

1 **Principles to Guide the Relationship between**  
2 **Graduate Medical Education, Industry, and Other Funding Sources**  
3 **for Programs and Sponsoring Institutions Accredited by the ACGME**  
4

5 The Accreditation Council for Graduate Medical Education (ACGME) establishes  
6 educational accreditation standards and periodically monitors compliance with them for more than  
7 8,800 residency programs and nearly 700 institutional sponsors of graduate medical education  
8 (GME) in the United States.<sup>1</sup> In 2002, the ACGME published “Principles to Guide the Relationship  
9 between Graduate Medical Education and Industry” to provide guidance for managing  
10 relationships between GME and industry at the program and institutional levels. Nearly 10 years  
11 later, GME exists in a setting where an escalating number of U.S. citizens are graduating from  
12 medical schools to meet the predicted shortage of domestic physicians available to serve the  
13 public. These physicians require completion of GME programs in order to meet the public's  
14 needs.<sup>2</sup> However, at present, the future of GME funding primarily through Medicare is being  
15 seriously questioned. The ACGME recognizes that removing the substantial sources of support  
16 for GME may stimulate responses by programs and institutions that bear unintended negative  
17 consequences.<sup>3</sup>  
18

19 In this context, the ACGME has determined the need to update and expand the 2002 set  
20 of guiding principles. The intent of this revision is to support efforts of those who are responsible  
21 for residents' and fellows' learning and working environments at a time when availability of  
22 industry and other potential funding sources may be critical to the survival of GME programs. By  
23 promulgating these principles, the ACGME strives to improve health care by providing guidance  
24 to sponsoring institutions and programs in helping to form residents and fellows as physicians  
25 who exemplify professionalism by serving the best interests of patients in a consistently ethical  
26 manner. (Note: These principles constitute guidance; they are not accreditation standards.)  
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28 **The Practice of Medicine**  
29 **and the Business of Industry**  
30

31 Over the past 10 years, industry has been an influential source of funding of GME. (For  
32 the purpose of this paper, the term “industry” includes pharmaceutical companies, manufacturers  
33 of medical devices, and biotechnology companies.) Major benefits often accrue to patients from  
34 industry collaboration with teaching hospitals through research and development. However,  
35 studies have confirmed that conflicts of interest in medical education, research, and physician  
36 practice result from promotional marketing and research funding by industry.<sup>4</sup> These practices,  
37 therefore, present a threat to the professionalism of physicians and of the institutions that sponsor  
38 GME programs.<sup>5</sup>  
39

40 In their broadest context, the goals of the medical profession and industry are aligned  
41 around efforts to improve human health through a direct and positive effect on patient care.  
42 Benefits to patients result from services provided by both physicians and industry. Closer scrutiny,  
43 however, of the core relationships maintained by each reveals an irreconcilable difference. The  
44 relationship of a company to its shareholders defines values and influences behaviors held by  
45 industry. Thus, for example, the responsibility of a pharmaceutical company must be to act in the  
46 best interests of its shareholders by maximizing their return on investment. In contrast, the  
47 altruism and stewardship responsibilities expected of medical professionals dictate that  
48 physicians put patients first.<sup>6,7,8</sup> The physician-patient relationship, with all its ensuing values, is  
49 the foundation of medical professionalism; the good of the patient must be preeminent.  
50  
51

52 **The Ongoing Challenge**  
53 **for Graduate Medical Education**

54  
55 This conflict between the professional responsibilities of the physician and the business  
56 objectives of industry is apparent in the conduct of industry's promotional activities. Industry  
57 engages in advertising campaigns and associated marketing activities because they work;  
58 successful promotion increases shareholder value.<sup>9</sup> It is the chief means by which industry relates  
59 to physicians, residents, and medical students. Promotion by industry frequently occurs through  
60 financial support for a broad array of educational programs, industry-sponsored research, and  
61 social events.

