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## FDA Regulation and Patient Assisted Suicides

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## FDA Regulation and Patient Assisted Suicides

David S. Weiss

The 20th century has witnessed a steady, marked increase in the average *life* expectancy of Americans. Advances in nutrition, an increased emphasis on preventative health care, and developments in the treatment and mitigation of cancer and other fatal illnesses are among the many factors which have contributed most recently to the ability of Americans to live longer, healthier lives.

Even with these advances, however, there are an increasing number of Americans who believe that the marginal benefit of surviving a few extra months is not worth the cost of suffering the pain, physical and/or mental deterioration, or increased dependency they would experience during that period due to a terminal illness or a debilitating condition. For these people, the right to opt to die painlessly, simply, and with dignity at the time and place of their choosing is paramount, and in recent years they have taken steps to secure that right. Their convictions have given rise to the Hemlock Society,<sup>1</sup> the passage of an Oregon referendum authorizing physician-assisted suicide,<sup>2</sup> and the work of Dr. Jack Kevorkian, who has personally assisted in the suicide of 20 people as of December 1993<sup>3</sup> using two patient-activated devices he created himself. Society

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<sup>1</sup>The Hemlock Society was founded in 1980 to secure the right of a terminally ill person to choose voluntary euthanasia. As of 1990, it had 38,000 members and 70 chapters. DEREK HUMPHRY, FINAL EXIT 180 (1991).

<sup>2</sup>Measure 16 permits a physician to assist a terminally ill patient (defined as a person who has less than six months to live due to a terminal illness) in committing suicide if several conditions are met, including: three separate requests for life-ending medication by the patient (two oral and one in writing); a 15 day waiting period between the first request and the writing of the prescription; and concurrence of the diagnosis of the patient's terminal condition by a second physician. *Under the Initiative, The Process of*, OREGONIAN, Oct. 7, 1994, at E1.

<sup>3</sup>*State High Court to Hear Kevorkian Suicide-Law Appeal*, WASHINGTON POST, June 7,

has rarely strongly opposed the exercise of this right; indeed, while 28 states currently have laws declaring assistance in suicide a crime,<sup>4</sup> no physician has been convicted for aiding in a suicide,<sup>5</sup> and conviction of other types of suicide assistants has been sporadic at best. On the other hand, Michigan did ultimately prohibit physician-assisted suicide (PAS) in order to legally stop Dr. Kevorkian, and an injunction has prohibited enforcement of Oregon's referendum pending the resolution of constitutional challenges.<sup>6</sup>

If the passage of Measure 16 and the popular support shown for Dr. Kevorkian are any indication, however, it appears likely that over the next few years, the law will increasingly accept, or at least continue to turn a blind eye toward, the use of drugs and medical devices in PAS. This development would create a uniquely difficult position for the Food and Drug Administration (FDA), as it is committed to protecting public health by ensuring that marketed drugs and medical devices are safe and effective for their intended use. How could one declare a product intended to cause death safe, and how could one

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1994, at A7 [hereinafter WASHINGTON POST].

<sup>4</sup>The table provided in JOAN BROVINS AND THOMAS OEHMKE, DR. DEATH: DR. JACK KEVORKIAN'S PRESCRIPTION: DEATH, 245 (1993) lists 25 states (including Michigan and Oregon) as having legislation in place making assisting a suicide a crime, along with 10 states in which such legislation was pending at the time of publication. Since then, four states (Indiana, Tennessee, Texas, and Wisconsin) have passed such legislation. See 35 IN. CODE ANN. §42-1-2.5 (West 1994); 34 TENN. CODE ANN. §13-216 (1994); 5 TEX. CODE ANN. §22.08 (West 1994); Wis. STAT ANN. §940.12 (West 1994). In addition, since publication Oregon passed Measure 16, effectively removing it from the abovementioned list of 25. Therefore, the current total number of states with legislation criminalizing assisting a suicide is 28.

<sup>5</sup>H. TRISTAM ENGLEHARDT, JR. AND MICHELE MALLOY, *Suicide and Assisting Suicide: A Critique of Legal Sanctions*, 36 Sw. L.J. 1003, 1029 n. 126. Dr. Kevorkian was charged with murder for assisting in two suicides, but the Michigan courts dismissed the cases in the absence of a clear state statute declaring that assisting a suicide is a crime. The Michigan Court of Appeals has reinstated the charges, though Oakland County Prosecutor Richard Thompson has said he will proceed with prosecution until the Michigan Supreme Court rules on the constitutionality of the suicide assistance ban passed in 1993. WASHINGTON POST, *supra* note 3, at A7.

