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## **The Patient's Role in Choice of Medications: Direct-to-Consumer Advertising and Patient Decision Aids**

**Marshall H. Chin, M.D., M.P.H.\***

### INTRODUCTION

Explicit patient involvement in the selection of medications has become more frequent. Pharmaceutical companies have targeted lay persons for direct-to-consumer advertising (DTCA), and the rise of the patient empowerment movement has helped lead to more egalitarian models of shared decision making between patient and physician. This Article explores the challenge of involving patients more actively in medication choice through DTCA and patient decision aids. I will outline the optimal conditions for shared decision making between patients and physicians in drug selection and then discuss some of the key evolving issues surrounding increased patient involvement in the drug selection process. In particular, I will explore the flow of information to patients, with a specific emphasis on issues involved with DTCA, and also cover some of the challenges and promise of patient decision aids for the choice of medication. The former will cover some of the difficult macro health policy issues related to free speech and consumer protectionism while the latter will address some of the practical challenges of trying to improve patient decision making at the level of the individual clinical encounter. Current regulatory and enforcement practices have been insufficient to prevent the dissemination of some inaccurate or misleading advertisement. Informed, empowered patients can make decisions with their physicians that are more likely to be consistent with their values and preferences.

### I. TRENDS IN PATIENT INVOLVEMENT

In the debate over the creation and diffusion of pharmaceutical products, active involvement of the patient has been an afterthought until recently. During the twentieth century, the pharmaceutical industry developed drugs, the FDA

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regulated drugs,<sup>1</sup> and the physician was the primary target for marketing of drugs. However, the sociopolitical environment has evolved. Over the past fifteen years or so, patient empowerment has become an increasingly valued goal within the health care field.<sup>2</sup> Patient self-management is crucial for chronic disease care, which now comprises a large percentage of health care in the United States.<sup>3</sup> As a result, substantial attention has been devoted to finding innovative ways to get patients more actively involved in their care.<sup>4</sup>

This trend toward increasing patient empowerment has provided a fertile context for involving patients more directly in the medication selection process. From a marketing standpoint, pharmaceutical companies have realized the value of DTCA.<sup>5</sup> Between 1997 and 2001, DTCA spending increased from \$1.1 billion to \$2.7 billion per year.<sup>6</sup> DTCA is likely to remain common, as the advertising

1. See John P. Swann, FDA, History of the FDA, at <http://www.fda.gov/oc/history/historyoffda/default.htm> (last visited Feb. 16, 2005).

2. Patient empowerment refers generally to patients playing a more active role in their care whereas patient self-management denotes the actual tasks that patients must do to manage their illnesses such as taking medications, following a diet, and exercising. See Martha Funnell et al., *Implementing an Empowerment-Based Diabetes Self-Management Education Program*, 31 DIABETES EDUCATOR 53-56 (2005). The move toward patient empowerment reflects broader societal trends, traceable to the Civil Rights Movement, Vietnam War protests, and the rise of feminism in the 1960s and 1970s, in which paternalism and authority have been challenged, and individual autonomy has become increasingly treasured. See FRANK FREIDEL & ALAN BRINKLEY, AMERICA IN THE TWENTIETH CENTURY 449-92 (5th ed. 1982).

3. Chronic disease is prevalent and costly in the United States. See Catherine Hoffman et al., *Persons with Chronic Conditions: Their Prevalence and Costs*, 276 JAMA 1473, 1473 (1996). For example, between 1999 and 2002, 30.1% of Americans over the age of twenty had hypertension. See NAT'L CTR. FOR HEALTH STATISTICS, HEALTH, UNITED STATES, 2004: WITH CHARTBOOK ON TRENDS IN THE HEALTH OF AMERICANS 238 (2004). The quality of chronic care management is frequently inadequate, and the Institute of Medicine has identified patient-centered care as one of the foundations of quality care. See INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (2001).

4. See Sheldon Greenfield et al., *Patients' Participation in Medical Care: Effects on Blood Sugar Control and Quality of Life in Diabetes*, 3 J. GEN. INTERNAL MED. 448, 448 (1988); Edward H. Wagner et al., *Organizing Care for Patients with Chronic Illness*, 74 MILBANK Q. 511, 512 (1996).

5. Pharmaceutical companies traditionally advertised drugs to physicians, hospitals, and other providers through print advertisements, marketing at medical meetings, distribution of free samples of medications, and direct visits from sales representatives. Direct-to-consumer advertising (DTCA) bypasses these intermediaries and markets drugs to patients directly through a variety of media including television, newspapers, magazines, direct mail, and the internet. Patients still need a prescription for drugs that require one, but the marketing of the drug is directly to the consumer.

