove several provisions, including outdated definitions,

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116. Mosiou et al., *Reform*, *supra* note 8, at 2114.

117. *Id.*

118. Anderson et al., *supra* note 12, at 62-63 (stating that opioid availability and the regulatory and administrative requirements currently in place at the time were unanimously identified as the primary barriers to pain relief, though poor education and bias against opioids by health-care professionals were considered underlying barriers); *see also* Mosiou et al., *Reform*, *supra* note 8, at 2114.

119. Anderson et al., *supra* note 12, at 62.

120. *Id.*

121. *Id.*

122. *Id.* at 62-63.

123. *Id.* at 63.

124. *Id.* at 63.

125. Mosiou et al., *Reform*, *supra* note 8, at 2114.

126. *Id.*

127. The pertinent language was that “the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering.” Single Convention, *supra* note 9, at preamble.

restrictive maximum doses, dose unit limitations, and the lengthy and burdensome authorization process for long-term prescribing.<sup>128</sup> The group also recommended changes to rules governing prescribing, institutional oversight, insurance, training, and medical education.<sup>129</sup>

After reviewing the Commission's recommendations, the MOH directed the pharmaceutical department to begin drafting legislation to change the national narcotics law.<sup>130</sup> A report on the proposed legislation was published and the information was distributed to the members of the Palliative Care Association, as well as the pain treatment community.<sup>131</sup> PPSG also reviewed and commented on drafts during working meetings in Romania.<sup>132</sup> During this time, Romanian officials from the National Anti-Drug Agency (ANA)<sup>133</sup> worked closely with experts to bring Romanian drug control policies in line with those of the European Union.<sup>134</sup> The legislation represented a dramatic change. Under the old law the production, possession, manufacturing, packaging, extraction, preparation, supply, marketing, sale, purchase, and distribution of drug products or substances was prohibited without the written permission of the MOH.<sup>135</sup> The new law places controlled substances into three schedules.<sup>136</sup> Each schedule dictates the acceptable uses of the substances according to their scheduled placement, with more detailed instructions provided by regulation.<sup>137</sup> These changes represent an effort to comply with the control requirements of international treaties,<sup>138</sup> while at the same time ensuring access for medical purposes.<sup>139</sup> With support from the ANA, the proposed law was adopted by the Romanian Parliament in November 2005.<sup>140</sup>

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128. Anderson et al., *supra* note 12, at 63.

129. *Id.*

130. *Id.* at 64.

131. Anderson et al., *supra* note 12, at 64.

132. *Id.*

133. The ANA is the coordinating body for drug control in Romania; its goals include coordinating various state and non-state actors in dealing with drug abuse, as well as monitoring and centralizing "results of the cooperation between Romanian and foreign institutions involved in this area." NAT'L ANTI-DRUG AGENCY, 2003 REPORT, *supra* note 28, at 9.

134. NAT'L ANTI-DRUG AGENCY, 2003 REPORT, *supra* note 28, at 23.

135. Control Regulations Applicable to Drug Products and Substances, 1969, Law No. 73/1969, art. 1, 3 (Rom.).

136. Law Regarding the Judicial Status of Stupeficient Psychotropic Plants, Substances and Compounds, 2005, ch. I, art. 1 (Rom.) [hereinafter Psychotropic Plants].

137. For example, Ch. VII outlines the Medical Use and Distribution of Stupeficient and Psychotropic Substances and Compounds, which are requirements for the prescription and medical use of compounds listed in schedules II and III. Psychotropic Plants, *supra* note 142, at ch. 7, art. 34-41.