<sup>6</sup>Lee v. Oregon, 1994 WL 728858 (D.Or. 1994).

ensure that it is effective without involving the tester in a mass suicide/murder? On the other hand, shouldn't the FDA ensure that such products meet their intended purpose in order to minimize the risk of a product's failure causing an undesired agonizing death or a patient being left in a vegetative state? Assuming that the agency could logically find a way to apply its safety and effectiveness requirements to this area, should the agency devote its limited resources to regulating items whose purpose is promoting death rather than life? These issues will be the focus of this paper. Section I will consider whether and how the existing Food, Drug and Cosmetic Act (FD&C Act) and FDA regulations could be applied in this area. The initial focus will be on the paradigm suicide machines, namely those developed by Dr. Kevorkian, which will serve as the starting point for a discussion of how the FDA could regulate not only drug-based machines, but pharmaceuticals as well. Section II will then address the policy considerations involved in regulating drugs and devices use in PAS: is it just an issue of efficient allocation of FDA resources, or is there more at stake? Finally, Section III will conclude with a prediction of where FDA is likely to come out on this issue, along with some recommendations on how FDA should proceed in this developing area of food and drug law.

## I

The creation and/or distribution of any product designed to assist in suicide would certainly fall under FDA purview, if only because the item would be intended to affect the structure or any function of the body of man.<sup>7</sup>

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<sup>7</sup>Id.

Before considering whether and how the FDA could regulate such an item, however, an understanding of the form any such product might take must be obtained. For this purpose, subsection A will describe the paradigm suicide products, Dr. Kevorkian's two machines.<sup>8</sup> Based on this example, subsection B will then analyze how existing FDA regulations and policies could be applied to such products. Subsection C will then give the same treatment to those drugs which may be used with or without a device in PAS.

#### *A. The Suicide Machines*

The goal of those seeking to end their lives before a terminal illness or debilitating disease produces conditions which are unbearable goes beyond the simple desire to control the time and place of death. Rather, one of the primary motivating factors for these individuals is death with dignity, a desire that the manner and appearance of the individual at the time of death not mar the otherwise pleasant memories of the individual in the minds of those who remain. For these people, this militates against the use of guns, knives, or other violent means of taking one's life; violation of the physical appearance of the corpse would detract from the decedent's dignity. Pharmaceuticals often provide the best of both worlds – a quick, theoretically painless death without desecration of the decedent's body –but self-medication with a lethal dose of a toxic substance is not possible for all patients who wish to end their lives. For while information on lethal dosages for the average person is readily available<sup>9</sup>

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<sup>8</sup>Although the second contraption Dr. Kevorkian used to induce death did not use any gears or motors or otherwise resemble what might ordinarily be considered a machine, this term will be used in this paper to refer collectively to Dr. Kevorkian's products as a matter of convenience.

<sup>9</sup>Derek Humphry provides a chart listing some drugs and their lethal dosages in his book,

and many physicians are willing to prescribe such dosages despite the state of the law,<sup>10</sup> patients may be unwilling to administer the drug on themselves because they are concerned about taking a sublethal dose or about regurgitating some of the medication. In addition, they may be unable to self-medicate either because they are unable to swallow the pills or because they lack the motor skills necessary to take the medication themselves. A drug-based suicide machine, however, provides the requisite solution for everyone involved. The physician could hook the machine up to the patient and then leave its activation up to the patient. The patient could thereby control the time of death and achieve the benefits of a drug-induced death, while the physician could justify her action by saying that while she provided the means, she did not cause the death. It was on the basis of such logic that Dr. Kevorkian sought to develop his suicide machines.

On April 26, 1990, Dr. Kevorkian appeared on The Donahue Show advertising and discussing his latest invention, the Mercitron.<sup>11</sup> Already the subject of a number of local and national newspaper articles,<sup>12</sup> the Mercitron was designed to be a vast improvement over the noose, shotgun, and even barbiturates; it would allow a patient to choose the time and place of death and

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Final Exit. See HUMPHRY, *supra*, note 1, at 117-123. There are also a database on Westlaw, Registry of Toxic Effects of Chemical Substances (RTECS) listing drugs that have toxic effects on human beings.

<sup>10</sup>One in five internists indicated in a 1992 informal poll that they have helped cause the death of a patient. Nancy Gibbs, *R.x for Death: Assisted Suicide Physician Jack Kevorkian*, TIME, May 31, 1993, at 34, 37.

<sup>11</sup>*The Donahue Show: Organ Donors on Death Row* (NBC television broadcast, Apr. 26, 1990).

<sup>12</sup>Stories on Dr. Kevorkian and the Mercitron first appeared in Pontiac, Michigan's *Oakland Press*. The story was later picked up by *Detroit News* and subsequently was spread over the regular wire services. JACK KEVORKIAN, PRESCRIPTION: MEDICIDE: THE GOODNESS OF PLANNED DEATH 215 (1991).

would ensure a non-violent, painless demise. The machine consisted of three bottles suspended from an aluminum frame and connected to a single intravenous line; a timer; and the motor from a toy car.<sup>13</sup> Once the intravenous needle was inserted in the patient's arm, the first bottle would provide a harmless saline drip; the bottle of saline solution could be drained into the patient and replaced repeatedly for as long as the patient chose to remain alive. When the patient was ready, she would push a large red button, starting the timer and switching the IV line to the second bottle, which contained thiopental (pentothal). The thiopental would induce sleep within approximately 30 seconds. About one minute later,<sup>14</sup> the machine would cut off the thiopental and switch the IV line to the third bottle, which contained a mixture of potassium chloride and succinylcholine (a muscle relaxant).<sup>15</sup> Upon reaching the heart, the muscle relaxant would stop the organ from beating, causing a painless heart attack and inducing death within minutes. Dr. Kevorkian built the machine himself using parts he found at flea markets; the total cost was approximately \$30.<sup>16</sup>

He tested the machine by running it and draining the solutions into a small bottle. It was never tested on an animal or human being before Dr. Kevorkian gave it to his first suicide patient, Janet Adkins, on June 4, 1990.<sup>17</sup>

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<sup>13</sup>*Id.* at 208-9; HUMPHRY, *supra* note 1, at 135.