6. U.S. GEN. ACCOUNTING OFFICE, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-

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has been effective.<sup>7</sup> In addition, novel ways to improve the shared decision making process between patient and physician, such as patient decision aids,<sup>8</sup> have shown promise. Yet, significant concerns with regard to DTCA and decision aids persist.

## II. SHARED DECISION MAKING

During a clinical encounter, the patient may be influenced by a variety of factors, including DTCA, personal beliefs, and the experiences of family and friends. Similarly, many factors influence physicians, including their medical education and drug advertising. Collectively, scientific evidence, physician clinical judgment, and patient preferences become incorporated into the decision making process and ultimately lead to a variety of outcomes in the drug selection process. Each of these three elements should be weighed differently depending upon the individual circumstance. For example, in some cases, clear scientific evidence shows the benefit of particular medications, such as beta blockers and angiotensin-converting enzyme inhibitors in many patients with heart failure.<sup>9</sup> Patients with this indication should generally receive these medications. In other situations, clinical judgment and patient preferences are essential. For example, little scientific evidence exists to guide the management of older persons with diabetes.<sup>10</sup> Whereas most younger patients with diabetes are likely to benefit from tight glucose control and intensive treatment of their cardiovascular risk factors, the situation is more variable among older persons. Some older persons

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CONSUMER ADVERTISING HAS LIMITATIONS 10 (2002), <http://www.gao.gov/new.items/d03177.pdf>.

7. Advertisements for prescription drugs are regularly displayed on television and radio and in print for the lay public. The General Accounting Office reported DTCA increases both prescription drug spending and utilization. Between 1999 and 2000, prescriptions for the fifty most heavily advertised drugs increased thirty-two percent compared to fourteen percent for all other drugs. Most of the increase in expenditures resulted from increased utilization rather than increased prices. *Id.* at 11-12.

8. Patient decision aids are evidence-based tools, such as pamphlets, workbooks, interactive CD-ROMS or videodiscs, that are designed to help inform patients, clarify their values, provide communication skills to facilitate interactions with physicians, and allow them to make decisions that more accurately reflect their true wishes. See Annette M. O'Connor et al., *Modifying Unwarranted Variations in Health Care: Shared Decision Making Using Patient Decision Aids: A Review of the Evidence Base for Shared Decision Making*, HEALTH AFF., Oct. 7, 2004, at VAR-64.

9. See Sharon A. Hunt et al., *ACC/AHA Guidelines for the Evaluation and Management of Chronic Heart Failure in the Adult: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines*, 38 J. AM. COLL. CARDIOLOGY 2101, 2109 (2001).

10. See Elbert S. Huang et al., *Practical Challenges of Individualizing Diabetes Care in Older Patients*, 30 DIABETES EDUCATOR 558, 558 (2004).

with diabetes are relatively healthy and likely to accrue the benefits of aggressive treatment, and others may have other life-limiting conditions that attenuate the benefit of intensive control.<sup>11</sup> Patient preferences are particularly critical in what John Wennberg has called “preference-sensitive” conditions.<sup>12</sup> These are conditions in which the relative costs and benefits of treatment options are unclear and subject to the relative values the individual patient places on them. For example, older men with benign prostatic hyperplasia may have difficulty urinating. These men may be treated by either drug or surgical treatment and the choice partly depends upon patient preferences.<sup>13</sup>

The shared decision making process emphasizes that neither the patient nor the physician can be viewed in isolation. While interventions to influence behavior such as DTCA may be directed at a single party, the ultimate decision and whether or not the patient adheres to the treatment over time are influenced by the interaction between the patient and physician. The ideal outcome of the shared decision making process is variable depending upon one’s perspective and goal. Possibilities include clinical outcomes, a cost-effective outcome, a better decision or decision process, concordance of patient values and the choice made, patient autonomy, and equity. The challenge is that these outcomes frequently conflict, particularly when weighing individual patient values versus societal values. For example, patients with moderate asthma benefit from inhaled corticosteroids.<sup>14</sup> They have decreased hospitalizations and improved quality of life. Yet some patients have an aversion to drugs and would prefer a more natural non-drug treatment approach. Though this approach may not be as effective as conventional medicines, the choice these patients make is more consistent with their values of a natural healing philosophy. Whether or not this is an optimal outcome or not depends upon how individual and societal values are prioritized.