138. Explanatory note from Prime Minister Calin Popescu-Tariceanu regarding the 2005 amendments to Law No. 73/1969.

139. *Id.* ("International documents were also taken into consideration, those underlining the necessity of making stupeficient drugs available for pain therapy."); *see also* Psychotropic Plants, *supra* note 142, at ch. 7, art. 37 (providing for the use of stupeficient and psychotropic substances and compounds for medical purposes). The law also reflects an effort to make the use of drugs for medical purposes easier, removing a provision from the 1969 law that required the return of products or substances "unused by deceased patients . . . within 10 days following death, to the

Concurrently, work was underway to draft regulations that would support the new legislation.<sup>141</sup> PPSG sponsored a one-week study visit to Madison, Wisconsin for a Romanian team in order to begin drafting new prescribing regulations.<sup>142</sup> The team members collectively represented the fields of general medicine, oncology, pharmacy, pharmacology, and law, with specializations in pain management and palliative care.<sup>143</sup> The goal of the workshop was to ensure that the new regulations would remove the unduly restrictive licensing requirements for prescribing opioid medications to outpatients.<sup>144</sup> The regulations drafted in that meeting presented a sharp departure from the old drug control regime. Under the draft regulations, specialists were given independent prescribing authority for the first time,<sup>145</sup> the prescription time was increased to thirty days with no limit on dosage,<sup>146</sup> limitations based on diagnosis were removed<sup>147</sup> and non-specialists were permitted to prescribe opioid analgesics after training.<sup>148</sup> Doctors were also given the authority to easily amend drug type, dosage, or administration route according to the needs of the patient.<sup>149</sup> Provisions prohibiting patients from choosing a certain

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issuing authority by those persons who had lived with these patients.” Control Regulations Applicable to Drug Products and Substances, 1969, Law No. 73/1969, art. 13 (Rom.).

140. Mosoiu et al., *Reform*, *supra* note 8, at 2114. The law means that special authorization is not “necessary for opioids to be prescribed for outpatients. Specialists will have independent prescribing authority, the proposed prescription amount is for 30 days with no limit to dose, patient eligibility based on diagnosis has been removed, and non-specialists will be able to prescribe opioid analgesics after receiving certified training.” *Id.*

141. Anderson et al., *supra* note 12, at 64.

142. Mosoiu et al., *Reform*, *supra* note 8, at 2114.

143. Mosoiu et al., *Reform*, *supra* note 8, at 2114-15

144. Anderson et al., *supra* note 12, at 63.

145. *Id.* Under the old regulations, only “the Health Departmental Administration, or depending on the case, the Bucharest Municipality’s Health Services, may issue authorizations . . . to obtain the necessary quantity of drug products for patients or representatives for long-term treatments.” Instructions No. 103/1970 From the Ministry of Health Concerning the Application of Legal Resolutions No 73/1969 Relating to the Control Regulation Applicable to Drug Products and Substances, art. 9 (1970) [hereinafter 1970 Regulations]. The new regulations allow *any* doctor to issue prescriptions for stupefacient and psychotropic compounds for outpatient treatment. Final Rom. Regs., 2007, ch. 6, art. 32(1).

146. Final Rom. Regs., 2007, ch. 6, art. 37(1) (“A prescription may contain a maximum of three compounds, or one medicine in up to three different pharmaceutical forms, and only the compound quantity necessary for a 30 day treatment.”).

147. *Id.* at ch. 6, art. 32(1) (“The medical prescription for stupefacient and psychotropic compounds may be issued for outpatient treatment, for medical purposes, by a doctor or veterinarian, to any patient, regardless of the nature of their illness, if the doctor believes the respective compound is a necessary treatment.”).

148. *Id.* (outlining the provisions that give *any* doctor the authority to prescribe).

149. *Id.* at ch. 6, art. 39(1) (“Doctors may issue a new prescription before the 30 days elapse, for the same patient, if the health of the patient changes during treatment, requiring changing the dose, the medicine or the consumption of the prescribed dose.”). Under the old regulations, changing a prescription to accommodate the needs of the patient involved a lengthy process. *See supra* notes 145, 151.

pharmacy were removed.<sup>150</sup> Recognizing the importance of training and education, a provision was also included directing the Romanian medical community to organize classes on appropriate pain therapy and the logistics of prescribing and administering controlled substances.<sup>151</sup>