<sup>14</sup>The sources describing the operation of the Mercitron were not clear whether this was one minute after the patient pressed the button or one minute after the 30 seconds allowed for the thiopental to take effect.

<sup>15</sup>HUMPHRY, *supra* note 1, at 134-5. According to Dr. Kevorkian, this is the same solution administered to prisoners sentenced to death by lethal injection. Susan Jezewski, *Can a Suicide Machine Trigger the Murder Statute*, Note, 37 WAYNE L. REV. 1921, 1923 *n.5*.

<sup>16</sup>KEVORKIAN, *supra* note 13, at 209.

<sup>17</sup>*Id.* at 227-30. Dr. Kevorkian did try to obtain a dog scheduled to be put to sleep in order to test the Mercitron. When he encountered significant bureaucratic problems, however, he decided not to test the machine and reverted to his personal philosophy, namely never do on any live animal anything aimed solely or primarily for human benefit, and for the performance

The Mercitron successfully assisted Mrs. Adkins in committing suicide that day, and eight months after Dr. Kevorkian was prohibited by Judge Alice Gilbert from using it on another patient, it also assisted in the suicide of Marjorie Wantz.<sup>18</sup> These have been the only two patients to use the Mercitron, which now sits in Dr. Kevorkian's attorney's office.

On the same day Mrs. Wantz used the Mercitron, Dr. Kevorkian was able to try out a new suicide contraption on another patient. This machine involved no gears or timers, but rather just a Kevorkian-designed mask attached by a tube to a canister of carbon monoxide.<sup>19</sup> At the same time Mrs. Wantz activated the Mercitron, Sherry Miller put the mask over her face, pulled the clip off of the hose and inhaled the carbon monoxide until it caused unconsciousness and, 18 minutes later, death. Dr. Kevorkian has since used this simpler contraption<sup>20</sup> on 17 other suicide patients, the last being in December 1993.

*B. Could the FDA Regulate a Medical Device Used in PAS?*

An initial concern for any regulatory agency is whether it has jurisdiction over the item or person at issue; without jurisdiction, the agency cannot take any legal action, no matter how heinous an activity may be. As a federal agency intended to implement the FD&C Act, FDA's jurisdiction is predicated on the authority of Congress to regulate interstate commerce. Courts' interpretation of this term have been broad, to say the least, with authority being

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of which live subjects are available under ethically unassailable circumstances. *Id.* at 209-11.

<sup>18</sup>BROVINS AND OEHMKE, *supra* note 4, at 69-71. Mrs. Wantz died on October 23, 1991.

<sup>19</sup>*Id.* at 71.

<sup>20</sup>Unlike the first machine, the contraption was never given a formal name. For the purpose of this paper, it will be referred to as the CO mask.



granted to the FDA to regulate a drug which is only sold intrastate but whose components were involved in interstate commerce.<sup>21</sup> FDA was empowered with an even broader authority to regulate medical devices. Under 21 U.S.C. §334(a), the FDA can proceed against adulterated or misbranded devices regardless of whether they or any of their component parts were involved in interstate commerce.<sup>22</sup> Thus, the FDA can assert jurisdiction over any medical device, while it must show that at least a component part of a given drug was involved in interstate commerce in order to take any legal action regarding that drug.

The different scope of FDA authority over drugs and medical devices, though functionally minimal, raises the issue of how to categorize suicide machines which are based on delivery of a lethal drug into the human body. This determination is actually a rather important one, since it would not only affect the extent of FDA jurisdiction, but would also affect whether any pre-market approval process might be necessary for the item and what considerations would be involved in such a process.

Under the definition of medical device in §201(h) of the FD&C Act, such products could be deemed either drugs or medical devices. According to the statute, a product is a drug if the primary intended purpose of the item is achieved through chemical action within or on the body of the patient.<sup>23</sup> Thus, if the primary purpose of the suicide machine is considered to be causation of

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<sup>21</sup>*See, e.g.*, U.S. v. Dianovin Pharmaceuticals, Inc., 475 F.2d 100, 102-103 (1st Cir. 1973) (citing U.S. v. Cassaro, Inc., 443 F.2d 153 (1st Cir. 1971)).

<sup>22</sup>U.S. v. Undetermined Quantities of an Article of Device labeled in part Depilatron Epilator, 473 F.Supp. 913. Indeed, §709 of the FD&C Act states that the connection with interstate commerce in any action taken to enforce the medical device regulations shall be presumed to exist. 21 U.S.C. §379(a).