Individual and societal cost-effectiveness tradeoffs can be particularly difficult to reconcile. For example, in patients with prior myocardial infarction, prior stroke, or peripheral vascular disease, clopidogrel is more effective than aspirin in preventing a recurrent vascular event.<sup>15</sup> The estimated increased cost

11. Cal. Healthcare Found. & Am. Geriatrics Soc’y Panel on Improving Care for Elders with Diabetes, *Guidelines for Improving the Care of the Older Person with Diabetes Mellitus*, 51 J. AM GERIATRICS SOC’Y S265, S266 (2003).

12. John E. Wennberg et al., *Geography and the Debate over Medicare Reform*, HEALTH AFF., Feb. 13, 2003, at W96, W100.

13. See Carl Gjertson et al., *Benign Prostatic Hyperplasia: Now We Can Begin to Tailor Treatment*, 71 CLEV. CLIN. J MED. 857, 857 (2004).

14. See NAT’L ASTHMA EDUC. & PREVENTION PROJECT, NAT’L INSTS. OF HEALTH, PUB. NO. 97-4051, EXPERT PANEL REPORT 2: GUIDELINES FOR THE DIAGNOSIS AND MANAGEMENT OF ASTHMA 60 (1997).

15. CAPRIE Steering Comm., *A Randomised, Blinded, Trial of Clopidogrel Versus Aspirin in*

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for patients with a prior stroke who receive clopidogrel rather than aspirin is \$31,200 per quality adjusted life year.<sup>16</sup> For the individual patient, clopidogrel would seem to be the best choice. In addition, the \$31,200 incremental cost-effectiveness figure is less than the \$50,000 threshold traditionally used in medical cost-effectiveness analysis for defining a "cost-effective" treatment.<sup>17</sup> However, if there is a fixed health care budget such as within a capitated health care plan or conceivably a government budget such as a state's appropriation to the Medicaid program, whether or not the use of clopidogrel rather than aspirin is the most cost-effective way to allocate resources is less clear.

## III. DIRECT-TO-CONSUMER ADVERTISING

Direct-to-consumer advertising leads to more drug information for patients. The regulatory challenge is ensuring that accurate, understandable data are provided in the advertisements.

A. *Flow of Information to Patients*

Traditionally, patients have received most of their information about prescription drugs from their physicians.<sup>18</sup> This mechanism assumes that physicians know the relevant drug information and have the inclination, time, and communication skills necessary to convey the data to their patients. Recently, however, DTCA has been used as a marketing technique and way to reach patients directly in order to reduce the information and power imbalance between patient and physician.

DTCA holds promise for improving patient education and patient empowerment, making patients more effective partners in their care, and encouraging patients to seek treatment for conditions that may be underdiagnosed

*Patients at Risk of Ischemic Events (CAPRIE)*, 348 THE LANCET 1329, 1333 (1996).

16. Mark D. Schleinitz et al., *Clopidogrel Versus Aspirin for Secondary Prophylaxis of Vascular Events: A Cost-Effectiveness Analysis*, 116 AM. J. MED. 797 (2004).

17. Cost-effectiveness thresholds are controversial and highly dependent upon the societal and decisional context. MARTHE GOLD ET AL., COST-EFFECTIVENESS IN HEALTH AND MEDICINE 295 (1996). However, the \$50,000 cost-effectiveness threshold has been a commonly cited benchmark for discussion purposes. See Peter A. Ubel et al., *What Is the Price of Life and Why Doesn't It Increase at the Rate of Inflation?* 163 ARCHIVE INTERNAL MED. 1637, 1637 (2003).

18. Between 1997 and 2001, the pharmaceutical industry directed more than eighty percent of its promotional expenditures towards physicians. These efforts included giving drug samples to physicians and sending sales representatives to speak to physicians. See U.S. GEN. ACCOUNTING OFFICE, *supra* note 6, at 10. In addition, physicians have retained control over the diffusion of most medical knowledge to patients. See PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 3-29, 79-144 (1982).

or stigmatized. In particular, DTCA can legitimize patients' valid but untreated health concerns such as depression or erectile dysfunction, and other stigmatized conditions.<sup>19</sup> However, if the advertisements do not fairly convey the risks and benefits of the drug,<sup>20</sup> patient misperception of the drug's effectiveness could lead to patient pressure to prescribe inappropriate drugs. Patient misperception of DTCA could also lead to patient pressure to prescribe new drugs that have no significant benefit over similar, cheaper, older medications.<sup>21</sup>