62  
63 Faculty members, residents, and fellows alike communicate professional values through  
64 the learning and working environment created by sponsoring institutions and residency programs.  
65 The structured curriculum, i.e., conferences, grand rounds, and other formal learning activities, is  
66 the most obvious of the contexts in which transmittal of values occurs. While less apparent,  
67 though with equal and sometimes even greater intensity, the hidden or informal curriculum  
68 communicates values at the level of organizational structure and culture, influencing such areas  
69 as policy development, evaluation, resource allocation, and institutional jargon.<sup>10</sup> Transmittal of  
70 values thus becomes a pervasive component of the educational process relative to all manner of  
71 professional relationships within the sponsoring institution and the individual program. Residents  
72 and fellows learn to relate to industry in much the same manner they develop other professional  
73 relationships, by observing administration and faculty behavior. The learning and working  
74 environment, therefore, has a direct bearing on the "learned" professionalism of the residents and  
75 fellows training being educated within it.<sup>11</sup> Regrettably, with regard to support from industry, the  
76 learning environment sometimes manifests an "entitlement to largesse of drug companies."<sup>12</sup>

77  
78 Instances of inappropriate relationships with industry and its "largesse" are often found in  
79 the expectations for outside support demonstrated by residency programs and sponsoring  
80 institutions. Examples that remain all-too-familiar practices include: "drug lunches" with obvious  
81 promotional intent; industry-sponsored lectures with negative results of clinical trials given less or  
82 no attention; social functions attached to "information sessions" having a clearer marketing  
83 objective than scientific purpose; and promotional activity in which residents and even medical  
84 students receive slides, lecture materials, and honoraria, and subsequently act as "experts,"  
85 delivering the packaged information at continuing medical education events. A more subtle  
86 promotional activity involves funding of fellowships established by some pharmaceutical  
87 companies that retain their companies' names. Thus, a fellowship program and/or an individual  
88 fellow supported by a particular pharmaceutical company is indelibly tied to the company.<sup>13</sup> The  
89 risk of compromising professional judgment resulting from these and other activities can be  
90 egregious, and both the profession and the public express concern over blatant misuse of  
91 industry support.<sup>14,15,16</sup> Promotional support has been proven to influence medical decision-  
92 making, and studies find that decision makers are unable to recognize its impact.<sup>17,18</sup>

93  
94 Over the last several years, some residency programs, fellowships, and sponsoring  
95 institutions have adopted policies that curtail these promotional activities relating to their GME  
96 programs.<sup>19</sup> However, the increasingly constrained funding environment under which programs  
97 and institutions may operate will likely fuel the temptation to justify increased dependence on  
98 industry funding.

99  
100 Recently, other sources of funding for GME outside of Medicare and other government  
101 programs, (i.e., "other sources") have also emerged. Sponsoring institutions occasionally receive  
102 requests from parents to fund a son or daughter, or even from foreign governments to fund a  
103 group of individuals in a residency program or fellowship. Likewise, individuals may offer to pay  
104 their own way through residency or fellowship programs. The influence inherent in such instances

105 does not directly undermine values and influence behaviors of individuals as in the case of  
106 industry. However, these often well-meaning gestures have the potential for compromising the  
107 recruitment, selection, and promotion policies of sponsoring institutions, creating class differences  
108 among peer residents and fellows, causing relaxation of acceptance standards for particular  
109 individuals, or developing unequal expectations for satisfactory completion of programs.

## 110 **Guidance from Related Resources**

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112  
113 The ACGME and other groups have published guidelines and resources to inform  
114 physicians and organizations about conflicts of interest in medical education, particularly  
115 regarding gifts and support from industry. Among these are: the ethical opinion “Gifts to  
116 Physicians from Industry” in the American Medical Association’s Code of Medical Ethics;<sup>20</sup> “In the  
117 Interest of Patients: Recommendations for Physician Financial Relationships and Clinical  
118 Decision Making”<sup>21</sup> and “Industry Funding of Medical Education”<sup>14</sup> by the Association of American  
119 Medical Colleges; the Accreditation Council for Continuing Medical Education’s Standards for  
120 Commercial Support;<sup>22</sup> and “Code for Interactions with Companies” by the Council of Medical  
121 Specialty Societies.<sup>23</sup> The Association of American Medical Colleges has addressed issues  
122 regarding financial conflicts of interest in research through its Task Force on Financial Conflicts of  
123 Interest in Research.<sup>24</sup> In addition, the Institute of Medicine published an extensive report with  
124 recommendations on “Conflict of Interest in Medical Research, Education, and Practice,” with a  
125 chapter devoted specifically to “Conflicts of Interest in Medical Education.”<sup>25</sup>

126  
127 These guidelines and resources outline what constitutes ethical behavior for both  
128 physicians and their related organizations. Without exception, they establish that it is unethical for  
129 physicians to accept gifts or support in any form that results in prescription or recommendation of  
130 a particular drug or product, or delivery of particular clinical action.