<sup>23</sup>21 U.S.C. §321(h).

death through the chemical reaction of the drug delivered, the whole contraption is technically a drug. On the other hand, if these machines are viewed as simple delivery systems, no different from a regular intravenous line, they would be regulated as a medical device. In short, the statute itself provides little guidance in this matter.

The key to deciding this issue, ironically, is the manner in which the item is ultimately distributed. According to the 1991 agreement reached by the Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH) regarding jurisdiction over combination products, if an item is distributed unfilled and without any drug in the package, it is generally regulated as a medical device by the CDRH.<sup>24</sup> If it is distributed unfilled but with the drug in the same package and with labeling directing use of the contraption with that drug, it is considered a true combination product over which the CDRH has ultimately authority but to which the CDER can apply the drug regulations as necessary.<sup>25</sup> Finally, if the product is distributed filled with the drug, then it is considered a combination product subject to CDER regulation, with both the drug and device regulations applied as necessary.<sup>26</sup> Of course, FDA's intercenter jurisdiction committee is free to make *ad hoc* jurisdictional decisions regarding particular items.<sup>27</sup> However, based just on the terms of the agreement, regulation of drug-based suicide machines would depend on

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<sup>24</sup>THE CENTER FOR DRUG EVALUATION AND RESEARCH AND THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION, MEDICAL DEVICES REPORTER (CCH), *Ø1784*, p. 801 (1991) [hereinafter MEDICAL DEVICES REPORTER].

<sup>25</sup>*Id.* at 803.

<sup>26</sup>*Id.* at 802.

<sup>27</sup>*Id.* at 804.

the form in which they are distributed.

At first blush, it might seem most logical for any suicide machine manufacturer to avoid the constraints of the drug regulations by packaging the contraption unfilled and unaccompanied by the requisite drug. Under §505 of the FD&C Act, it is illegal to introduce a drug into interstate commerce with the intent that it be used for a purpose not approved by the FDA. And since FDA has never approved a drug for use in suicide or euthanasia for man or animals,<sup>28</sup> any manufacturer commercializing a drug for that purpose would have to go through the full new drug approval (NDA) procedure before putting the product on the market.

On the other hand, if the manufacturer could show that the unfilled, unaccompanied apparatus is substantially equivalent to a medical device on the market before 1976, then it could be marketed 90 days after filing a pre-market notification (PMN) with the FDA. To establish substantial equivalence, the manufacturer would have to show either 1) that the products have the same intended use and technological characteristics, or 2) that they have the same intended use and that the new product is as safe and effective as the marketed device. This, of course, would require that the manufacturer represent the product as a pure drug delivery system, ignoring any potential use in assisting suicide, since this would be the only way to meet the intended use requirement for PMN status.

Even if the manufacturer could justify the suicide machine as sub-

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<sup>28</sup>U.S. v. Articles of Drug... Labeled in Part... Beuthanasia, FOOD, DRUG, & COSM. L. REp, 038,265 (1979).

stantially equivalent to a pre-1976 drug delivery system in its PMN, it would still not be able to provide any instructional labeling for the use of the device in assisting suicide. First, FDA considers it a violation of the FD&C Act to market a device with instructions directing an unapproved use of an FDA approved drug.<sup>29</sup> Therefore, the label could not name any individual drug for use in the unapproved purpose of causing death. Second, under §502(j) of the FD&C Act, a device is deemed misbranded if it is dangerous to health when used in the dosage or manner... prescribed, recommended, or suggested in the labeling thereof. Indeed, §518(e) requires the FDA to order the cessation of distribution of any device it finds would cause serious, adverse health consequences or death.<sup>30</sup> Therefore, if the FDA concluded that suicide was dangerous to health (an admittedly logical conclusion), it could bring an action against any manufacturer or other party involved with the distribution of a suicide machine whose label suggest a fatal use.

Clearly, then, FDA has the authority to regulate, and even prohibit, the manufacture and distribution of most any suicide machine. Even the provision regarding custom devices in §520(b) provides little solace. They only exempt such items from the performance standards and pre-marketing approval requirements of §§514 and 515; no exemption is provided regarding §502. Further, this subsection only applies to devices which are not generally marketed and which are intended for use by a specific patient or to meet the special needs of... [a] physician... in the course of professional practice;<sup>31</sup> it is doubtful that

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<sup>29</sup>FDA Regulatory Letter No. 89-HFD313-26, Apr. 28, 1989, at 3.

<sup>30</sup>21 U.S.C. §360h(e).

<sup>31</sup>Id.

even Dr. Kevorkian could justify his Mercitron under such a standard. Likewise, the exemptions in §520(m) of the FD&C Act would probably not be applied to this class of products, since they would affect more than 4,000 Americans.