In a recent national survey of 643 physicians regarding their perception of DTCA,<sup>22</sup> overall perceptions of DTCA were mixed. Forty percent of respondents thought that DTCA had a positive effect, 30% thought it had a negative effect, and 30% thought it had no effect.<sup>23</sup> About 70% of respondents reported that DTCA helped educate and inform patients about treatments and led to better discussions. However, about 80% perceived that DTCA had unbalanced information and led to unnecessary treatments.<sup>24</sup> Only 32% of physicians reported that patients had less confidence in physician judgment,<sup>25</sup> and 39% stated that they had prescribed a drug because of DTCA.<sup>26</sup> The most common conditions that patients have discussed with their physicians as a result of DTCA included traditionally underdiagnosed ones such as impotence (11%) and depression (6%),<sup>27</sup> conditions which were also common among the new diagnoses that were made based upon a visit spurred on by DTCA.<sup>28</sup> Diagnosis is the first step on the path to treatment and improved quality of life for conditions such as depression, since diseases must be recognized before they are treated.

### *B. Regulatory Challenges*

The challenge for the FDA, Centers for Medicare and Medicaid Services (CMS), and other regulatory and financing agencies is how to best balance

19. See C.E. Hoesl et al., *Erectile Dysfunction (ED) is Prevalent, Bothersome and Underdiagnosed in Patients Consulting Urologists for Benign Prostatic Syndrome (BPS)*, 47 EUR. UROLOGY 511 (2005); Andrew A. Nierenberg, *Current Perspectives on the Diagnosis and Treatment of Major Depressive Disorder*, 7 AM. J. MANAGED CARE S353 (2001).

20. See Joel S. Weissman et al., *Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising*, HEALTH AFF., Apr. 28, 2004, at W4-219, W4-224 (2004).

21. U.S. GEN. ACCOUNTING OFFICE, *supra* note 6, at 1.

22. Weissman et al., *supra* note 20.

23. *Id.* at W4-224.

24. *Id.*

25. *Id.*

26. *Id.* at W4-225.

27. *Id.* at W4-224.

28. *Id.* at W4-225.

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innovation, consumer protection, cost containment, and free speech. The political and economic environments are complex. With the re-election of President George W. Bush, one would initially think that the ideology of deregulation would reign supreme and that government intrusion into the drug market would be minimized.<sup>29</sup> However, several factors make increased government regulation of drugs a real possibility over time. We are in an era of continually rising health care costs, and the federal government is about to become the largest purchaser of drugs in 2006 when the Medicare prescription drug benefit takes effect. Many analysts believe that the cost of this benefit has been grossly underestimated.<sup>30</sup> Severe economic pressures are likely to cause increased demands for justification of the value of prescription drugs. Even today, CMS has been enacting policies that will reimburse certain pharmaceutical products only if studies demonstrate that they have a beneficial effect.<sup>31</sup>

Currently the FDA has several requirements for prescription drug advertisements, which include that advertisements must be neither false nor misleading, and must provide a "fair balance" of information about risks and benefits, "facts" that are "material" to advertised use of the drug, and a "brief summary" that discloses every risk from the product's approved labeling or else "adequate provision" for disseminating the labeling.<sup>32</sup> These preceding terms are

29. While the overall picture is mixed, President George W. Bush has favored deregulation in several industries such as energy. See NAT'L ENERGY POLICY DEV. GROUP, RELIABLE, AFFORDABLE, AND ENVIRONMENTALLY SOUND ENERGY FOR AMERICA'S FUTURE (2001), <http://www.whitehouse.gov/energy>.

30. Many "Baby Boomers" are within four years of cashing their first social security checks. Dr. Mark B. McClellan, the Administrator of CMS, estimates that the Medicare prescription drug benefit program will cost \$720 billion over ten years rather than the \$400 billion originally estimated by the Congressional Budget Office. Robert Pear, *New White House Estimate Lifts Drug Benefit Cost to \$720 Billion*, N.Y. TIMES, Feb. 9, 2005, at A1.

31. Gina Kolata, *Medicare Covering New Treatments, but with a Catch*, N.Y. TIMES, Nov. 5, 2004, at A1. Tiered formularies in the private sector represent another example of how cost pressures are likely to create incentives to restrict choice of medications for patients. See Steven A. Pearson et al., *Changing Medication Use in Managed Care: A Critical Review of the Available Evidence*, 9 AM. J. MANAGED CARE 715, 715 (2003); Thomas S. Rector et al., *Effect of Tiered Prescription Copayments on the Use of Preferred Brand Medications*, 41 MED. CARE 398, 399 (2003).