National and international collaboration played an integral role in finalizing the regulatory changes. The MOH and the WHO sponsored a meeting in Bucharest in March 2006.<sup>152</sup> The meeting aimed to review the new regulations, plan for their dissemination and design education and training programs to implement them.<sup>153</sup> In 2007, the government assembled stakeholders, including the ANA, to review and endorse the proposed changes. The ANA announced its full support of the new regulatory scheme and the new regulations became effective in 2007.<sup>154</sup>

#### 4. Implementation and Evaluation: The Beginning of a New Cycle

The legal and regulatory changes of 2005 and 2007 were welcome reforms. But reform processes do not end with the adoption of new laws and regulations. How the laws are implemented is often just as important as the content of reform. Implementation and evaluation are essential ingredients of reform. In Romania, work is on-going to operationalize new legal changes in regulations.

A national training program, which was not included in the original implementation plan, has been successfully created and implemented.<sup>155</sup> This program was created by Hospice Casa Sperantei with funding from OSI and several drug companies.<sup>156</sup> It includes educational courses throughout the nation, organization of a strategic conference and the establishment of partnerships and agreements with local ANA bureaus, health boards, physicians and pharmacist organizations.<sup>157</sup> There have also been efforts to educate law enforcement agencies about the legal changes and their underlying policy rationales.<sup>158</sup>

The new laws, regulations, and the national education program are clearly positive developments. But there is always more to be done. For example, statutory language is needed recognizing narcotic drugs as indispensable for the relief of pain and suffering, as in the Single Convention.<sup>159</sup> These expressions in national law strengthen substantive reforms by changing social norms on the ground.<sup>160</sup> In

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150. Under the 1970 Regulations the pharmacy was indicated in the authorization released to the patient by the Ministry of Health. 1970 Regulations, art. 62. No such provision was included in the 2007 Regulations.

151. Final Rom. Regs., 2007, ch. 6, art. 50.

152. Mosoiu, *Reform*, *supra* note 7, at 7-8.

153. *Id.*

154. Final Rom. Regs., 2007.

155. *Id.*

156. *Id.*

157. *Id.*

158. Mosoiu et al., *Reform*, *supra* note 7, at 2114.

159. Anderson et al., *supra* note 12, at 66.

160. See Aaron M. Gilson, et al., *Progress to Achieve Balanced State Policy Relevant to Pain Management and Palliative Care: 2000-2003*, 19 J. OF PAIN & PALLIATIVE CARE PHARMACOTHERAPY 13, 21-22 (2005), available at

addition, the duties of the government in estimating the need for opioid medications and reporting their use are still not clearly set forth in either the law or the regulations.<sup>161</sup> More generally, as the country becomes familiar with the new policies, ongoing evaluation must be undertaken to reveal opportunities for additional policy calibrations.

## ***B. Reform in Medicine Assisted Treatment***

### **1. Catalyzing Change**

Just as in the pain realm, a group of Romanian health care and public health professionals working on HIV/AIDS prevention and drug treatment were among the first groups to advocate for change in Romanian drug treatment policy.<sup>162</sup> In 1992, the Romanian Association Against AIDS (ARAS) was founded and began its work by providing basic case management and education services.<sup>163</sup> In 1998, the first syringe exchange program was developed.<sup>164</sup> Through this program, ARAS workers came to recognize the difficulties IDUs faced in accessing public health services due to the stigma and risks of criminal prosecution.<sup>165</sup> In realizing the need for lower threshold services and more effective interventions, some of these healthcare providers became advocates for MAT.<sup>166</sup>

In 1997, a drug treatment unit for drug-dependency was created within the Gheorghe Marinescu Hospital.<sup>167</sup> Equipped with 31 beds, the unit was the only provider of methadone in Romania; it provided only short-term, inpatient treatment. When the unit lost funding at the end of 1998, two centers housed within psychiatric units of hospitals began to provide methadone for drug dependent patients.<sup>168</sup> However, inability of the hospitals to meet regulatory requirements resulted in interruptions in treatment and fragmented care.<sup>169</sup> In response to these difficulties, in 2000, the Ministry of Health acted to expand services and established the first long term methadone maintenance clinic.<sup>170</sup> Around the same time, stakeholder groups began to coordinate effort to build

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<http://www.painpolicy.wisc.edu/publicat/05jppcp/05jppcp.pdf> (discussing how positive language encouraging pain management can support professionals in their use of pain medicine).