The only real exception to potential FDA control over this would be if a device like the CO mask were distributed as a regular drug delivery device without any suicide-related labeling but which relied on word-of-mouth instructions on how to use it for PAS. Such an item might avoid the constraints of §520(j) and §520(m) and would probably satisfy the PMN substantial equivalence standard. Indeed, so long as the manufacturer made no claims and provided no instructions regarding its use in PAS, such products would be the functional equivalent of barbiturates and other toxic drugs, which are currently market for other approved purposes but which are used in PAS based on non-label knowledge about the product.

The FDA could, of course, ignore or creatively interpret §502(j) and §518(e) so as to permit a device specifically intended to be used in PAS to be marketed.<sup>32</sup> Such a device would most certainly be deemed Class III in the absence of information regarding the sufficiency of general or specific controls in assuring its safety and effectiveness and because it could pose an unreasonable risk of illness or injury.<sup>33</sup> As such, the device would have to undergo the full pre-market approval process for devices, as laid out in FD&C Act §5 15.<sup>34</sup> Testing of the device itself would probably be limited to a demonstration of safety

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<sup>32</sup>Admittedly, this would be a strain of FDA discretion under *Chaney*, see *infra* page ?, but it is an option theoretically available to the FDA.

<sup>33</sup>See 21 U.S.C. §360c(a)(1)(C)(i), (ii).

<sup>34</sup>21 U.S.C. §360e.

and effectiveness in delivering the drug; the safety and efficacy of the drug in inducing death would be covered under its approval process for this intended use.<sup>35</sup> Further, the manufacturer would be subject to the preproduction design validation requirements of §520(f); this basically would mean that even before approval for marketing the product is obtained, the facilities in which it is developed and packaged must meet FDA standards. Were the device to meet the standards set by the FDA and be allowed on the market, it would be subject to the same constraints as any other medical device.

Among the constraints such a device might face is the authority of the FDA to restrict the sale of the product,<sup>36</sup> much the way the FDA can require drugs to be distributed only on a prescription basis. As a practical matter, the FDA currently does not strictly regulate the prescription of drugs for unapproved uses,<sup>37</sup> so the agency probably would take a similar approach with regard to restricted devices. Some have suggested, however, that the FDA has the authority to limit the use of prescription/restricted products to their approved uses.<sup>38</sup> Were the FDA to opt to use this authority, it could not only limit the introduction of a new PAS device, but also prohibit the use of currently marketed devices in PAS.

#### *B. Could the FDA Regulate a Drug Used in PAS?*

The course of potential FDA regulation of drugs intended for use in

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<sup>35</sup>MEDICAL DEVICE REPORTER, *supra* note 25, at 801. See subsection C, *infra* p. ?, for a discussion of FDA approval of drugs for use in PAS.

<sup>36</sup>21 U.S.C. 360j(r).

<sup>37</sup>See discussion *infra*, p. 15.

<sup>38</sup>See, e.g., David A. Kessler, *Regulating the Prescribing of Human Drugs for Nonapproved Uses Under the Food, Drug, and Cosmetic Act*, 15 HARV. J. LEGIS. 693.

PAS would closely mirror that of medical devices designed for the same purpose. Section 502(j) presents the same nearly insurmountable hurdle for FDA approval of a new PAS use for pharmaceuticals. Were the FDA to sidestep this obstacle and consider approving a drug for PAS, that product would also have to undergo a lengthy approval process, as outlined in §505 of the FD&C Act.<sup>39</sup> At the heart of this process, as in any FDA approval process, is an agency determination that the product is safe and effective for its intended use. Effectiveness would be a fairly easy standard to meet: the manufacturer would have to show that there is substantial evidence that the drug will produce the results claimed for it.<sup>40</sup> Meeting the safety requirements might be more difficult, however. Though no definition of the term safe has been spelled out in the statute or regulations, toxicity is one factor the FDA has considered in declaring a product unsafe.<sup>41</sup> If the FDA employed a broader definition of the term, such a positive benefit/risk analysis or a finding that the product does not produce any severe side effects in the course of its use, it might be able to justify approving a drug for a lethal use. Again, this would be a stretch of FDA discretion, but if the FDA were set on allowing such products on the market so that they could be carefully regulated, the agency might be able to justify its actions.

The FDA could also take the extreme opposite approach, denying approval for any new PAS use and cracking down on unauthorized use of currently marketed pharmaceuticals in PAS. This move may necessitate a reversal

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<sup>39</sup>21 U.S.C. §355.

<sup>40</sup>U.S. v. Rutherford, 442 U.S. 544, 555 (citing *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 608, 629-34).

<sup>41</sup>5. REp. No. 946, 82d Cong., 1st Sess. (1951).

of a long-standing policy of recognizing physicians' autonomy and permitting them to prescribe approved drugs for unapproved uses in the course of medical practice.<sup>42</sup> At minimum, it would require the FDA to limit its interpretation of medical practice so as to exclude treatments intended to cause the death of the patient. Were it to take this tack, the FDA could seize improperly prescribed drugs and bring criminal actions against physicians, their patients, and possibly even manufacturers for distributing and/or receiving a drug with the intent that it be used for an unapproved purpose.

