

1
2
3 Title: Gonad Shields: Regulatory and Legislation Advocacy to Oppose Routine Use
4 in Response to Recent Research
5
6 Introduced by: Gunjan Malhotra, MD, for the Resident and Fellow Section
7
8 Original Author: Gunjan Malhotra, MD
9
10 Referred To: Reference Committee B
11
12 House Action: **APPROVED AS AMENDED**
13

14
15 Whereas, led by the Society of Pediatric Radiology (SPR), the Image Gently Alliance was
16 formed in late 2006 with the goal of “changing practice by raising awareness of the opportunities
17 to lower radiation dose in the imaging of children,” and
18

19 Whereas, the SPR recruited other organizations/members of the imaging team into the
20 alliance in 2007 including the American College of Radiology (ACR), American Association of
21 Physicists in Medicine (AAPM), and American Society of Radiologic Technologists (ASRT), and
22

23 Whereas, the practice of shielding reproductive organs and in utero fetuses began in the
24 1950s given concerns about the long-term effects of radiation and the potential for passing on
25 genetic mutations through genetic inheritance, and
26

27 Whereas, in response to these concerns, state and federal laws and regulations have been
28 created requiring the use of gonad shields in medical imaging studies, and
29

30 Whereas, through technological advances, medical physicists estimate the dose from
31 routine diagnostic imaging to reproductive organs has been reduced by 95 percent without
32 compromising diagnostic quality, and
33

34 Whereas, technological advances and optimization have resulted in marginal hereditary risk
35 reduction from gonad shielding ranging from 1×10^{-6} in women and 5×10^{-6} in men, and
36

37 Whereas, research on radiation dosing has shown that routine diagnostic imaging does not
38 produce harmful levels of radiation to patients and fetuses, and
39

40 Whereas, modern mechanisms to optimize imaging parameters such as automatic exposure
41 control (AEC) are negatively affected by shielding, and
42

43 Whereas, the gonad shield results in decreased activity on the detector, triggering AEC to
44 increase radiation output, which results in increased exposure and patient dose along with the
45 degradation of image quality, and
46

47 Whereas, the gonad shield produces artifacts and can obscure relevant anatomy and
48 diagnostic information, and
49

50 Whereas, non-diagnostic or obscured images may need to be repeated increasing patient
51 dose when shields are used, and

52
53 Whereas, the gonad surface shield is ineffective at reducing internal scatter, and

54
55 Whereas, studies have shown that gonad shields are incorrectly placed for females in 91
56 percent of radiographs and for males in 66 percent of radiographs, rendering them ineffective, and

57
58 Whereas, on January 12, 2021, the National Council on Radiation Protection and
59 Measurements (NCRP) issued a statement that the risks of utilizing gonad shields far outweigh the
60 negligible benefits to reproductive organs and therefore they should not be routinely used, and

61
62 Whereas, similar statements opposing routine or mandatory use of gonadal shields were
63 released by the ACR and the AAPM in 2019 and by the ASRT in 2021, and

64
65 Whereas, this resolution was presented at the 2021 MSMS Virtual House of Delegates
66 Meeting, but no live testimony was heard on the subject, and

67
68 Whereas, the original resolution from 2021 was amended as follows: "That the Michigan
69 Delegation to the American Medical Association (AMA) ask our AMA to study whether the U.S.
70 Food and Drug Administration should amend the code of federal regulations to remove language
71 regarding the routine use of gonad shields in medical imaging," and

72
73 Whereas, the justification for the amended language rather supports the author's original
74 language and intent to avoid legislative regulation of the practice of medicine, and

75
76 Whereas, if the authors in 2021 were able to provide testimony it could have been
77 demonstrated that the research on this subject has already been performed and another AMA
78 study of the topic would be unnecessary and costly, and

79
80 Whereas, the solution to this issue would be to remove the current regulatory control of the
81 practice of medicine in regard to this topic, and

82
83 Whereas, this resolution and its original intent brought up in 2021 seeks to remove
84 outdated government regulations and allow the practice of medicine to reside under the control of
85 physicians; therefore be it

86
87 RESOLVED: That MSMS advocate for the removal of state and national laws and regulations
88 that mandate the routine use of gonad shields in medical imaging.

89
90
91 WAYS AND MEANS COMMITTEE FISCAL NOTE: \$12,000-\$24,000 for regulatory and/or industry
92 advocacy.

Relevant MSMS Policy:

Oppose Routine Use of Gonad Shields - Resolution 03-21 (Approved as Amended)

RESOLVED: That the Michigan Delegation to the American Medical Association (AMA) ask our AMA to study whether the U.S. Food and Drug Administration should amend the code of federal regulations to remove language regarding the routine use of gonad shields in medical imaging.

Relevant AMA Policy:

AMA Stance on the Interference of the Government in the Practice of Medicine H-270.959

1. Our AMA opposes the interference of government in the practice of medicine, including the use of government-mandated physician recitations.
2. Our AMA endorses the following statement of principles concerning the roles of federal and state governments in health care and the patient-physician relationship:
 - A. Physicians should not be prohibited by law or regulation from discussing with or asking their patients about risk factors, or disclosing information to the patient (including proprietary information on exposure to potentially dangerous chemicals or biological agents), which may affect their health, the health of their families, sexual partners, and others who may be in contact with the patient.
 - B. All parties involved in the provision of health care, including governments, are responsible for acknowledging and supporting the intimacy and importance of the patient-physician relationship and the ethical obligations of the physician to put the patient first.
 - C. The fundamental ethical principles of beneficence, honesty, confidentiality, privacy, and advocacy are central to the delivery of evidence-based, individualized care and must be respected by all parties.
 - D. Laws and regulations should not mandate the provision of care that, in the physician's clinical judgment and based on clinical evidence and the norms of the profession, are either not necessary or are not appropriate for a particular patient at the time of a patient encounter.

Sources:

1. <https://www.imagegently.org/About-Us/Campaign-Overview>
2. <https://www.aappublications.org/news/2020/03/31/xrayshields040120>
3. <https://www.radiologyinfo.org/en/info.cfm?pg=safety-patient-shielding>
4. https://www.ecfr.gov/cgi-bin/text-idx?SID=c6fd98dfc8955d41420798f3e5357c66&mc=true&node=se21.8.1000_150&rgn=div8
5. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1000.50>
6. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7005227/>
7. <https://www.aapm.org/org/policies/details.asp?id=468&type=PP%C2%A4t=true>
8. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3292647/>
9. <https://pubmed.ncbi.nlm.nih.gov/28437549/>
10. <https://ncrponline.org/wp-content/themes/ncrp/PDFs/Statement13.pdf>
11. <https://www.acr.org/Advocacy-and-Economics/Advocacy-News/Advocacy-News-Issues/In-the-June-8-2019-Issue/ACR-Endorses-AAPM-Position-on-Patient-Gonadal-and-Fetal-Shielding>
12. <https://www.asrt.org/main/news-publications/news/article/2021/01/12/asrt-statement-on-fetal-and-gonadal-shielding>