32. 21 C.F.R. § 202.1 (2004); KATHRYN AIKIN ET AL., PATIENT AND PHYSICIAN ATTITUDES AND BEHAVIORS ASSOCIATED WITH DTC PROMOTION OF PRESCRIPTION DRUGS—SUMMARY OF FDA SURVEY RESEARCH RESULTS: FINAL REPORT 9-10 (2004), <http://www.fda.gov/cder/ddmac/Final%20Report/FRfinal111904.pdf>; James M. Jeffords, *Direct-to-Consumer Drug Advertising: You Get What You Pay For*, HEALTH AFF., Apr. 28, 2004, at W4-253, W4-254.



frequently difficult to define precisely, leaving much latitude for how aggressively the FDA pursues consumer protection.<sup>33</sup> In addition, challenges exist in meeting the real intent of the law rather than merely the letter of the law. For example, many DTCA advertisements reproduce the product insert's lengthy list of side effects in a corner of the page, leading one FDA official to note the need to "help pharmaceutical companies design brief summaries that are potent public health tools rather than Mensa tests or eye exams."<sup>34</sup> Presented effectively, these summary boxes hold promise as a way to fulfill the legal requirement that information is comprehensible to consumers.<sup>35</sup>

In 2002, the General Accounting Office (GAO) raised concerns over misleading DTCA and delays in FDA enforcement actions against them.<sup>36</sup> Representative Henry Waxman noted that delays remained in 2003, with as long as six months passing between complaint and action.<sup>37</sup> Moreover, the choice of enforcement sanction was frequently weak, such as a warning letter to the pharmaceutical company, as opposed to a stronger sanction such as one that would result in a financial penalty. Rep. Waxman summarized the situation by stating, "There simply is no incentive for drug manufacturers to tell the whole truth to consumers, and there is no real penalty for them if they do not."<sup>38</sup>

In February 2004, the FDA released three guidance documents for manufacturers of pharmaceutical products and restricted devices.<sup>39</sup> The recommendations call for more consumer-friendly language for the risk and side effect information in print advertisements. They also recommend increasing help-seeking and disease-awareness advertisements that do not specifically market a

33. The FDA can send regulatory letters to companies when it finds a violation of DTCA rules. For examples, see U.S. GEN. ACCOUNTING OFFICE, *supra* note 6, at 18-20.

34. Peter J. Pitts, *Turning Point or Tipping Point: New FDA Draft Guidances and the Future of DTC Advertising*, HEALTH AFF., Apr. 28, 2004, at W4-259, W4-261.

35. Steven Woloshin et al., *The Value of Benefit Data in Direct-to-Consumer Drug Ads*, HEALTH AFF., Apr. 28, 2004, at W4-234, W4-235.

36. U.S. GEN. ACCOUNTING OFFICE, *supra* note 6, at 21-23.

37. Henry A. Waxman, *Ensuring that Consumers Receive Appropriate Information from Drug Ads: What Is the FDA's Role?*, HEALTH AFF., Apr. 28, 2004, at W4-256, W4-257.

38. *Id.*

39. FDA, GUIDANCE FOR INDUSTRY: BRIEF SUMMARY: DISCLOSING RISK INFORMATION IN CONSUMER-DIRECTED PRINT ADVERTISEMENTS (2004), <http://www.fda.gov/cber/gdlns/consumad.pdf>; FDA, DRAFT GUIDANCE FOR INDUSTRY AND FDA, CONSUMER-DIRECTED BROADCAST ADVERTISING OF RESTRICTED DEVICES (2004), <http://www.fda.gov/cdrh/comp/guidance/1513.pdf>; FDA, GUIDANCE FOR INDUSTRY: "HELP-SEEKING" AND OTHER DISEASE AWARENESS COMMUNICATION BY OR ON BEHALF OF DRUG AND DEVICE FIRMS (2004), <http://www.fda.gov/cber/gdlns/helpcomm.pdf>; Press Release, FDA, New FDA Draft Guidances Aim To Improve Health Information (Feb. 4, 2004), <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01016.html>.