161. *Id.*

162. *See supra*, notes 42-63 and accompanying text (discussing the need for reform in MAT).

163. *See supra*, notes 42-63 and accompanying text (discussing the need for reform in MAT).

164. Reitox Nat'l Focal Point, "Romania" New Development, Trends and In-depth Information on Selected Issues 19 (2006), *available at* [http://www.ana.gov.ro/rom/drug\\_situation.pdf](http://www.ana.gov.ro/rom/drug_situation.pdf).

165. *Id.* at 25.

166. *Id.*

167. Nat'l Anti-Drug Agency, 2010 Report, *supra* note 48, at 114 (2010).

168. *Id.*

169. *Id.*

170. *Id.* (describing the effects of Law no. 143/2000).

support for MAT in Romania. The National Institute for Infectious Diseases combined with the ARAS, the National Authority of Penitentiaries, the National Institute for Infectious Disease, and the ANA to form the Romanian Harm Reduction Network in 2002.<sup>171</sup> UNICEF Romania supported the creation of the network.<sup>172</sup>

International assistance in the HIV prevention field provided yet another important stimulus for MAT adoption. International Organizations (IOs) helped by providing technical and advocacy assistance on HIV prevention and harm reduction.<sup>173</sup> These groups, including WHO, UNAIDS, and OSI, advocated for MAT as an important component of the HIV response and provided NGOs with resources to amplify the message.<sup>174</sup> In response to funding from Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) in 2004, Romania placed MAT on its HIV agenda.<sup>175</sup> This funding reportedly enabled the ANA to consolidate support for MAT.<sup>176</sup>

## 2. Assessment

Assessment efforts in the realm of MAT have lacked the focused, high-level support or technical assistance provided to those in the field of pain treatment. Unlike the palliative care policy reform experience described above, MAT in Romania has historically depended on NGO supported more intermittently by international donors.<sup>177</sup> Due in part to the more atomized infrastructure supporting MAT, a systematic assessment of the sort lead by WHO and OSI for pain policy in 2002 is still lacking. Nevertheless, advocates report that existing assessments are useful in challenging policies impeding MAT access and policy reform. For example, NGOs and professionals in both HIV/AIDS and drug treatment have consistently used program data to argue for policy change at the MOH and the ANA.<sup>178</sup> Additionally, the Romanian Monitoring Center for Drugs and Drug

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171. See *About Us*, ROMANIAN HARM REDUCTION NETWORK, <http://www.rhrn.ro/index.php?l=en&t=43> (last visited Oct. 25, 2010) (describing the creation of this network). The Harm Reduction Network advocates “a set of practical strategies that reduce negative consequences of drug use, incorporating a spectrum of strategies from safer use, to managed use to abstinence.” *Id.*

172. Today it is supported by a variety of international organizations. Anderson et al., *supra* note 12, at 68 (indicating that support for the Romanian Harm Reduction Network comes from the United Nations Development Program (UNDP), the United Nations Children’s Fund (UNICEF), and the United Nations Office on Drugs and Crime (UNODC)).

173. Anderson et al., *supra* note 12, at 68.

174. *Id.*

175. *Id.*

176. *Id.*

177. INT’L DRUG POLICY CONSORTIUM, DRUG POLICIES AND HARM REDUCTION IN SOUTH EAST EUROPE 3 (Jan. 2011), available at <http://idpc.net/sites/default/files/library/IDPC-briefing-paper-harm-reduction-south-east-europe.pdf> [hereinafter IDPC].