## 131 **The Role of ACGME:**

### 132 **The General Competencies**

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134  
135 In 1999 the ACGME identified six general physician competencies in its program and  
136 institutional requirements. These competencies--Patient Care, Medical Knowledge, Practice-  
137 based Learning and Improvement, Interpersonal and Communication Skills, Professionalism, and  
138 Systems-based Practice--serve as organizing principles around which all GME residency and  
139 fellowship curricula should be developed.<sup>26</sup> Residents and fellows must demonstrate achievement  
140 in these competencies during and upon completion of their programs through appropriate  
141 educational outcomes. ACGME-accredited residency and fellowship programs must demonstrate  
142 improvement based upon the outcomes identified through assessments of learning activities  
143 organized around the competencies.

144  
145 The competencies are not prescriptive rules; instead, they are a conceptual framework  
146 within which the institution and program define educational curricula and evaluation, as well as  
147 program and institutional policies regarding all professional relationships in GME. At present,  
148 ACGME accreditation standards do not directly address the nature of the professional  
149 relationships that exist between residency and fellowship programs, their sponsoring institutions,  
150 and industry. However, these standards do shed light on behaviors appropriate to the integrity  
151 and objectivity that must be maintained within the GME learning and working environment. Using  
152 a framework shaped by the general competencies, the principles that follow should guide conduct  
153 of the relationships maintained by ACGME-accredited programs and sponsoring institutions with  
154 industry, and inform policies of sponsoring institutions related to acceptance of funding from other  
155 sources as well.

### 156 Professionalism

157

158 Professionalism is an expression of the values and norms that guide the relationships in  
159 which physicians are engaged.<sup>27</sup> It is, therefore, the competency that stands at the core of how  
160 programs and institutions model behavior with regard to relationships with industry. In her review  
161 of the literature, Arnold identified those traits commonly associated with professionalism as  
162 altruism, respect for others as embodied in humanistic qualities, honor, integrity, ethical behavior,  
163 accountability, excellence, a sense of duty, and advocacy.<sup>28</sup> Ginsburg, et.al., described these  
164 traits as context-dependent, that is, demonstrated through behaviors that occur in particular  
165 circumstances, often manifesting themselves in conflicts between values.<sup>29</sup>

166  
167 Professionalism demands that program and sponsoring institution policies must guide  
168 action in light of particular differences in objectives between industry and the medical profession  
169 and also inform the acceptance of funding from other sources. The following principles promote  
170 Professionalism in programs and sponsoring institutions with regard to funding:

- 171  
172 1. Ethics curricula include instruction in and discussion of published guidelines regarding  
173 gift-giving to physicians. Among these guidelines are the ethical opinion “Gifts to  
174 Physicians from Industry” in the Code of Medical Ethics of the American Medical  
175 Association<sup>20</sup> and the ethics statements of various medical specialty societies.
- 176 2. All program- and institution-sponsored events require full and appropriate disclosure of  
177 sponsorship and financial interests, above and beyond those already governed by the  
178 Standards for Commercial Support promulgated by the Accreditation Council for  
179 Continuing Medical Education.<sup>22</sup> Likewise, full disclosure of research interests are  
180 published in keeping with the local policies of institutional review boards and following  
181 the recommendations of the Association of American Medical College’s Task Force on  
182 Financial Conflicts of Interest in Research.<sup>24</sup>
- 183 3. Programs and sponsoring institutions determine, through policy, which contacts, if any,  
184 between residents, fellows, and industry representatives may be suitable, and exclude  
185 occasions in which involvement by industry representatives or promotion of industry  
186 products is inappropriate.
- 187 4. Sponsoring institutions ensure that residents, fellows, and programs are not identified  
188 publically by their funding sources.<sup>25</sup>
- 189 5. Sponsoring institutions maintain policies that ensure non-preferential treatment of  
190 residents and fellows in the learning and working environment, based upon sources of  
191 funding for their positions.