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drug but which would help drug sales indirectly by raising consumer awareness of the condition that the drug is intended to treat. These documents do not, however, mention FDA commitment to increased enforcement of FDA pharmaceutical advertising regulations.<sup>40</sup>

One could argue that some lenience in enforcing existing advertising regulations might be permitted because the patient must work with the physician, a presumably knowledgeable intermediary, to obtain prescription drugs. Although this mechanism offers another level of protection, physicians frequently misperceive the relative benefits of medications and thus may provide inaccurate information to the patient.<sup>41</sup> Regardless of how DTCA and its regulation evolve over time, the shared decision making encounter between patient and physician will remain a vital part of the pathway for actual use of the medication. Thus, improvements in the societal regulatory process must be made simultaneously as the individual patient-physician shared decision making process is enhanced.

#### IV. PREFERENCE-SENSITIVE CONDITIONS, DECISION AIDS, AND SHARED DECISION MAKING

Preference-sensitive conditions are ones in which the optimal treatment choice depends upon patients' preferences or values for benefits, harms, and uncertainties. I have previously described a shared decision making ideal that incorporates scientific evidence, clinical judgment, and patient preferences. In actual clinical practice, preference-sensitive conditions are often difficult, controversial, and time-consuming problems for physicians to address adequately with patients. For example, prostate specific antigen screening, discussion of surgical versus medical management of certain cancers, and aggressive treatment of chronic illnesses in frail older persons each share these complexities.<sup>42</sup>

One way to explore patient preferences is through patient decision aids.<sup>43</sup> Compared to standard patient education materials, patient decision aids tend to be more interactive and go beyond merely imparting facts since the goal is to help the patient identify the best clinical decision for him or herself. While they have

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40. See sources cited *supra* note 39.

41. Marshall H. Chin et al., *Differences in Generalist and Specialist Physicians' Knowledge and Use of Angiotensin-Converting Enzyme Inhibitors for Congestive Heart Failure*, 12 J. GEN. INTERNAL MED. 523 (1997).

42. See, e.g., Louise C. Walter & Kenneth E. Covinsky, *Cancer Screening in Elderly Patients: A Framework for Individualized Decision Making*, 285 JAMA 2750 (2001); U.S. PREVENTIVE SERVS. TASK FORCE, U.S. DEPT. HEALTH & HUM. SERVS., *GUIDE TO CLINICAL PREVENTIVE SERVICES* (2d ed. 1996).

43. See *supra* note 8.

been used in the research setting, diffusion of such aids has been limited in general clinical practice.<sup>44</sup> However, several factors make patient aids attractive as part of a program to help patients choose medications for preference-sensitive conditions and other situations where the appropriate decision is unclear. First, patient decision aids can impart information and explore relevant factors in much more detail than is possible in brief DTCA commercials. Second, given the complexity and time-consuming nature of understanding and discussing some medical decisions, aids can supplement the actual patient-physician dialogue about choice of medication. In addition, most physicians receive relatively little training on how best to conduct such discussions and may not be aware of the most recent scientific evidence. The patient decision aid can serve as a reference tool for both patient and physician and can provide patients with the information and communication skills necessary to engage in a meaningful conversation with their physicians.

One of the best studied clinical decision aids exploring choice of a drug was for postmenopausal hormone replacement prior to the publication of literature demonstrating negative cardiovascular effects for these medications.<sup>45</sup> Patient decision aid tools described benefits and risks of postmenopausal hormone replacement with information individualized for the specific patient's risk stratum. The aids also described the probabilities of disease with and without hormone replacement therapy, and helped clarify the patient's values regarding how they rated the relative benefits, risks, and uncertainties of the therapy.<sup>46</sup> Compared to patients who received an information pamphlet, patients with the decision aid had more realistic expectations of the benefits and risks, lower decisional conflict, and higher perceived acceptability of the intervention.

Patient decision aids may be used for a variety of clinical situations. For example, either Cox-2 inhibitors or less expensive non-steroidal anti-inflammatory agents can be used for arthritis. These two different drug classes

44. Patient decision aids might be used prior to a physician visit or after an initial visit. They could also be used at home or in the doctor's office.

45. Annette M. O'Connor et al., *A Decision Aid for Women Considering Hormone Therapy After Menopause: Decision Support Framework and Evaluation*, 33 *PATIENT EDUC. COUNS.* 267 (1998). Prior to the publication of literature demonstrating negative cardiovascular effects for these medications, the decision to prescribe postmenopausal hormone replacement therapy involved consideration of osteoporosis prevention, treatment of symptoms, and, at that time, possible cardiovascular protection versus risk of breast cancer and endometrial cancer. See Herbert B. Peterson et al., *Hormone Therapy: Making Decisions in the Face of Uncertainty*, 164 *ARCHIVE INTERNAL MED.* 2308 (2004).