178. Anderson et al., *supra* note 12, at 68. One assessment suggested that there were 24,000 IDUs in Bucharest alone. *Id.* Not only did the figure suggest that 1% of the Bucharest population was injecting drugs, but it underscored the risks of HIV/AIDS, hepatitis and other blood-borne diseases as public health challenges for the general population. *Id.* at 68-69. In

Addiction (Center), created as a department of the ANA, is working to increase the quality and quantity of data on drug use and related issues.<sup>179</sup> In 2005, efforts were isolated to Bucharest. By 2006, efforts had expanded nation-wide.

<sup>180</sup> The Center continues to work with the MOH, the Ministry of Youth, the Ministry of Education, and with the Romanian Harm Reduction Network.<sup>181</sup>

Reports prepared during the development of the Center consistently described serious deficiencies in the provision of MAT.<sup>182</sup> One problem was policy, another was personnel. In 1999, there were only four people in Romania who were trained to treat drug addiction: two psychiatrists, one medical doctor, and one pharmacist.<sup>183</sup> In 2000, the Romanian authorities admitted that such numbers were inadequate, stating that “[p]rolonged methadone treatment was done at the decision and according to the experience and own criteria of some psychiatric doctors” because, in Romania, “there is no generally accepted treatment guide and a corresponding program for this therapy.”<sup>184</sup> Despite official endorsement of MAT post-reform, the problem of inadequate personnel to deliver MAT continues to inhibit implementation efforts.<sup>185</sup>

### 3. Reforming Drug Control Laws and Regulations

Romania’s laws governing illicit drug use, including both its controlled substances regulations and general criminal code, have been significantly revised since 2000.<sup>186</sup> A key change in that year was the authorization of the use of methadone and buprenorphine.<sup>187</sup> In 2005, law was passed to establish an integrated, three-tier, care and assistance system for drug dependent patients.<sup>188</sup> The law also certified treatment centers as outpatient or inpatient MAT centers.<sup>189</sup> The same year, talks to reform overly burdensome regulatory requirements began. In 2007, the National HIV/AIDS Commission was reorganized under the MOH. It

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recent years, local advocates note that illicit drug use has more visibly expanded into middle class populations and youth groups. Tanasecu, *supra* note 80. Such expansion, in turn, prompts government officials to look toward professionals in the field for services. *Id.*

179. Anderson et al., *supra* note 12, at 69.

180. *Drug Treatment Overview for Romania*, EMCDDA, <http://www.emcdda.europa.eu/data/treatment-overviews/Romania#registries> (last visited April 6, 2011).

181. Anderson et al., *supra* note 12, at 69.

182. *Id.*

183. *Id.* The government report acknowledged this deficiency in 2000, stating “[d]ue to the lack of all the therapeutic links as well as of the specialized personnel, it can be said that during 1999, no complete and appropriate treatment was offered to addicted persons.” *Id.*

184. *Id.*

185. *Id.* (“the treatment system available for drug addicted in 2003 was not very different from previous years. The therapeutic chain was incomplete.”).

186. *Id.*

187. Anderson et al., *supra* note 12, at 69.

188. See also NAT’L ANTI-DRUG AGENCY, 2007 REPORT, *supra* note 82, at 38 (describing the effects of Law no. 339/2005).

189. *Id.*

was made responsible for governmental policy in the area of HIV/AIDS prevention, treatment, and care services.<sup>190</sup> A comprehensive document detailing the national HIV/AIDS strategy for 2008-2013 was developed after an active process that included key governmental and non-governmental stakeholders.<sup>191</sup> This strategy addresses the needs of the most vulnerable groups, including IDUs, by setting out specific objectives and strategies.<sup>192</sup> Unfortunately, however, no action plan or budget has been attached to the strategy.<sup>193</sup> At the moment, legislative reform to enable improved access to MAT is reportedly blocked by the Ministry of Justice.<sup>194</sup> The recent closure of the oldest MAT provider in Bucharest for funding reasons further underscores the need for national commitment to expanding MAT.<sup>195</sup> Reforms specific to improving treatment for opioid dependence require the same type of coordinated support from multiple stakeholders that proved vital to improving access to analgesics. The 2003 National Report pointed out that, despite the changes in statutes, Romania still lacked adequate coverage for MAT because sites offering methadone treatment were limited.<sup>196</sup> Persistent absence of national funding and support is also recognized as ongoing challenge.<sup>197</sup>