## II

The fact the FDA has the authority to regulate a given item does not mean that the agency is required to do so. On the contrary, FDA regulation is largely discretionary; given a limited amount of resources to achieve its broad general mandate of trying to protect the public welfare by determining whether food, drugs, cosmetics and medical devices are safe and effective, FDA would *de facto* have to autonomously determine whether action was necessary and desirable in a given situation. Indeed, the courts have recognized this fact, holding in *Heckler v. Chaney*<sup>43</sup> that the FDA may decline to bring an action against or investigate a particular use of a marketed product. However, in that case the court also warned that where the agency has 'conspicuously and expressly

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<sup>42</sup>in 1972, the FDA issued a proposed rule which would have codified this principle. *Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration. Notice of Proposed Rule Making*, 37 Fed. Reg. 16503, Aug. 15, 1972. This rule was never finalized, though it has been treated as agency policy ever since. See, e.g., *Use of Approved Drugs for Unlabeled Indications*, 12 FDA DRUG BULL. 4 (1982). The FDA recently declined to withdraw this proposed rule, deciding instead to continue to review the appropriateness of its enactment. *Withdrawal of Certain Pre-1986 Proposed Rules: Final Action*, 56 Fed. Reg. 67440, Dec. 30, 1991.

<sup>43</sup>470 U.S. 821 (1985).



adopted a general policy' that is so extreme as to amount to an abdication of its statutory responsibilities... the statute conferring authority on the agency might indicate that such decisions were not 'committed to agency discretion.'<sup>44</sup> Within the realm of this discretion, the FDA may have to decide whether and to what extent it wishes to regulate drugs and/or medical devices used for PAS, a decision which would involve the weighing of the countervailing interests of the agency and other interested parties. Therefore, before one can determine how the FDA would and should handle this situation, it is necessary to take a reading of the views of the parties affected by any decision the agency makes in this regard.

#### *PAS Consumers*

From the prospective patient's standpoint, regulation of drugs and medical devices could be both a blessing and a curse. On the one hand, the patient using such a PAS product is entitled to the same protection as a person taking an aspirin, namely the guarantee that, within reasonable limits, the product will safely and effectively do its job. Indeed, the prospective suicide patient could be considered an even stronger candidate for FDA protection; the product being used is known to have harmful consequences, and its potential failure might leave the patient in an even more painful and/or debilitating state than before. Without instructions on weight/dosage ratios on a product inducing death through barbiturate poisoning, for example, a patient may receive a sublethal dose and be left in a persistent vegetative state.<sup>45</sup> Likewise, if the

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<sup>44</sup>470 U.S. at 832, fn. 4.

<sup>45</sup>See, Patrick O'Neill, *Now the Big Question: How Best to Kill?* OREGONIAN, Nov. 28,

patient has built up a tolerance to a particular lethal drug due to other medications the patient has taken, failure to provide this contraindication on the labeling may result in a devastating underdose even when the weight/dose ratio is properly followed.<sup>46</sup> Finally, if a product like the Mercitron were improperly designed or manufactured, the patient may not be unconscious before the otherwise painful heart attack is induced, resulting in a far more painful, agonizing death than the patient bargained for.

These concerns, however, are counterbalanced by a fear that the FDA will overregulate this market and deny access to drugs and/or medical devices for use in PAS altogether. As noted below,<sup>47</sup> the logistics of determining what products are safe and effective for suicide are daunting, and they may force the FDA to prohibit the use of all drugs and devices for this purpose. Such a move would functionally trump state laws like Oregon's Measure 16 and would ultimately deny the right to death with dignity for patients with terminal illnesses and debilitating diseases. Therefore, unless there was a guarantee that the FDA would not overregulate drugs and devices which might be used in PAS, consumers would most likely rather see a maintenance of the status quo, where the medical profession and groups like the Hemlock Society can unofficially police and prescribe the safe and effective use of these items in PAS.

#### *Opponents to Physician-Assisted Suicide*

From the standpoint of those opposing the practice of PAS, FDA regulation of medical devices and drugs used for suicide would not only be

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1994, at A8.

<sup>46</sup>*Id*

<sup>47</sup>*Infra*, p. 21.

appreciated, but expected. Their reasoning would be simple. At base, the FDA's mission is to protect the health and welfare of the American public. Products used to take a person's life violate that agency goal. Therefore, where the agency has jurisdiction over the product, it would be incumbent on the FDA to prohibit suicide machines and drugs from entering the market and to prevent currently market drugs and devices from being employed to take one's own life.

*The Medical Profession*

Like their patients, physicians would have conflicting concerns on this issue. For those physicians who are concerned about their terminally ill or debilitated patients and wish to help them achieve the dignified death their patients desire, the approach to the issue would mirror the analysis of the consumer's perspective, discussed above.<sup>48</sup> Indeed, many doctors may be willing to rely on their own expertise and decry the need for FDA-regulated instructions on use of the device or on how much of a given drug will produce a lethal effect. On the other hand, fear of a malpractice suit in the case of a prescription of a sublethal dose might drive physicians to call for package inserts and PDR listings regarding accurate weight/dose ratios and contraindications for use of a given product in PAS. The motivation behind such a call, of course, would be that if sued, the doctor could claim that she relied on the package insert and could attempt to shift liability to the manufacturer.