46. Annette M. O'Connor et al., *Randomized Trial of a Portable, Self-Administered Decision Aid for Postmenopausal Women Considering Long-Term Preventive Hormone Therapy*, 18 *MED. DECISION MAKING* 295, 295-298 (1998).

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have different side effect profiles. Factors to consider when choosing between these two drug classes are pain relief, gastrointestinal side effect profiles in high-risk patients, and, now, uncertainty over potential negative cardiovascular events in the wake of the removal of rofecoxib (Vioxx) and valdecoxib (Bextra) from the market.<sup>47</sup> Even within-class medication choices could be the subject of patient decision aids. For example, statins for hypercholesterolemia could be compared based upon relative efficacy, cost to the patient or society, and possibly length of time on the market, since there is likely more uncertainty regarding possible side effects of newer medications since they have been used in significantly fewer patients. A Cochrane review of patient decision aids found that patients who used decision aids had greater knowledge, more realistic expectations, and lower decisional conflict.<sup>48</sup> The study also found that patients using decision aids were more active in decision making, and demonstrated improved agreement between values and choices.<sup>49</sup> Cost-effectiveness of decision aids has not been studied in great detail, but United Kingdom trials of menorrhagia, menopause, and benign prostatic hyperplasia reported cost-neutral or cost-saving patient decision aid interventions.<sup>50</sup>

O'Connor et al. describe a process for decision support for preference-sensitive conditions that involves brief counseling and referral to intensive decision support as needed.<sup>51</sup> The goals of brief counseling are to clarify the decision by discussing benefits, harms, uncertainties, and costs; clarify values;

47. On May 21, 1999, the FDA granted approval to Merck to place rofecoxib (Vioxx) on the market. By 2001, concerns had been raised about possible cardiovascular side effects in medications of this drug class. A later trial demonstrated increased rates of myocardial infarction or stroke in patients taking rofecoxib. Concern has been raised whether Merck and the FDA should have taken earlier action to investigate possible adverse cardiovascular effects of rofecoxib or else withdraw the drug from the market. See Jennifer Couzi, *Withdrawal of Vioxx Casts a Shadow over Cox-2 Inhibitors*, 306 SCIENCE 384, 384-85 (2004); Debabrata Mukherjee et al., *Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitor*, 286 JAMA 954, at 954 (2001); Eric J. Topol, *Arthritis Medicines and Cardiovascular Events—"House of Coxibs,"* 293 JAMA 366, 366 (2005); Eric J Topol, *Failing the Public Health—Rofecoxib, Merck, and the FDA*, 351 NEW ENG. J. MED. 1707, 1707 (2004). The FDA also persuaded Pfizer to remove valdecoxib (Bextra) from the market because of possible cardiovascular side effects. See Gardiner Harris, *FDA Announces Strong Warnings for Painkillers: Pfizer Drug Withdrawn*, N.Y. TIMES, Apr. 8, 2005, at A1.

48. Annette O'Connor et al., *Decision Aids for People Facing Health Treatment or Screening Decisions*, 1 COCHRANE DATABASE SYS. REV. CD001431 (2003).

49. See MICHAEL F. DRUMMOND ET AL., *METHODS FOR THE ECONOMIC EVALUATION OF HEALTH CARE PROGRAMMES* (2d ed. 1997).

50. Annette M. O'Connor et al., *supra* note 43, at 67.

51. Annette M. O'Connor et al., *Risk Communication in Practice: The Contribution of Decision Aids*, 327 BRIT. MED. J. 736, 737-39 (2003).

and attempt to determine if benefits exceed harms; and screen for problems in the decision making process including decisional uncertainty, knowledge deficits, lack of clarity regarding values, and problems with support. The intensive phase of decision support involves assessing patient needs as well as their barriers to decision making. Then interventions are tailored to specific barriers such as insufficient information, difficulty clarifying what values are important to the patient, and lack of communication skills required for interacting most effectively with his or her physician.

While patient decision aids and decision support have promise, several significant challenges exist. Key problems include identifying the most useful situations to use aids and identifying patients who are comfortable judging the risks involved. For example, some patients prefer a paternalistic, authoritarian approach from their physicians, while others want to play an active role as full partners in their care who make the final decisions. Other concerns are whether fair, relevant, useful, timely, and comprehensible information can be ensured in decision aids. In particular, decision aids need to be understandable when describing probabilities and risk information for patients. Additional challenges include architectural design issues with multimedia decision aids and finding the best mix of text, graphics, and audio to communicate information most effectively.