### 192 193 Practice-based Learning and Improvement 194 and Medical Knowledge

195  
196 Practice-Based Learning and Improvement refers to how physicians apply Medical  
197 Knowledge by investigating and evaluating their own patient care, appraising and assimilating  
198 scientific evidence, and making subsequent improvements in the care of their patients. The  
199 following principles, informed by Practice-Based Learning and Improvement and Medical  
200 Knowledge, apply to the relationship between GME and industry:

- 201  
202 1. Residency and fellowship curricula include clinical skills and judgment fostered in an  
203 objective and evidence-based learning environment.
  - 204 2. Residents learn how promotional activities can influence judgment in prescribing  
205 decisions and research activities through specific instructional activities.
  - 206 3. Residents understand the purpose, development, and application of drug formularies  
207 and clinical guidelines. Discussion includes such issues as branding, generic drugs,  
208 off-label use, and use of free samples.
- 209  
210

211 Systems-based Practice

212  
213 Systems-based Practice includes behaviors that demonstrate an awareness of and  
214 responsiveness to the larger context of health care, and the ability to engage system resources to  
215 provide care that is of optimal value. The following principles of Systems-based Practice apply to  
216 relationships with industry:

- 217  
218 1. Residency and fellowship curricula include how to apply appropriate considerations of  
219 cost-benefit analysis as a component of prescribing practice.  
220 2. Advocacy for patient rights within health care systems includes attention to pharmaceutical  
221 costs.  
222

223 Interpersonal and Communication Skills

224  
225 Interpersonal and Communication Skills provide the foundation upon which the  
226 satisfactory relationship between doctor and patient central to medicine is established. With  
227 regard to relationships with industry, particular aspects of Interpersonal and Communication Skills  
228 should be fostered through application of the following principles:

- 229  
230 1. Residency and fellowship curricula include discussion and reflection on managing  
231 encounters with industry representatives.  
232 2. Communication skills curricula include illustrative cases of how to handle patient  
233 requests for medication, particularly with regard to direct-to-consumer advertising of  
234 drug.  
235

236 **The ACGME's Role:**  
237 **Institutional Accreditation**

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239 In 2005, several years after the initial principles were published, the ACGME formalized its  
240 process for institutional accreditation, which recognizes sponsoring institutions for maintaining an  
241 infrastructure to oversee all aspects of the GME learning and working environment. The  
242 Institutional Requirements apply both to institutional responsibilities for maintaining a single  
243 residency program and to the complexities of managing multiple residency and fellowship  
244 programs. These standards specify that sponsoring institutions must provide GME that facilitates  
245 residents' professional, ethical, and personal development.<sup>31</sup> In addition, sponsoring institutions  
246 must provide the necessary educational, financial, and human resources to support GME.<sup>32</sup>  
247 Identified among the responsibilities of the sponsoring institution's graduate medical education  
248 committee (GMEC) is the provision of a statement or institutional policy that addresses  
249 interactions between vendor representatives, corporations, and residents, fellows, and GME  
250 programs.<sup>33</sup>  
251

252 Consistent with the Institutional Requirements, the GMEC exercises oversight authority of  
253 all GME programs sponsored by an institution. Although the current Institutional Requirements do  
254 not specify how a sponsoring institution should appropriate funding for its residency and  
255 fellowship programs, the authority of the GMEC should logically extend to how the sponsoring  
256 institution and its ACGME-accredited programs apply the guiding principles outlined in this paper.  
257  
258

259 **Conclusion**

260  
261 The principles outlined in this paper cannot guarantee individual or institutional  
262 professional behavior. Evidence exists, however, that policies relating to sources of educational  
263 support appear to affect what physicians believe and how they behave.<sup>34</sup> The value of these

264 principles, therefore, lies in their ability to inform policymaking and oversight by programs and  
265 institutions sponsoring GME programs and to represent to the public the integrity and objectivity  
266 of the professional relationships expected by residency and fellowship programs and their  
267 sponsoring institutions. The ultimate goal of these relationships is to foster effective Patient Care,  
268 the general competency that underlies the mission of medical education.

269  
270 Promotional activities by industry can seriously compromise the professional relationships  
271 that form the substance of medicine. Such compromising activities must not be allowed to  
272 continue where they exist. The interests of patients must be paramount and not influenced by the  
273 interests of industry to make profits for their shareholders. Residency and fellowship programs  
274 and their sponsoring institutions must teach and model core values that are demonstrated by the  
275 general competencies. Residents and fellows must be treated non-preferentially, regardless of the  
276 source from which the sponsoring institution receives funding for positions. The public and the  
277 profession look to GME programs and sponsoring institutions to demonstrate particular clarity  
278 around issues of patient advocacy, complete and unbiased medical knowledge, and the  
279 application of that knowledge to continually improve the practice of medicine.

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