#### 4. MAT Today

The social context for the provision of MAT has changed markedly for the better over the last decade.<sup>198</sup> But, despite some growth in MAT sites over the past ten years, coverage still exists only for a small portion of Bucharest's IDUs.<sup>199</sup> Local counselors estimate that of the 15,000 IDUs currently requiring treatment in Bucharest, only 1,100 receive the necessary MAT.<sup>200</sup> Other civil society groups estimate that the number of IDUs in Romania is as many as 34,318<sup>201</sup> and that less than 5% of IDUs in Romania receive MAT.<sup>202</sup> As of 2010, only two centers offering MAT are available outside Bucharest.<sup>203</sup> Additionally, the centers in Bucharest that offer MAT are under-resourced and overwhelmed by patient

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190. UNGASS COUNTRY PROGRESS REPORT, *supra* note 51, at 8.

191. *Id.* The main objective of the strategy was to maintain the HIV incidence for 2013 at the level registered in 2006 while ensuring the universal access to treatment, care and social services for infected and affected people. *Id.*

192. *Id.*

193. *Id.*

194. IDPC, *supra* note 177, at 5.

195. *Id.* at 3.

196. NAT'L ANTI-DRUG AGENCY, 2003 REPORT, *supra* note 28, at 31.

197. UNGASS COUNTRY PROGRESS REPORT, *supra* note 51, at 9.

198. Tanasecu, *supra* note 80.

199. *Id.*

200. *Id.*

201. INT'L HARM REDUCTION ASS'N, REGIONAL OVERVIEW EURASIA 34, *available at* <http://www.ihra.net/files/2010/06/13/GSHREurasia.pdf>.

202. UNGASS COUNTRY PROGRESS REPORT, *supra* note 51, at 12.

203. *Id.*

need.<sup>204</sup> One of the centers recently reported a waiting list of, on average, 350 people.<sup>205</sup> Thus, while expressions of government interest to expand services reflects necessary government interest in MAT, major reductions in policy barriers and improved resources are critical to real change in MAT access.

Regulations continue to challenge MAT access throughout Romania.<sup>206</sup> High admission criteria at various treatment clinics, for example, continue to restrict access to MAT.<sup>207</sup> Moreover, high cost associated with treatment, identified as an historic cause for relapse by ANA authorities,<sup>208</sup> remains a problem as do health insurance limitations.<sup>209</sup> A shortage of qualified medical personnel continues to be a barrier to expansion of treatment.<sup>210</sup> Access is also hindered by bureaucratic inefficiencies that hinder the licensing process for MAT clinics affiliated with government agencies or hospitals.<sup>211</sup> In addition, although voluntary drug treatment is kept confidential by Romanian law, drug users are often deterred from seeking help due to the stigma associated with treatment and fear of involvement with the police.<sup>212</sup> Of the nine MAT centers operating in Bucharest, three are run by police groups that are also tasked with preventing illicit drug use.<sup>213</sup> Thus, the fear of discovery continues to make drug abuse and HIV “invisible” epidemics, especially outside Bucharest, where communities are smaller and confidential services for IDUs are virtually non-existent.<sup>214</sup>

The steady increase in methadone use in Romania is evidence of a need for increased services, as well as proof of a dedicated national advocate base.<sup>215</sup> New initiatives to open additional MAT clinics are on-going, including ones outside Bucharest.<sup>216</sup> In addition, the regulatory climate may be more receptive to increasing harm reduction services, including MAT. For example, three laws implemented in 1998, 2005, and 2006, respectively, encourage the government to sub-contract social welfare services to NGO groups.<sup>217</sup> At the same time, recent

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204. *Id.*

205. Tanasecu, *supra* note 80.

206. Anderson et al., *supra* note 12, at 59.

207. *Id.*

208. NAT'L ANTI-DRUG AGENCY, 2010 REPORT, *supra* note 48, at 114 (describing the historic inability of facilities to provide treatment to drug dependent individuals because of lack of resources and legal requirements for methadone provision (e.g. Order no. 963/1998.)).