Trying to include individual and societal costs into the decision making process for patients presents another challenge for decision aids. Societal economic costs are frequently difficult to incorporate into the individual decision making process if the patient has insurance that insulates him or herself from true costs. In contrast, out-of-pocket costs to the patient may be more feasible to include. For example, tiered pharmaceutical insurance plans offer a choice of medications that have differential cost implications for patients and these options can be explicitly presented to the patient. Logistically, however, it may be a challenge to provide the time and equipment necessary to offer decision aids. In addition, the patient decision cannot be viewed in isolation. Physicians need to be trained to have the communication skills needed to facilitate this aided patient decision making process.

## V. RECOMMENDATIONS FOR PATIENT DECISION AIDS

Given these challenges in developing and implementing patient decision aids, I offer several practical recommendations to make aids as useful as possible:

- 1) Maintain the flexible conceptual model that incorporates patient preferences, clinical judgment, and scientific evidence into the shared decision making process and weighs each differently depending upon the individual patient and clinical situation.

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2) Create educational materials matched to the literacy and numeracy levels of the users as well as their sociocultural context.

3) Allow the patient to navigate the tool so that he or she can acquire the information most important to him or herself. Patients have diverse needs and learning styles: Some patients might want comprehensive information such as every possible side effect of a medication, while others may prefer a simpler approach learning only about the most frequent or severe side effects.

4) Highlight individualized risk-stratified data to patients. Data derived from individuals who are similar to the patient are more applicable than general population data.<sup>52</sup>

5) Incorporate both quantitative and qualitative data. Patients learn complementary information from numbers and stories. For example, quantitative population outcome data in conjunction with testimonials from patients who have made different medication choices provide a more complete picture. Some patients tend to think in a reductionist manner, disaggregating the individual components of a decision, while others take a more holistic approach trying to get an overall feel for the issue.

6) Make patients aware of both objective and subjective criteria. Some patients might choose the medication or treatment approach that minimizes the risk of mortality, while others will factor in the type of risk. For example, some patients fear cancer more than cardiovascular disease, and might choose a medication that has low cancer risk in exchange for a proportionately higher risk of cardiovascular mortality.

7) Update data regularly so that the aids remain current.

8) Design decision aids for older persons. Medication choice issues are particularly common in older persons, and thus architectural issues pertaining to limited vision, orthopedics (e.g., use of computer mouse), and cognitive status are vital.

9) Train providers in communication and behavior change, ethical issues of patient autonomy versus paternalism, and equity issues in resource allocation. The issues surrounding choice of medications are often complex. Therefore, patient decision aids should not be viewed within a vacuum. An informed, guided discussion between provider and patient is critical.

10) Make the cost ramifications explicit. Different perspectives are possible, including the patient's out-of-pocket costs, costs to the health system, and costs to society. The appropriate perspective to take depends upon what the policymaker's goal is, whether minimizing individual burden or maximizing societal cost-effectiveness. Even though both patients and physicians believe that

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52. DAVID L. SACKETT ET AL., *CLINICAL EPIDEMIOLOGY: A BASIC SCIENCE FOR CLINICAL MEDICINE* (2d ed. 1991).

discussions about out-of-pocket costs are important, costs have frequently not been explicitly incorporated into the individual patient's decision-making process.<sup>53</sup>

11) Encourage more thought and research on determining ideal outcomes for patient decision aids.

12) Fund development of decision aids from multiple interested parties including pharmaceutical companies, insurance companies, and the government.

The challenges raised in my recommendations are significant but solvable with resources and will.

### CONCLUSION

We have entered an exciting new era in which patient empowerment and shared decision making are important components. We need to preserve free speech and the flow of information while, at the same time, protecting consumers. In addition, while patient empowerment sounds attractive as a general concept, we need to think creatively about how to facilitate a process in which patients become educated about their choices in a comprehensible way and make choices that reflect their true values and wishes. The challenge is creating incentives and regulations that will ensure a fair process to inform patients and facilitate shared decision making, leading to optimal, cost-effective outcomes.<sup>54</sup> Appropriately regulated and enforced direct-to-consumer advertising could lead to more informed, empowered patients. Decision aids can help patients define their own values and preferences, and engage in better discussions and make wiser decisions with their physicians.

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53. G. Caleb Alexander et al., *Patient-Physician Communication About Out-of-Pocket Costs*, 290 JAMA 953, 955-57 (2003).

54. For a more complete discussion of cost-effectiveness analysis, see MARTHE GOLD ET AL., *COST-EFFECTIVENESS IN HEALTH AND MEDICINE* (1996).