The deciding factor on the approach of physicians on this issue may, ironically, be based not on a concern for the patient or the individual doctor, but

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<sup>48</sup>*Supra*, p. 16.

for the medical profession as a whole. As indicated above,<sup>49</sup> FDA has followed a policy of not regulating prescription of medications for unapproved uses and other elements of medical practice. The act of PAS, at heart, could be considered medical practice; it involves the provision of a drug or medical device by a physician to her patient for the mitigation of pain or of a disease. Accordingly, physicians might regard any limitation on PAS as a breach of the FDA's general policy and might oppose such limitations in order to prevent a precedent establishing FDA's right to encroach on the actual practice of medicine. Thus, doctors would probably oppose any regulation of the use of currently marketed drugs, medical devices and custom devices in PAS. Because they lack the same interest in devices not already on the market, however, physicians may not be as opposed to the regulation of new drugs and/or medical devices intended specifically for use in PAS.

*The Business World*

Since there currently is no industry producing and/or distributing drugs or medical devices for use in PAS (unless you count Dr. Kevorkian as a one-man industry), any decision regarding FDA regulation in this area would pre-date the efforts of any businesses. Therefore, should FDA prohibit all new PAS drugs and medical devices altogether, there most likely would be no industry outcry or complaint. Likewise, there would be little basis for industry complaint should the FDA choose a different level of regulation, since the businesses would be assuming the burdens of those regulations when they enter this

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<sup>49</sup>*Supra*, p. 15 and accompanying note.

market.

Industry opposition might arise, however, if the FDA went beyond prohibiting new drugs and medical devices and began regulating the use of currently-marketed drugs and/or devices. Though unlikely in most cases, should the FDA conclude that the risk associated with a particular product due to its use in PAS outweighs the benefits generated by its other uses, FDA could withdraw approval of the product and/or ban it from the market. Such a move could bankrupt a small pharmaceutical company and seriously cripple a larger one. Therefore, the pharmaceutical and medical device industries would probably fight to draw the line of FDA regulation at new drugs and devices specifically intended for use in PAS, though they would probably not oppose any action the FDA took regarding those products.

*The Food and Drug Administration*

Counterbalanced against the potential pressures from other groups to act or not to act lie the internal operational concerns of the FDA. At the top of the list, at least in 1995, would be the adequacy of resources to enforce any regulatory decision the agency chose to make. Faced with a possible five percent budget cut in the coming year, FDA may have enough trouble handling the programs and products currently in its regulatory purview without adding a whole new class of products or a new, stricter policy regarding the use of currently marketed products. In short, the FDA may not have the manpower or money to take any affirmative stand on this issue.

Further, were the FDA to permit PAS drugs and devices onto the

market, the agency would face the thorny problem of authorizing clinical studies to test the safety and effectiveness of the products. Manufacturers might be able to justify the safety of their products based on tests using a reasonable clinical surrogate endpoints short of death or on the results of prior studies of the active ingredients. However, a large number of patient deaths might still be required to establish accurate weight/dose ratios, information necessary to ensure the effective use of the product. Efforts to extrapolate such information from animal trials would draw the ire of animal rights activists, who would decry the slaughter of the lab animals in the clinical studies, and would increase the risk of erroneous lethal dosage tables. Without sufficient testing, however, the FDA would have no basis for authorizing the marketing of the product.<sup>50</sup> Thus, the FDA would be faced with weighing the testing options against the social benefit of authorizing the use of drugs and/or devices in PAS. More than likely, this balance would tip against granting products intended for PAS use even investigational drug or device status, much less market approval.

On the other hand, the FDA might shy away from strongly regulating the use of currently marketed drugs and devices in PAS, so long as their manufacturers do not blatantly violate federal law by recommending such a use for their products. Many of the drugs and devices which might be subject to FDA action due to their unapproved use in PAS, including an anesthetist mask, an IV needle, and thiopental, have significant uses unrelated to suicide, and medicine would suffer tremendously if manufacturers of these products quit the

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<sup>50</sup> *See*, Lake v. FDA, Medical Devices Reporter (CCH) ̘15,117, p. 771 (It could not have been in the intent of Congress to allow the marketing of unproven medical devices about which no scientific evidence is available).

market due to overregulation. Further, as indicated above,<sup>51</sup> the FDA might face the wrath of the medical profession if the agency were to attempt to limit the prescription and use of already approved products.

### III

So where will the FDA go from here? Peering into the crystal ball and predicting the future is a precarious art at best, but the foregoing analysis provides some basis for extrapolating the FDA's role in this potential regulatory field and for making some suggestions as to how the FDA might play such a role successfully.

First, it is doubtful that FDA will make any exceptions under the law to permit new PAS drugs and devices onto the market. To do so would require not only a tortured reading of §502(j) 518(e), but also a huge commitment of FDA's already strained resources in reinterpreting statutory language and developing new testing and/or approval procedures to accommodate the morbid intended purpose of such products.