209. Tanasecu, *supra* note 80.

210. *Id.*

211. *Id.* (stating that of the nine clinics in Bucharest, almost all are government affiliated).

212. Anderson et al., *supra* note 12, at 60.

213. Tanasecu, *supra* note 80 (discussing the centers run by ANA, which are affiliated with national police).

214. *Id.*

215. *See generally Drug Treatment Overview for Romania*, *supra* note 23.

216. *Id.*

217. Law No. 143/2000 on the Prevention and Fighting Drug Trafficking and Illicit Drug Use (Rom.) (establishing legal identity for associations and foundations); Law No. 350/2005 (Rom.) & Law 34/ 2006 (Rom.) (emergency ordinances permitting public acquisition of social services up to 100,000 euros).

funding from the European Union for MAT specific services has encouraged the development of new MAT treatment centers.<sup>218</sup> In 2008, the UNODC and the National Authority for Penitentiaries launched a program to provide MAT to IDUs in three Romanian prisons<sup>219</sup> – a bellwether perhaps of increased government acceptance of the indispensability of MAT.

## V. CONCLUSION: POLICY AS A REFORM CYCLE

The Romanian drug policy reform experience, with respect to palliative care, is notable for its speed, efficiency, and comprehensiveness.<sup>220</sup> Few countries present a better example of successful reform for improving access to opioid therapy for the treatment of pain. Three elements were essential to the Romanian experience. First, national advocates, including some in the government, were willing to champion reform efforts. Second, external financial and technical support for reform was made available to sustain reform efforts. Third, there was systematic collaboration between reform-minded groups within the country and international bodies with specialized technical expertise.

The absence of an equivalent success story with regard to Romania's national roll-out of MAT underscores the importance of systematic partnership between external groups with technical expertise and government. Without high levels of official collaboration in this area, Romania's reform in the MAT context has been limited. The legalization of methadone and buprenorphine and the broader government recognition MAT<sup>221</sup> are necessary but not sufficient to achieving the population health benefits that come with improved access to MAT.

While every country will require a reform processes unique to their medical needs and political processes,<sup>222</sup> the Romanian experience is a great model for other countries to consider. Once individuals and organizations within a country begin to mobilize around the problem of inadequate access to opioid medicines, outside organizations can help diagnose needs and direct support activities towards reform. This external support can sustain momentum for reform at key points in the process and facilitate collaborations with partners with specialized technical expertise in drug policy regulation like PPSG. Such collaboration can result in significant policy change at the national level and begin processes that ensure access to essential opioid medicines for all patients in need. The Romanian

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218. Tanasecu, *supra* note 80.

219. Catalina Iliuta, *UNODC and the National Administration of Penitentiaries Launched Harm Reduction Programme in Romanian Prisons*, 5 INT'L. J. OF PRISONER HEALTH 52, 52-53 (2009).

220. See Mosoiu et al., *Reform*, *supra* note 8, at 2114 (discussing the short time frame within which new laws were adopted).

221. See generally Anderson et al., *supra* note 12, at 55-72.

222. Burris & Davis, *supra* note 18, at 4 (stating that in Romania “there was a fast track for pain reform that brought the country to the implementation phase in just a few years,” while in other places the “phases of the cycle have repeated themselves several times over a decade and a half, with partial reforms and implementation problems feeding back into further advocacy, assessment and reform.”).

experience highlights that reform is a realistic goal in many countries. As a result, a significant amount of unnecessary pain and suffering can be reduced.