On the other hand, FDA will probably continue to turn a blind eye to the use of currently market drugs and devices in PAS. Prohibiting such use would pit the FDA against manufacturers, physicians, the public at large and/or PAS supporters, with no chance for a real winner to emerge from the fray. If the FDA prosecutes the original source of the products, claiming that they were market with an intended use in PAS, manufacturers might be discouraged from producing such items. The drying up of markets in these otherwise

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<sup>51</sup>*Supra*, p. 19.

essential products would drastically increase health care costs and would deprive patients of needed drugs and medical devices. If the FDA prosecuted physicians for prescribing and/or dispensing drugs and/or devices for unapproved use in PAS, the agency might succeed in ending not only unapproved use in PAS, but also all unauthorized, experimental treatment regimens using products for unapproved uses. The impact such an event would have on the advance of medical technology would be vast, since experimentation by individual physicians has been one of the leading sources of new methods of treating disease. Further, any limitation on physician prescriptions would lead the AMA to bring its political and social weight to bear on the FDA, a position no agency would willingly assume. Of course, any of the aforementioned effects would drastically impact the general public, causing the FDA to draw its ire, with potentially serious political consequences for the agency. In addition, an effort to change the status quo would meet with an immediate reaction from the Hemlock Society and the increasing number of Americans who share its ideology, who are trying at the state level to push the law in the opposite direction. As an agency whose programs depend in large part in popular belief in and respect for it, the FDA would suffer badly from a negative media campaign instituted by those favoring PAS. In light of these potential costly conflicts with different sectors of society, the FDA would do well not to tamper with the existing policy of not regulating the use of currently-marketed drugs and medical devices in PAS.

This overall policy of virtual non-action does not mean that the FDA should ignore this problem. Should the Oregon law pass constitutional



muster, the Oregon Medical Association (OMA) is likely to go ahead and recommend specific drugs and dosages for their use in PAS.<sup>52</sup> To ignore this report would be to violate one of the agency's principles:

Where the unapproved use of an approved new drug becomes widespread or endangers the public health, the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public.<sup>53</sup> However, to require NDA's for all of the recommended drugs would be to open the whole can of regulatory worms mentioned above. This potential disaster could and should be headed off by the FDA, by recommending either 1) that the OMA not issue its report at all, or 2) that the report refer physicians to already existing reliable treatises and databases on pharmacological toxicology without recommending any drugs for PAS by name.<sup>54</sup> This way, the OMA can achieve its goal of informing its membership, and the FDA can avoid the direct challenge of a state medical association recommending a drug for an unapproved use which is not regulable from the agency's perspective.

The FDA would also be well-served by taking a hard public stance regarding Dr. Kevorkian's flagrant disregard for FDA regulations on everything from good manufacturing practices to distribution of untested, unapproved drugs and/or devices. As a practical matter, it may be a little late now for the FDA to first begin bringing charges against Dr. Kevorkian; his last assisted suicide was in December 1993. Further, it is questionable whether FDA

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<sup>52</sup>0'Neill, *supra* note 46, at A8.

<sup>53</sup>37 FR 16503, 16504.

<sup>54</sup>Such a report would not violate the FD&C Act, since a doctor may legally advocate to other doctors an unapproved use of a drug so long as she does not distribute that drug to other doctors and is not holding the drug for sale. *U.S. v. Evers*, 643 F.2d, 1043, n. 16.

has jurisdiction over Dr. Kevorkian. Since the Mercitron and CO mask were both distributed to patients filled with drugs, they would arguably have to be regulated as combination products rather than as simple medical devices, potentially depriving the FDA of the advantage of the broader authority granted by 21 U.S.C. §334(a). Since all of the suicides were performed in Michigan, where the machines were created and distributed, the machines themselves arguably were not involved in interstate commerce. Therefore, FDA may have to demonstrate that some of the machine's components were involved in interstate commerce, a potentially difficult task. Far easier and just as effective for its purposes, however, would be for the FDA to publish a policy statement regarding PAS products, outlining the regulatory steps the agency would take if any such item tried to enter the market. The statement would, of course, have to recognize a *de minimis* exception of custom devices as provided in §520(b) of the FD&C Act. However, notification of an intention to seize a new PAS product and bring charges for failure to follow FD&C standards regarding pre-market testing, notification and approval, proper labeling, and good manufacturing practices would instill the desired fear in any manufacturer thinking of following in Dr. Kevorkian's footsteps. Thus, FDA might be able to solve a potential problem before it ever resurfaces.

If the FDA adopts this general approach to the rise of PAS, the agency may be able to continue to walk the fine line between looking away from the actions of individual physicians and their patients in the course of medical practice and the agency's overall goal of protecting the welfare of the American

public. Time will tell, of course, whether organizations like the Hemlock Society or individuals opposing the practice of PAS will force FDA's hand on this issue and directly or indirectly compel FDA to take action regarding the increasing use of drugs and medical devices in PAS. For the sake of those who may opt for PAS, however, it is hoped that this does not come to pass and that the FDA will be able to maintain a respectful coexistence with the practice of PAS for many years to come.